3

s47G

20 June 2013

Attention: s47F
Bh: 03 9096 5355.
Bh: 1300 364 545
Mobile s47F
Fax 1300 360 830
E-mail s47F @health.vic.gov.au

s47G

T: (03) 9565 4400
F: (03) 9565 4488
s47G

Re: Morphine Sulphate solution, 50mg in 50mL 0.9% Sodium Chloride Syringe, Batch: 45/BM270

Dear Ms s47F ,

Following internal investigation, s47G wishes to advise the compounded product listed above has not been manufactured according to specified protocols and is therefore, not deemed suitable for patient use due to reduced efficacy.

This item was made as a batch of 20 units and was supplied to a single customer on the 18th June 2013.

Following the internal identification of this anomaly (and potential patient effect) on the 19th June 2013, the customer was immediately notified of an unspecified deficiency and requested to quarantine the batch on the evening of 19th June 2013. The customer (pharmacy) advised that no units had been distributed to the hospital wards at this time.

Replacement stock was provided to the customer on the 20th June 2013, where the batch in question (45/BM270) was retrieved. The customer could not store the increased quantities according to Schedule 8 requirements, due to the small size of the pharmacy safe.

The entire affected batch was received by s47G and immediately quarantined on site, on 20th June 2013.

Details of the event are provided on the following pages for your information.

If additional information is required, please feel free to contact me.

s47G is committed to the resolution of this issue and full co-operation with the TGA is assured.

Yours sincerely,

s47F

Digitally signed by s47F
Date: 2013.06.20 16:41:37 +10'00'

s47F
Site Quality Manager
s47G
T: 03 9565 4454 | F:03 9565 4488
s47F @s47G

Details of the Problem

Name, telephone and facsimile number of the person reporting the problem:
Name: s47F
Telephone: +613 9565 4454
Fax: +613 9565 4488

Date of report:
20th June 2013

Physical location of problem;
s47G

Nature of the problem;
Morphine sulphate manufactured at a lower strength than specified:
21mg/50mL instead of 50mg/50mL

Number of similar reports received:
Nil

Results of tests and other investigations on suspect or other samples;
No retention samples were kept for affected batch, no testing (apart from physical integrity testing) conducted for affected batch.

Availability for investigation of suspect sample or other samples; and
100% of the affected batch located and quarantined.
Currently these products are available for retrieval and further investigation, pending TGA advice.
Plan to destroy according to internal procedure

Details of the Product

Product name, strength and description including dosage form: Morphine Sulphate solution, 50mg in 50mL 0.9% Sodium Chloride Syringe
ARTG number: N/A
Pack size: 1
Batch number: 45/BM270
Part Number: MORP01S050
Serial number: N/A
Donation number(s): N/A
Tissue bank number(s): N/A
Expiry date: 15 September 2013
Manufacturer/Australian sponsor and contact telephone and facsimile numbers:
s47G
pH: +613 9565 4400
Fax: +613 9565 4488

Date manufactured:
17 Jun 2013

Date released:
17 Jun 2013

Quantity of the batch:
20 syringes

Date and amount released;
20 syringes released 17 Jun 2013

Local distribution;
All 20 syringes shipped by courier directly to:
s47G
The Valley Private Hospital
Corner Police and Gladstone Roads
Mulgrave, Vic 3170

Overseas distribution of product exported from Australia:
Nil

Number of complaints received:
Nil

Whether the product is meant to be sterile; and
Sterile, aseptically processed

Risk assessment and proposed action:

Type of hazard, and assessment of risk to user:
Potential patient effect of under-medication

Action proposed by sponsor:
Product quarantined, to be destroyed:

- Non-Conformance NCR514 raised
- Full investigation, including root cause analysis and action plan to be developed and executed

Proposed recall classification:
Class II

Proposed recall level:
Hospital level (pharmacy only)

Availability of alternative product:
Single batch affected
Replacement stock compounded and supplied

Australian Government

Department of Health

Therapeutic Goods Administration

AMENDED - URGENT MEDICAL DEVICE RECALL*

The sponsor recently advised the TGA that 2 additional batches and 46 additional customers were identified as being affected by this recall action.

LEVEL: Hospital

CLASS: Class I

REFERENCE: RC-2014-RN-01091-1

DATE AGREED: 10/10/2014

PRODUCT : **0.9% Sodium Chloride for Irrigation 2000ml and Water for Irrigation 2000ml**

Newly identified batches :

Product Code	Batch	Description	Expiry Date
AHB7616	**S78F1**	**0.9% Sodium Chloride for Irrigation 2000mL**	**Aug 2016**
AHB7606	**S78A6**	**Water for Irrigation 2000mL**	**Aug 2016**

Previously identified batches :

Product Code	Batch	Description	Expiry Date
AHB7616	S77N6	0.9% Sodium Chloride for Irrigation 2000mL	July 2016
AHB7616	S77R8	0.9% Sodium Chloride for Irrigation 2000mL	July 2016
AHB7606	S77N5	Water for Irrigation 2000mL	July 2016

ARTG Number: 155928

SPONSOR: s47G

PHONE: s47G

REASON: Investigation of a small number of customer complaints has confirmed a reported problem of solution leaking into the overpouch. It has been identified that the issue was caused by a component used in the manufacture of the lots above, and is confined to these batches. There are no other affected products. This issue potentially impacts the sterility of the irrigation fluid.

PROPOSED ACTION: Customers are advised to locate and remove all of the affected products and lot numbers from their facility. The affected product should be returned for credit by contacting s47G Customer Service. Additionally, customers are advised to bring this matter to the attention of relevant

prescribers within their hospital so that any patient who is undergoing infusion, or has very recently received an infusion of this product, can be monitored.

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product Distribution: **195 hospitals/distributors/medical centres in ACT, NSW, QLD, VIC & WA**

Product export status: New Zealand and Singapore

This issue was first identified by the Sponsor.

*For further details about Recall Actions, please refer to http://tga.gov.au/safety/recalls-about.htm

TGA Recalls Unit Broadcast Distribution Sheet **Recall RC-2014-RN-01091-1**

Approval under subsection 61 (7) of the *Therapeutic Goods Act 1989*
Under subsection 61(7) of the Therapeutic Goods Act 1989, the delegate of the Secretary may release therapeutic goods information where release is necessary to ensure the safe use of particular therapeutic goods or relating to the reasons for withdrawal of therapeutic goods from supply in Australia.

In relation to issues with the 0.9% Sodium Chloride for Irrigation 2000ml and Water for Irrigation 2000ml I, as delegate of the Secretary for the purposes of section 61(7) of the *Therapeutic Goods Act*, approve the release of the information of the therapeutic goods information relating to recall action (i.e., Recall action notice and list of affected customers) to the following personnel or organisation. The information to be released can be found in TRIM: R14/1136104, R14/1136191, R14/1136199 & R14/1136213

Section 61(7) Delegate Name: s47F **Position Number: 20010778 (Signed electronically)**
Date: 4/11/2014

Medicine Recall Actions	**(to be dispatched after 2 working days after the approval date)**	
☐ #Recalls_Medicines Group which includes state and territory nominees for medicines identified in Appendix IV of the URPTG as well as appropriate contacts identified within Appendix V of the URPTG.		
[ ]ARPANSA (Recalls of Radioactive Materials)	(03) 9433 2210	s47F @arpansa.gov.au
☐ Operations Mgr, Australian Retailers Association (Medicines sold by Grocery Retailers)	(03) 8600 3399	info@retail.org.au
☐ Metcash [IGA Supermarkets] (Medicines sold by Grocery Retailers)	1800 021 731/1300 135 690	s47F @metcash.com consumersupport@metcash.com
☐ Export of Class I/II recalled products	Send to countries:	____
☐ Class I recalls of Australian manufactured medicines	Send to Rapid Alert list	
Device recall actions	**(to be dispatched after 2 working days after the approval date)**	
☒ #Recalls_Devices Group which includes state and territory nominees for medical devices identified in Appendix IV of the URPTG as well as appropriate contacts identified within Appendix V of the URPTG.		
☐ Orthopaedic Implants:	☐ (02) 8071 8002 s47F, Australian Orthopaedic Association ☐(08) 8223 4075 s47F, National Joint Replacement Registry	s47F @aoa.org.au s47F @aoanjrr.org.au
☐ Operations Mgr, Australian Retailers Association (Devices sold by Grocery Retailers)	(03) 8600 3399	info@retail.org.au
☐ Metcash [IGA Supermarkets] (Devices sold by Grocery Retailers)	1800 021 731	s47F @metcash.com consumersupport@metcash.com
Devices that relate to poisons / poisoning:		
☐ WA Poison Information	(08) 9346 3493	poisonscentre@health.wa.gov.au s47F @health.wa.gov.au
☐ NSW Poison Information	(02) 9845 3597	nswpoisons@chw.edu.au
☐ QLD Poison Information	(07) 3252 1903	Poisons.Info@health.qld.gov.au
☐VIC Poison Information	(03) 9496 4912	s47F @austin.org.au
☒ Export of Class I/II recalled products	Send to countries:	Singapore
Consumer recall actions		
☐ Editor, Choice		ausconsumer@choice.com.au
☐ President, PSA	(02) 6285 2869	psa.net@psa.org.au
☐ Executive Director, Pharmacy Guild	(02) 6270 1800	s47F @guild.org.au s47F @guild.org.au

Note: Individual fax numbers added to as follows: Addressee/Organisation/faxnumber@fax.tga.gov.au
Control Document: R14/878447 **Date 18/08/2014**

		khinwin.may@guild.org.au

Blood recall actions which includes state and territory nominees for medicines identified in Appendix IV of the URPTG as well as appropriate contacts identified within Appendix V of the URPTG

☐ #Recalls_Blood and Human Tissues Group

☐ NSW: s47F, NSW Health	(02) 9424 5860	s47F@doh.health.nsw.gov.au
☐ NT : s47F, NT Health	(08) 8922 8027	s47F@nt.gov.au
s47F, NT Health	(08) 8999 2412	s47F@nt.gov.au
☐ SA: s47F, SA Health	(08) 8463 5540	s47F@health.sa.gov.au bloodorganandtissueprograms@health.sa.gov.au
☐ TAS: s47F TAS Health	(03) 6233 6392	s47F@dhhs.tas.gov.au
☐ WA: s47F, WA Health	(08) 9222 2463	s47F@health.wa.gov.au poisons@health.wa.gov.au

Safety Alerts (to be dispatched with a signed copy of the Safety Alert letter)

☐ #Recalls_Medicines Group which includes state and territory nominees for medicines identified in Appendix IV of the URPTG

☐ #Recalls_Devices Group which includes state and territory nominees for medical devices identified in Appendix IV of the URPTG.

Additional comments:

Note: Individual fax numbers added to as follows: Addressee/Organisation/faxnumber@fax.tga.gov.au

From: s47F
To: Recalls
Subject: FW: Sterility test failure - Sodium chloride for injection MS 0.9% w/v 5 mL plastic ampoule, AUST R 199991, Batch No: 1F2983003, [SEC=UNCLASSIFIED]
Date: Thursday, 9 October 2014 11:35:32 AM
Attachments: Draft Recall Letter NaCl 5mL 1F2983003 10_2014.pdf
Draft Fax Reply Form Recall NaCl 5mL 1F2983003 10_2014.pdf
Water for Injection and Sodium chloride for Injection Stock on Hand by SKU and Batch Australia 1_10_2014.pdf
COA SOH 1_10_2014.pdf

Hi s4 7F
Please create a new problem for this in RAMP . Also create a new TRIM file and relate TRIM file 2014/043596 with the new one.

s47 F

From: s47F @interpharma.com.au]
Sent: Tuesday, 7 October 2014 2:49 PM
To: s47F
Cc: s47F Recalls
Subject: RE: Sterility test failure - Sodium chloride for injection MS 0.9% w/v 5 mL plastic ampoule, AUST R 199991, Batch No: 1F2983003, [SEC=UNCLASSIFIED]

Dear s4 7F
Thank you for your email and attachments

In response please note as follows:

a) Confirmation of the number of units of NaCl 5mL Batch Number 1F2983003 that s47G imported to Australia

-

2,844 Boxes (one box contains 50x5mL ampoules)

b) Number of units of NaCl 5mL Batch Number 1F2983003 distributed from s47G premises

-

s47G does not hold any stock and therefore does not 'distribute from our premises' InterPharma has a distribution contract with Clifford Hallam Healthcare whereby all stock imported to Australia is shipped directly to the Clifford Hallam Healthcare's warehouse – in this case Batch Number 1F2983003 was transported directly from Port Melbourne to Clifford Hallam Healthcare, Dandenong.

On arrival two units (boxes) were sampled by InterPharma staff to check packaging as part of the QA release.
Additionally 1 Box was sent to the TGA for testing.

c) Number of units of NaCl 5mL Batch 1F2983003 that InterPharma and contracted distributor (CH2) have withheld from further distribution

This batch has never been supplied to the market. As of 1 Oct 2014 2,841 Boxes are in quarantine at CH2, Dandenong warehouse. Please note: this represents all stock that arrived in Australia less the two boxes used by s47G for QA checking (destroyed on completion of checking)

d) Undertake a wholesale level recall of NaCl Batch 1F2983003…

-

Please see attached a draft recall letter and fax return form. We wish to discuss the necessity to undertake a wholesale recall as no stock has been distributed to the wholesalers in Australia and all stock imported to Australia is accounted for at our contracted receiving warehouse CH2 Dandenong.

e) Confirm distribution Details of NaCl 5mL Batches 1F2983002 and 1F2983001

1F2983002: 2,988 Boxes (50x5mL ampoules) were received from the manufacturer and 2,793 remain in stock as of today i.e. 7 October 2014
1F2983001: 3,024 Boxes (50x5mL ampoules) were received from the manufacturer and 2,853 remain in stock as of today i.e. 7 October 2014

f) Confirm any export of NaCl 5mL ARTG 199991

There has been no export

g) Provide suitable evidence to demonstrate that other batches of:
Sodium Chloride for Injection MS 0.9% in plastic ampoules and Water for Injection MS in plastic ampoules
that are in stock and manufactured on the same filling line as batch 1F2983003 are sterile

No batches of any stock are released for sale in Australia without the batch Certificates of Analysis being checked. These include the requirement for sterility

Please see attached ALL individual batch COA's (69 batches) of all stock currently for supply in Australia. All of these COA's confirm each batch is within specifications.

These COA's are scanned in order of the batches listed in the SOH report dated 1 Oct 2014 (also attached).

Regarding the further information that you have requested (by 23 October) we have informed the manufacturer of this requirement and they will respond in due course.

-

As initial feedback in relation to batch 1F2983003 we have been informed that the manufacture has already checked its retention samples for batch 1F2983003 and find them to conform to sterility. They have also started repeat sterility testing on the retention samples and the interim 2 day results show no contamination. We will continue to receive updates on this testing until completed

The manufacturer has also commenced sterility testing of two further batches of manufactured product that were manufactured on either side (time wise) of batch 1F2983003 and these two batches similarly show (in the interim) no sign of contamination

In Australia we have supplied 2 Boxes of 1F2983003 to Chemical Analysis Pty Ltd, Croydon, Melbourne for further independent sterility testing. Interim results will be available next week.

Regards

s47F

s47G
Manly NSW 2095
Phone: +61 2 9976 6876
Fax: +61 2 9976 6859
s47G

C/O Pharmaco (NZ) Ltd
Toll Free: 1300 308 213
Phone: +64 9 377 3336
Fax: +64 9 307 1307
s47G

From: s47F @tga.gov.au]
Sent: Thursday, 2 October 2014 1:59 PM
To: s47F Recalls
Subject: Sterility test failure - Sodium chloride for injection MS 0.9% w/v 5 mL plastic ampoule, AUST R 199991, Batch No: 1F2983003, [SEC=UNCLASSIFIED]

~~ Metadata for: 'R14/1078940 ' ~~~~	
Rec Num:	R14/1078940
Title:	1408003128 - Sodium Chloride 5 mL injection - Preliminary certificate - PDF
~~ Metadata for: 'R14/1079764 ' ~~~~	
Rec Num:	R14/1079764
Title:	1408003128 - Sodium chloride 5 mL injection ampoule - Letter 1 - PDF

Dear s47F

Please find attached, a copy of a letter and a preliminary laboratory report that will be mailed to you today concerning the sterility test failure for Sodium chloride for injection MS 0.9% w/v 5 mL plastic ampoule, AUST R 199991, Batch No: 1F2983003, Expiry September 2016 (TGA Sample Number 1408003128). A final laboratory report will be issued to you on completion of laboratory testing. The action that you have taken to date to ensure user safety and to assist the TGA to investigate this matter is appreciated. As explained in the letter, your early reply to this matter is requested, particularly the request that you recall the affected batch to wholesale level. If you have any further queries regarding testing of this product please do not hesitate to contact me directly on (02) 62328921 or via email s47F @tga.gov.au.

Kind regards

s47F

s47F
Principal Microbiologist
Microbiology
Office of Laboratories & Scientific Services

Phone: 02 6232 8921 Fax: 02 6232 8481
Email: s47F @tga.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: s47F @s47G .com.au]
Sent: Wednesday, 1 October 2014 9:50 AM
To: Recalls
Subject: RE: Possible sterility test failure for Sodium chloride for injection MS 0.9% w/v 5 mL plastic ampoule, Batch No: 1F2983003, [SEC=UNCLASSIFIED]

Dear s47F

Thank you for your notification and also your calls this morning regarding the possible test failure of Batch 1F2983003

We can confirm the following with regard to this batch:

1. None of this batch has been supplied to the market

2. It has been placed in quarantine at our contracted distributor (Clifford Hallam Healthcare, Melbourne)
3. The manufacturer was informed on receipt of your email on the 30th September and we await their response today
4. s47G plans to separately test further samples of this batch at a commercial facility in Melbourne as soon as possible

Sincerely

s47F
Managing Director

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s47G
s47G
Manly NSW 2095
Phone: +61 2 9976 6876
Fax: +61 2 9976 6859
s47G

Toll Free: 1300 308 213
Phone: +64 9 377 3336
Fax: +64 9 307 1307
s47G

From: s [redacted]@tga.gov.au] **On Behalf Of** Recalls
Sent: Tuesday, 30 September 2014 5:24 PM
To: s47F
Cc: Recalls
Subject: Possible sterility test failure for Sodium chloride for injection MS 0.9% w/v 5 mL plastic ampoule, Batch No: 1F2983003, [SEC=UNCLASSIFIED]

F

Hi s47
F

As discussed over the telephone, sterility test results at 6 days into 14 day incubation period indicate that the test sample for Sodium chloride for injection MS 0.9% w/v 5 mL plastic ampoule
Batch No: 1F2983003, Expiry: September 2016) will fail the Test for Sterility in that:

- microbial contamination has been detected in one of two pools of Fluid Thioglycollate Medium after 6 days of incubation;
- a wet prep from the contaminated broth indicates that the contaminant (or contaminants) is/are rod-shaped bacteria.

Important Note: These results are preliminary test results only; however, the test result to date indicates that the sterility test failure for the injection is likely to be valid sterility test failure as none of the conditions of the BP Test for Sterility that permit a sterility test to be invalidated have been met.

Based on the information above, it is recommended that s47G quarantine the above batch from further distribution.

We (TGA) will touch base with you tomorrow and discus any further actions are necessary.

Regards,

s47
F

s47F Recall Coordinator I Manager - Recalls Unit I Recalls & Advertising I Office of Product Review I Monitoring & Compliance Group I Therapeutic Goods Administration | PO Box 100, WODEN ACT 2606 I www.tga.gov.au
T: 02 6232 8636 I F: 02 6203 1451 I E: Joshan.Joy@tga.gov.au /Recalls@tga.gov.au

Do you know all Recall Actions undertaken in Australia are on the System for Australian Recall Actions (SARA)? For further information, please refer to the TGA Website http://tga.gov.au/safety/sara.htm

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s47G

October, 2014

To: All Pharmaceutical Wholesalers

Attention: Regulatory Affairs Manager

URGENT PHARMACEUTICAL RECALL

SODIUM CHLORIDE FOR INJECTION – MS 0.9% W/V, 50 X 5ML AMPOULES

REORDER NUMBER PBL500

BATCH NUMBER: 1F2983003

AUST R 199991

s47G following advice that the above batch may not be sterile and after consultation with the Therapeutic Goods Administration, is recalling Batch Number 1F2983003 of Sodium Chloride for Injection-MS 0.9% w/v 50 x 5mL ampoules. No other batches or pack sizes of this product are affected by this recall.

The batch number is clearly displayed on the top of each 50 x 5mL Box.

Please inspect your stocks and quarantine all units from the above batch number, then complete the attached Facsimile Reply Form and fax it to us so that we can arrange for your stock to be recovered and replacement stock, or a credit note, issued. Please complete the Facsimile Reply Form even if you have no stock which is subject to the recall as we require this information to reconcile the process.

Thank you for your assistance

s47F

s47G

Facsimile Reply Form

To: s47G

Attention: Regulatory Affairs Manager

Fax Number: 02 9976 6859

Postal Address: PO Box 115, Manly NSW 1655

Subject: Recall of Sodium Chloride –MS 0.9% w/v 50 x 5mL Ampoules

Batch Number: 1F2983003

From: _____
(Company)

Contact Person: _____

Telephone: _____

Fax: _____

- We do/do not have stock which is subject to this recall
- Stock Received: Batch _____ Qty _____
- Unused Stock Subject to Recall: Batch _____ Qty _____
- Any other relevant details: _____

Signature:

Date:

Description	Code	Batch Number	Expiry Date	Total SOH 1/10/14	
WATER FOR INJECTION 5ML AMPS 50 AMPS PER PACK					
WATER FOR INJECTION 5ML AMPS 50 AMPS PER PACK	PBL400	1F543050	31/08/2016	2,715	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK					
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254035	30/06/2017	1,812	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254034	30/06/2017	1,296	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254029	30/04/2017	1,824	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254028	30/04/2017	1,836	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254026	30/04/2017	1,834	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254025	30/04/2017	1,834	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254024	30/04/2017	1,822	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254023	30/04/2017	1,822	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254022	30/04/2017	1,822	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254021	30/04/2017	1,846	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254020	30/04/2017	1,834	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254019	30/04/2017	1,834	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254018	31/03/2017	1,824	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254017	31/03/2017	1,824	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254016	30/03/2017	1,798	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254015	30/03/2017	1,750	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254014	28/02/2017	378	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254013	28/02/2017	1,513	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254012	28/02/2017	1,726	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254011	28/02/2017	1,702	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254009	28/02/2017	1,818	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254008	28/02/2017	1,822	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254007	31/01/2017	848	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254006	31/01/2017	105	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254005	31/01/2017	1,728	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254004	31/01/2017	1,737	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254003	31/01/2017	460	
WATER FOR INJECTION 10ML AMPS 50 AMPS PER PACK	PBL410	1T3254001	30/12/2016	19	
WATER FOR INJECTION 20ML AMPS 30 AMPS PER PACK					
WATER FOR INJECTION 20ML AMPS 30 AMPS PER PACK	PBL420	1TW3294002	30/04/2017	1,350	
WATER FOR INJECTION 20ML AMPS 30 AMPS PER PACK	PBL420	1TW3294001	30/04/2017	890	
SODIUM CHLORIDE INJ 5ML AMPS 50AMPS PER PACK					
SODIUM CHLORIDE INJ 5ML AMPS 50AMPS PER PACK	PBL500	1F2983003	30/09/2016	2,841	s47G
SODIUM CHLORIDE INJ 5ML AMPS 50AMPS PER PACK	PBL500	1F2983002	30/09/2016	2,794	
SODIUM CHLORIDE INJ 5ML AMPS 50AMPS PER PACK	PBL500	1F2983001	30/09/2016	2,988	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK					
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984101	30/06/2017	1,776	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984100	30/06/2017	1,800	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984099	30/06/2017	1,788	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984098	30/06/2017	1,800	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984097	30/06/2017	1,776	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984096	30/06/2017	1,776	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984095	30/06/2017	1,812	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984085	31/05/2017	1,812	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984084	31/05/2017	1,812	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984083	31/05/2017	1,824	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984082	31/05/2017	1,788	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984081	31/05/2017	1,788	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984080	31/05/2017	1,800	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984079	31/05/2017	1,452	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984078	31/05/2017	72	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984077	31/05/2017	48	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984076	30/05/2017	1,800	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984075	30/05/2017	1,800	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984074	30/05/2017	681	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984073	30/05/2017	1,080	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984072	30/05/2017	637	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984071	30/05/2017	24	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984064	31/03/2017	1,800	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984063	31/03/2017	1,824	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984062	31/03/2017	1,824	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984061	31/03/2017	1,800	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984059	31/03/2017	1,824	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984058	31/03/2017	134	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984051	28/02/2017	480	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984050	28/02/2017	480	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984048	28/02/2017	90	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984047	28/02/2017	98	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984036	31/01/2017	108	
SODIUM CHLORIDE INJ 10ML AMPS 50 AMPS PER PACK	PBL510	1T2984032	31/01/2017	30	
SODIUM CHLORIDE INJ 20ML AMPS 30 AMPS PER PACK					
SODIUM CHLORIDE INJ 20ML AMPS 30 AMPS PER PACK	PBL520	1TW2983003	31/10/2016	233	
SODIUM CHLORIDE INJ 20ML AMPS 30 AMPS PER PACK	PBL520	1TW2983002	31/10/2016	119	

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Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/54-09**
MATERIAL NAME	**: WATER FOR INJECTION – MS STERILISED WATER FOR INJECTIONS BP -5ML**		
Batch No.	**: 1F543050**	**AR NO.**	**: FP/S-01/13/317**
Manufacturing Date	**: SEP-13**	**Expiry Date**	**: AUG-16**
Batch Size	**: 1000 Litre**	**Quantity. sampled**	**: 250 Nos.**
Testing Date	**: 09/09/13**	**Date of completion**	**: 23/09/13**

Sr	Test	Observation	Limit
1	Appearance	A clear and colorless solution	A clear and colorless solution
2	Extractable Volume (ml)	5.1ml	Not less than nominal volume and not more than 115% of the nominal volume for ≤5ml; or not less than nominal volume and not more than 110% of the nominal volume for ≥5ml
3	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1 ml of 0.01 M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 ml of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 ml of 0.01 M hydrochloric acid
4	Conductivity	1.152 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 ml or less at 25 °C ± 1°C; or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10ml at 25 °C ± 1°C
5	Oxidisable substances	The solution remains faintly pink	The solution remains faintly pink
6	Chlorides	<0.5 ppm	Maximum 0.5 ppm
7	Nitrates	<0.2 ppm	Maximum 0.2 ppm
8	Sulphates	The solution shows no change in appearance for at least 1 h.	The solution shows no change in appearance for at least 1 h.
9	Ammonium	<0.6 ppm	For containers with a nominal volume less than 50 ml: Maximum 0.6 ppm.
10	Calcium and magnesium	A pure blue colour is produced	A pure blue colour should be produced
11	Residue on evaporation	0.0001%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 ml or less; or maximum 3 mg (0.003 per cent) for containers with a nominal volume greater than 10 ml
12	Particulate contamination	89 particles/container of ≥10µm 46 particles/container of ≥25µm	Average particles not more than 6000/container ≥ 10 µm and not more than 600/container ≥25µm
13	Sterility	Sterile	Should be sterile
14	Bacterial Endotoxin	<0.25EU/ml	Less than 0.25 EU/ml
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear	The mixture remains clear
17	pH	5.72	Between 5.0 and 7.0 at 25 °C + 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1 ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per Specification.

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DATE: 24/9/13 DATE: 24/09/13 DATE: 24/09/13 DATE: 24/09/13

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Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	: Quality Control	Reference Specification No:	FP/SPEC/325-00
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	: 1T3254035	A.R. NO.	: FP/S-01/14/235
Manufacturing Date	: JUL-14	Expiry Date	: JUN-17
Batch Size	: 1000 Litre	Quantity sampled	: 125 Nos
Testing Date	: 11/07/14	Completion Date	: 25/07/14

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.2 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	1.503 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C, or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0005%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	36 Particles/container of ≥10µm 3 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.68	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

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Name			
DATE:01/08/14	DATE:01/08/14	DATE:01/08/14	DATE:01/08/14

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Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/325-00**	
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: IT3254034**	**A.R. NO.**	**: FP/S-01/14/234**
Manufacturing Date	**: JUL-14**	**Expiry Date**	**: JUN-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 11/07/14**	**Completion Date**	**: 25/07/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.3 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	1.338 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C. or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0007%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	75 Particles/container of ≥10µm 37 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.66	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

Prepared By	s47F	Reviewed By	s47F
Name		Name	
DATE:01/08/14	DATE:01/08/14	DATE:01/08/14	DATE:01/08/14

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/325-00**
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254029**	**A.R. NO.**	**: FP/S-01/14/177**
Manufacturing Date	**: MAY-14**	**Expiry Date**	**: APR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 29/05/14**	**Completion Date**	**: 12/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.3 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	1.090 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C. or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0003%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	51 Particles/container of ≥10µm 18 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.78	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

Prepared By	s47F		
Name			
DATE:20/06/14	DATE:20/06/14	DATE:20/06/14	DATE:20/06/14

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Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/325-00**	
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254028**	**A.R. NO.**	**: FP/S-01/14/176**
Manufacturing Date	**: MAY-14**	**Expiry Date**	**: APR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 29/05/14**	**Completion Date**	**: 12/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.2 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	1.093 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C. or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0004%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	98 Particles/container of ≥10µm 20 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.77	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

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Prepared By:			
Name :			
DATE:20/06/14	DATE:20/06/14	DATE:20/06/14	DATE:20/06/14

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Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/325-00**	
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254026**	**A.R. NO.**	**: FP/S-01/14/166**
Manufacturing Date	**: MAY-14**	**Expiry Date**	**: APR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 20/05/14**	**Completion Date**	**: 03/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.2 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	0.932 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C. or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0006%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	225 Particles/container of ≥10µm 151 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.54	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

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Prepared By:			
Name :			
DATE:05/06/14	DATE:05/06/14	DATE:05/06/14	DATE:05/06/14

Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/325-00**
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254025**	**A.R. NO.**	**: FP/S-01/14/165**
Manufacturing Date	**: MAY-14**	**Expiry Date**	**: APR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 19/05/14**	**Completion Date**	**: 02/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.1 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	0.948 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C. or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0004%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	195 Particles/container of ≥10µm 52 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.52	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

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Prepared By:			
Name :			
DATE:05/06/14	DATE:05/06/14	DATE:05/06/14	DATE:05/06/14

Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/325-00**	
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254024**	**A.R. NO.**	**: FP/S-01/14/164**
Manufacturing Date	**: MAY-14**	**Expiry Date**	**: APR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 18/05/14**	**Completion Date**	**: 02/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.2 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	0.950 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C. or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0003%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	230 Particles/container of ≥10µm 54 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.70	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

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Prepared By:			
Name :			
DATE:05/06/14	DATE:05/06/14	DATE:05/06/14	DATE:05/06/14

Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/325-00**
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254023**	**A.R. NO.**	**: FP/S-01/14/163**
Manufacturing Date	**: MAY-14**	**Expiry Date**	**: APR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 18/05/14**	**Completion Date**	**: 02/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.2 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	0.957 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C. or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0004%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	45 Particles/container of ≥10µm 17 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.68	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

s47F

Prepared By:			
Name :			
DATE:05/06/14	DATE:05/06/14	DATE:05/06/14	DATE:05/06/14

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT : Quality Control		Reference Specification No: FP/SPEC/325-00	
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	: 1T3254022	A.R. NO.	: FP/S-01/14/162
Manufacturing Date	: MAY-14	Expiry Date	: APR-17
Batch Size	: 1000 Litre	Quantity sampled	: 125 Nos
Testing Date	: 17/05/14	Completion Date	: 31/05/14

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.1 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	1.748 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C. or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0007%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	126 Particles/container of ≥10µm 60 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.65	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

Prepared By: s47F	Checl s47F	Reviev s47F	Approved By: s47F
Name :	Name	Name:	Name :
DATE:05/06/14	DATE:05/06/14	DATE:05/06/14	DATE:05/06/14

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Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/325-00**	
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254021**	**A.R. NO.**	**: FP/S-01/14/161**
Manufacturing Date	**: MAY-14**	**Expiry Date**	**: APR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 16/05/14**	**Completion Date**	**: 30/05/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.2 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	0.953 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C. or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0004%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	165 Particles/container of ≥10µm 112 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.62	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

Prepared By: s47F	Checke s47F	Reviev s47F	Approved By: s47F
Name :	Name:	Name:	Name :
DATE:05/06/14	DATE:05/06/14	DATE:05/06/14	DATE:05/06/14

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Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/325-00**
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254020**	**A.R. NO.**	**: FP/S-01/14/160**
Manufacturing Date	**: MAY-14**	**Expiry Date**	**: APR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 15/05/14**	**Completion Date**	**: 29/05/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.1 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	1.014 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C. or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0004%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	150 Particles/container of ≥10µm 89 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.53	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

Prepared By: s47F	Check s47F	Revi s47F	Approved By: s47F
Name :	Name	Nam	Name :
DATE:05/06/14	DATE:05/06/14	DATE:05/06/14	DATE:05/06/14

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Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/325-00**	
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254019**	**A.R. NO.**	**: FP/S-01/14/159**
Manufacturing Date	**: MAY-14**	**Expiry Date**	**: APR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 15/05/14**	**Completion Date**	**: 29/05/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.2 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	1.032 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C. or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0006%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	114 Particles/container of ≥10µm 70 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.50	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

Prepared By	Checke	Revie	Approved By:
Name : s47F	Name: s47F	Nam s47F	Name : s47F
DATE:05/06/14	DATE:05/06/14	DATE:05/06/14	DATE:05/06/14

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Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/325-00**	
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254018**	**A.R. NO.**	**: FP/S-01/14/127**
Manufacturing Date	**: APR-14**	**Expiry Date**	**: MAR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 06/04/14**	**Completion Date**	**: 21/04/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.1 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide: if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	1.082 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C, or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1 °C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0004%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	34 Particles/container of ≥10µm 15 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.88	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

Prepared By: s47F	Chec s47F	Reviev s47F	
Name :	Nam	Name:	
Date:29/04/14	Date:29/04/14	Date:29/04/14	Date:29/04/14

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/325-00**
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254017**	**A.R. NO.**	**: FP/S-01/14/126**
Manufacturing Date	**: APR-14**	**Expiry Date**	**: MAR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 05/04/14**	**Completion Date**	**: 19/04/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.2 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	1.136 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C, or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0008%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	43 Particles/container of ≥10µm 12 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.82	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

Prepared B	Chec	s47F	
Name	Nam		
Date:29/04/14	Date:29/04/14	Date:29/04/14	Date:29/04/14

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Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/325-00**
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254016**	**A.R. NO.**	**: FP/S-01/14/125**
Manufacturing Date	**: APR-14**	**Expiry Date**	**: MAR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 04/04/14**	**Completion Date**	**: 18/04/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.2 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	1.304 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C, or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0006%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL.	Less than 0.25 EU/mL.
13	Particulate contamination: Sub-visible particles	43 Particles/container of ≥10µm 5 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.73	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

Prepared B	s47F	Revie	s47F
Name		Name	
Date:29/04/14	Date:29/04/14	Date:29/04/14	Date:29/04/14

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Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/325-00**
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254015**	**A.R. NO.**	**: FP/S-01/14/124**
Manufacturing Date	**: APR-14**	**Expiry Date**	**: MAR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 04/04/14**	**Completion Date**	**: 18/04/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.1 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	1.187 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C, or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0010%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	70 Particles/container of ≥10µm 8 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.66	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

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Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/325-00**	
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254014**	**A.R. NO.**	**: FP/S-01/14/106**
Manufacturing Date	**: MAR-14**	**Expiry Date**	**: FEB-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 18/03/14**	**Completion Date**	**: 02/04/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.1 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	1.358 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C, or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0008%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	44 Particles/container of ≥10µm 29 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.96	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

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Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/325-00**
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254013**	**A.R. NO.**	**: FP/S-01/14/093**
Manufacturing Date	**: MAR-14**	**Expiry Date**	**: FEB-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 09/03/14**	**Completion Date**	**: 24/03/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.2 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	0.825 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C, or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0008%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	69 Particles/container of ≥10µm 12 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.76	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

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Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/325-00**
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254012**	**A.R. NO.**	**: FP/S-01/14/092**
Manufacturing Date	**: MAR-14**	**Expiry Date**	**: FEB-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 08/03/14**	**Completion Date**	**: 22/03/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.1 mL.	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide: if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	1.019 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C, or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0004%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	55 Particles/container of ≥10µm 11 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.97	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

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Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/325-00**
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254011**	**A.R. NO.**	**: FP/S-01/14/091**
Manufacturing Date	**: MAR-14**	**Expiry Date**	**: FEB-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 07/03/14**	**Completion Date**	**: 21/03/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.2 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	0.906 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C, or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0004%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	41 Particles/container of ≥10µm 5 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.89	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

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MARCK BIOSCIENCES LTD.

Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/325-00**	
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254009**	**A.R. NO.**	**: FP/S-01/14/089**
Manufacturing Date	**: MAR-14**	**Expiry Date**	**: FEB-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 06/03/14**	**Completion Date**	**: 20/03/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.1 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	1.032 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C. or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0006%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	54 Particles/container of ≥10µm 15 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.81	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

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Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/325-00**	
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254008**	**A.R. NO.**	**: FP/S-01/14/088**
Manufacturing Date	**: MAR-14**	**Expiry Date**	**: FEB-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 06/03/14**	**Completion Date**	**: 20/03/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.1 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	1.083 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C. or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0002%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	39 Particles/container of ≥10µm 5 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.75	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

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Date:08/04/14	Date:08/04/14	Date:08/04/14	Date:08/04/14

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Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/325-00**	
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254007**	**A.R. NO.**	**: FP/S-01/14/084**
Manufacturing Date	**: FEB-14**	**Expiry Date**	**: JAN-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 02/03/14**	**Completion Date**	**: 18/03/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.1 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	0.911 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C. or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0005%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	43 Particles/container of ≥10µm 23 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.73	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

Prepared By: s47F			
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Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/325-00**	
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254006**	**A.R. NO.**	**: FP/S-01/14/083**
Manufacturing Date	**: FEB-14**	**Expiry Date**	**: JAN-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 01/03/14**	**Completion Date**	**: 18/03/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.1 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	0.801 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C. or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0007%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	41 Particles/container of ≥10µm 25 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.76	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

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Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/325-00**	
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254005**	**A.R. NO.**	**: FP/S-01/14/082**
Manufacturing Date	**: FEB-14**	**Expiry Date**	**: JAN-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 01/03/14**	**Completion Date**	**: 18/03/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.2 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	0.809 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C. or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0004%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	23 Particles/container of ≥10µm 9 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.80	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

s47F

Prepared By:			
Name :			
DATE:28/03/14	DATE:28/03/14	DATE:28/03/14	DATE:28/03/14

Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/325-00**	
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254004**	**A.R. NO.**	**: FP/S-01/14/081**
Manufacturing Date	**: FEB-14**	**Expiry Date**	**: JAN-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 28/02/14**	**Completion Date**	**: 14/03/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.2 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	1.144 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C. or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C + 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0007%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	133 Particles/container of ≥10µm 22 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.73	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

s47F

Prepared By			
Name			
DATE:28/03/14	DATE:28/03/14	DATE:28/03/14	DATE:28/03/14

Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/325-00**
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254003**	**A.R. NO.**	**: FP/S-01/14/080**
Manufacturing Date	**: FEB-14**	**Expiry Date**	**: JAN-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 27/02/14**	**Completion Date**	**: 13/03/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.1 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	1.148 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C. or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0006%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	200 Particles/container of ≥10µm 14 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.72	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

s47F

Prepared By			
Name			
DATE:28/03/14	DATE:28/03/14	DATE:28/03/14	DATE:28/03/14

Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/325-00**	
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-10 ML			
Batch No.	**: 1T3254001**	**A.R. NO.**	**: FP/S-01/14/034**
Manufacturing Date	**: JAN-14**	**Expiry Date**	**: DEC-16**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125 Nos**
Testing Date	**: 24/01/14**	**Completion Date**	**: 08/02/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	10.1 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	1.139 $\mu s.cm^{-1}$	Maximum 25 $\mu s.cm^{-1}$ for containers with a nominal volume of 10 mL or less at 25 °C ± 1 °C, or maximum 5 $\mu s.cm^{-1}$ for containers with a nominal volume greater than 10 mL at 25 °C ± 1°C.
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	For containers with a nominal volume less than 50 mL: Maximum 0.6 ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0003%	Maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less.
12	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	217 Particles/container of ≥10µm 2 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.88	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

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Prepared By:			
Name :			
DATE:27/02/14	DATE:27/02/14	DATE:27/02/14	DATE:27/02/14

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Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/329-00**	
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-20 ML			
Batch No.	**: 1TW3294002**	**A.R. NO.**	**: FP/S-01/14/168**
Manufacturing Date	**: MAY-14**	**Expiry Date**	**: APR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 80 Nos**
Testing Date	**: 22/05/14**	**Completion Date**	**: 05/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	20.2 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	1.162 $\mu s.cm^{-1}$	Maximum 5$\mu s.cm^{-1}$
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	Maximum 0.6ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0009%	Maximum 3mg (0.003 percent)
12	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	76 Particles/container of ≥10µm 12 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.74	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

Prepared By	s47F		
Name :			
DATE:20/06/14	DATE:20/06/14	DATE:20/06/14	DATE:20/06/14

Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/329-00**	
TITLE : WATER FOR INJECTION -MS (STERILISED WATER FOR INJECTIONS BP)-20 ML			
Batch No.	**: 1TW3294001**	**A.R. NO.**	**: FP/S-01/14/167**
Manufacturing Date	**: MAY-14**	**Expiry Date**	**: APR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 80 Nos**
Testing Date	**: 21/05/14**	**Completion Date**	**: 04/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear and colorless solution.	A clear and colorless solution
02	Extractable Volume	20.3 mL	Not less than nominal volume and not more than 110% of the nominal volume
03	Acidity or Alkalinity	The solution is yellow, it becomes red on the addition of 0.1mL of 0.01M sodium hydroxide.	If the solution is yellow, it becomes red on the addition of 0.1 mL of 0.01 M sodium hydroxide; if red, it becomes yellow on the addition of 0.15 mL of 0.01 M hydrochloric acid
04	Conductivity	0.948 $\mu s.cm^{-1}$	Maximum $5\mu s.cm^{-1}$
05	Oxidisable Substances	The solution remains faintly pink.	The solution remains faintly pink
06	Chlorides	<0.5ppm	Maximum 0.5 ppm
07	Nitrates	<0.2ppm	Maximum 0.2 ppm
08	Sulfates	The solution shows no change in appearance for at least 1hour.	The solution shows no change in appearance for at least 1 h.
09	Ammonium	<0.6ppm	Maximum 0.6ppm
10	Calcium and Magnesium	A pure blue colour is produced.	A pure blue colour should be produced
11	Residue on Evaporation	0.0007%	Maximum 3mg (0.003 percent)
12	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
13	Particulate contamination: Sub-visible particles	60 Particles/container of ≥10µm 7 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25 µm
14	Sterility	Sterile	Should be sterile
ADDITIONAL TEST AS PER USP			
15	Calcium	No turbidity is produced.	No turbidity should be produced
16	Carbon Dioxide	The mixture remains clear.	The mixture remains clear
17	pH	5.52	Between 5.0 and 7.0 at 25 °C ± 2 °C
ADDITIONAL TEST AS PER IP			
18	Heavy metals (Method D)	<0.1ppm	Not more than 0.1 ppm

Report : The product complies with the prescribed standard of the quality as per above specification.

Prepared By: s47F			
Name :			
DATE:20/06/14	DATE:20/06/14	DATE:20/06/14	DATE:20/06/14

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Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-00**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1F2983003**	**A.R. NO.**	**: FP/S-01/13/366**
Manufacturing Date	**: OCT-13**	**Expiry Date**	**: SEP-16**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 250Nos.**
Testing Date	**: 23/10/13**	**Date of completion**	**: 06/11/13**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	5.1mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5 mL
04	Assay of Sodium Chloride	99.0%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/ml.
06	Particulate Contamination	5Particles/container of≥10µm 1Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.67	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report: The product complies with the prescribed standard of the quality as per specification.

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Prepared By			
Name			
Date:14/05/14	Date:14/05/14	Date:14/05/14	Date:14/05/14

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Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-00**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1F2983002**	**A.R. NO.**	**: FP/S-01/13/365**
Manufacturing Date	**: OCT-13**	**Expiry Date**	**: SEP-16**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 250Nos.**
Testing Date	**: 22/10/13**	**Date of completion**	**: 06/11/13**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	5.2mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5 mL
04	Assay of Sodium Chloride	99.0%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	11Particles/container of≥10µm 2Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.69	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report: The product complies with the prescribed standard of the quality as per specification.

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Prepared By:			
Name :			
Date:14/05/14	Date:14/05/14	Date:14/05/14	Date:14/05/14

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Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-00**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1F2983001**	**A.R. NO.**	**: FP/S-01/13/364**
Manufacturing Date	**: OCT-13**	**Expiry Date**	**: SEP-16**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 250Nos.**
Testing Date	**: 21/10/13**	**Date of completion**	**: 06/11/13**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	5.2mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5 mL
04	Assay of Sodium Chloride	99.0%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	5Particles/container of≥10µm 0.67Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.65	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Storage: Kept in well-closed containers and stored at a temperature not exceeding 25°C.
Report: The product complies with the prescribed standard of the quality as per specification.

Prepared By: s47F		Reviev s47F	
Name :		Name:	
Date:27/02/14	Date:27/02/14	Date:27/02/14	Date:27/02/14

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Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-01**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984101**	**A.R. NO.**	**: FP/S-01/14/248**
Manufacturing Date	**: JUL-14**	**Expiry Date**	**: JUN-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 22/07/14**	**Date of completion**	**: 05/08/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.1mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	100.6%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	80 Particles/container of≥10µm 62 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.69	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

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Prepared By		Reviev	
Name		Name:	
DATE:21/08/14	DATE:21/08/14	DATE:21/08/14	DATE:21/08/14

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Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-01**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984100**	**A.R. NO.**	**: FP/S-01/14/247**
Manufacturing Date	**: JUL-14**	**Expiry Date**	**: JUN-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 21/07/14**	**Date of completion**	**: 04/08/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.1mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	99.9%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	178 Particles/container of≥10µm 125 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.79	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By Name	s47F	Reviev Name:	s47F
DATE:21/08/14	DATE:21/08/14	DATE:21/08/14	DATE:21/08/14

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Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-01**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984099**	**A.R. NO.**	**: FP/S-01/14/246**
Manufacturing Date	**: JUL-14**	**Expiry Date**	**: JUN-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 20/07/14**	**Date of completion**	**: 04/08/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.2mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	99.9%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	193 Particles/container of≥10µm 30 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.74	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By s47F	Checke s47F	Reviev s47F	
Name	Name:	Name:	
DATE:21/08/14	DATE:21/08/14	DATE:21/08/14	DATE:21/08/14

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Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/298-01**	
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984098**	**A.R. NO.**	**: FP/S-01/14/245**
Manufacturing Date	**: JUL-14**	**Expiry Date**	**: JUN-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 19/07/14**	**Date of completion**	**: 02/08/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.2mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	99.3%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	235 Particles/container of≥10µm 164 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.78	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

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Prepared I		Reviewe	
Name		Name:(	
DATE:21/08/14	DATE:21/08/14	DATE:21/08/14	DATE:21/08/14

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Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	: Quality Control	Reference Specification No:	FP/SPEC/298-01
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
Batch No.	: IT2984097	A.R. NO.	: FP/S-01/14/241
Manufacturing Date	: JUL-14	Expiry Date	: JUN-17
Batch Size	: 1000 Litre	Quantity sampled	: 125Nos.
Testing Date	: 16/07/14	Date of completion	: 30/07/14

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.1mL.	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL.
04	Assay of Sodium Chloride	100.6%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL.	Less than 0.25 EU/mL.
06	Particulate Contamination	226 Particles/container of≥10µm 161 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.71	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report: The product complies with the prescribed standard of the quality as per specification.

Prepared By: s47F		Reviev s47F	
Name :		Name:	
DATE:01/08/14	DATE:01/08/14	DATE:01/08/14	DATE:01/08/14

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Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	: Quality Control	Reference Specification No:	FP/SPEC/298-01
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	: 1T2984096	A.R. NO.	: FP/S-01/14/240
Manufacturing Date	: JUL-14	Expiry Date	: JUN-17
Batch Size	: 1000 Litre	Quantity sampled	: 125Nos.
Testing Date	: 15/07/14	Date of completion	: 29/07/14

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	 (A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	 (A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.2mL.	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL.
04	Assay of Sodium Chloride	99.9%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	121 Particles/container of≥10µm 88 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.87	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By	s47F	Review	s47F
Name		Name:	
DATE:01/08/14	DATE:01/08/14	DATE:01/08/14	DATE:01/08/14

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Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	: Quality Control	Reference Specification No:	FP/SPEC/298-01
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
Batch No.	: IT2984095	A.R. NO.	: FP/S-01/14/239
Manufacturing Date	: JUL-14	Expiry Date	: JUN-17
Batch Size	: 1000 Litre	Quantity sampled	: 125Nos.
Testing Date	: 15/07/14	Date of completion	: 29/07/14

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.2mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	99.3%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL.	Less than 0.25 EU/mL.
06	Particulate Contamination	275 Particles/container of≥10µm 217 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.76	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By: s47F		Reviev s47F	
Name :		Name:	
DATE:01/08/14	DATE:01/08/14	DATE:01/08/14	DATE:01/08/14

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/298-01**	
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984085**	**A.R. NO.**	**: FP/S-01/14/197**
Manufacturing Date	**: JUN-14**	**Expiry Date**	**: MAY-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 13/06/14**	**Date of completion**	**: 27/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.2mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	100.5%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	147 Particles/container of≥10µm 89 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.79	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By: s47F		Revie s47F	
Name :		Name	
DATE:02/07/14	DATE:02/07/14	DATE:02/07/14	DATE:02/07/14

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Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/298-01**	
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984084**	**A.R. NO.**	**: FP/S-01/14/196**
Manufacturing Date	**: JUN-14**	**Expiry Date**	**: MAY-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 12/06/14**	**Date of completion**	**: 26/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.2mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	100.5%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	64 Particles/container of≥10µm 46 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.78	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

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Prepared By		Reviewed By	
Name		Name	
DATE:02/07/14	DATE:02/07/14	DATE:02/07/14	DATE:02/07/14

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Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-01**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984083**	**A.R. NO.**	**: FP/S-01/14/195**
Manufacturing Date	**: JUN-14**	**Expiry Date**	**: MAY-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 12/06/14**	**Date of completion**	**: 26/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.2mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	100.5%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	21 Particles/container of≥10µm 11 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.78	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By: s47F		Reviev s47F	
Name :		Name:	
DATE:02/07/14	DATE:02/07/14	DATE:02/07/14	DATE:02/07/14

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CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/298-01**	
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984082**	**A.R. NO.**	**: FP/S-01/14/194**
Manufacturing Date	**: JUN-14**	**Expiry Date**	**: MAY-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 11/06/14**	**Date of completion**	**: 25/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.2mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	99.8%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	41 Particles/container of≥10µm 21 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.76	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By: s47F		Reviev s47F	
Name :		Name:	
DATE:02/07/14	DATE:02/07/14	DATE:02/07/14	DATE:02/07/14

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Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT : Quality Control **Reference Specification No: FP/SPEC/298-01**

TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)

.Batch No.	**: 1T2984081**	**A.R. NO.**	**: FP/S-01/14/193**
Manufacturing Date	**: JUN-14**	**Expiry Date**	**: MAY-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 10/06/14**	**Date of completion**	**: 24/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.4mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	99.2%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	131 Particles/container of≥10µm 62 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.73	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By Name : s47F		Review Name: s47F	
DATE:02/07/14	DATE:02/07/14	DATE:02/07/14	DATE:02/07/14

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/298-01**	
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984080**	**A.R. NO.**	**: FP/S-01/14/192**
Manufacturing Date	**: JUN-14**	**Expiry Date**	**: MAY-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 09/06/14**	**Date of completion**	**: 23/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	 (A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	 (A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.2mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	100.5%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	100 Particles/container of≥10µm 61 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.78	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By: s47F		Reviev s47F	
Name :		Name:	
DATE:02/07/14	DATE:02/07/14	DATE:02/07/14	DATE:02/07/14

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/298-01**	
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984079**	**A.R. NO.**	**: FP/S-01/14/191**
Manufacturing Date	**: JUN-14**	**Expiry Date**	**: MAY-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 09/06/14**	**Date of completion**	**: 23/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.1mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	100.5%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	55 Particles/container of≥10µm 25 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.78	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By: s47F		Review s47F	
Name :		Name:	
DATE:02/07/14	DATE:02/07/14	DATE:02/07/14	DATE:02/07/14

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-01**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984078**	**A.R. NO.**	**: FP/S-01/14/190**
Manufacturing Date	**: JUN-14**	**Expiry Date**	**: MAY-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 08/06/14**	**Date of completion**	**: 22/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.3mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	99.9%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	109 Particles/container of≥10µm 66 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.78	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By	s47F	Revi	s47F
Name		Nam	
DATE:15/07/14	DATE:15/07/14	DATE:15/07/14	DATE:15/07/14

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Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-01**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984077**	**A.R. NO.**	**: FP/S-01/14/189**
Manufacturing Date	**: JUN-14**	**Expiry Date**	**: MAY-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 07/06/14**	**Date of completion**	**: 21/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.2mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	99.9%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	86 Particles/container of≥10µm 44 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.78	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By: s47F		Revie s47F	
Name :		Name	
DATE:02/07/14	DATE:02/07/14	DATE:02/07/14	DATE:02/07/14

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Marck

MARCK BIOSCIENCES LTD.

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-01**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984076**	**A.R. NO.**	**: FP/S-01/14/188**
Manufacturing Date	**: JUN-14**	**Expiry Date**	**: MAY-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 06/06/14**	**Date of completion**	**: 20/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.1mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	100.5%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	17 Particles/container of≥10µm 12 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.80	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared E s47F		Review s47F	
Name		Name:(	
Date:24/06/14	Date:24/06/14	Date:24/06/14	Date:24/06/14

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Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-01**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984075**	**A.R. NO.**	**: FP/S-01/14/187**
Manufacturing Date	**: JUN-14**	**Expiry Date**	**: MAY-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 06/06/14**	**Date of completion**	**: 20/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.3mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	100.5%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	89 Particles/container of≥10µm 63 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.72	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By: s47F		Reviewed By: s47F	
Name :		Name:	
Date:24/06/14	Date:24/06/14	Date:24/06/14	Date:24/06/14

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-01**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984074**	**A.R. NO.**	**: FP/S-01/14/186**
Manufacturing Date	**: JUN-14**	**Expiry Date**	**: MAY-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 05/06/14**	**Date of completion**	**: 19/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.2mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	100.5%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	7 Particles/container of≥10µm 2 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.68	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By: s47F		Revie s47F	
Name :		Name	
Date:24/06/14	Date:24/06/14	Date:24/06/14	Date:24/06/14

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-01**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984073**	**A.R. NO.**	**: FP/S-01/14/185**
Manufacturing Date	**: JUN-14**	**Expiry Date**	**: MAY-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 04/06/14**	**Date of completion**	**: 18/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.2mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	99.9%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	104 Particles/container of≥10µm 66 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.76	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By	s47F	Review	s47F
Name		Name:	
Date:24/06/14	Date:24/06/14	Date:24/06/14	Date:24/06/14

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-01**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984072**	**A.R. NO.**	**: FP/S-01/14/184**
Manufacturing Date	**: JUN-14**	**Expiry Date**	**: MAY-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 04/06/14**	**Date of completion**	**: 18/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.1mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	100.5%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	43 Particles/container of≥10µm 17 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.80	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By: s47F		Reviewed By: s47F	
Name :		Name:	
Date:24/06/14	Date:24/06/14	Date:24/06/14	Date:24/06/14

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT : Quality Control **Reference Specification No: FP/SPEC/298-01**

TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)

.Batch No.	**: 1T2984071**	**A.R. NO.**	**: FP/S-01/14/183**
Manufacturing Date	**: JUN-14**	**Expiry Date**	**: MAY-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 03/06/14**	**Date of completion**	**: 17/06/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.3mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	99.2%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	23 Particles/container of≥10µm 9 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.97	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By: s47F		Reviev s47F	
Name :		Name:	
Date:24/06/14	Date:24/06/14	Date:24/06/14	Date:24/06/14

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/298-01**	
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984064**	**A.R. NO.**	**: FP/S-01/14/141**
Manufacturing Date	**: APR-14**	**Expiry Date**	**: MAR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 18/04/14**	**Date of completion**	**: 02/05/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.2mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL. or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL.
04	Assay of Sodium Chloride	99.1%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL.	Less than 0.25 EU/mL.
06	Particulate Contamination	30 Particles/container of≥10µm 3 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.69	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By: s47F		Revie s47F	
Name :		Name	
Date:05/05/14	Date:05/05/14	Date:05/05/14	Date:05/05/14

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/298-01**	
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984063**	**A.R. NO.**	**: FP/S-01/14/140**
Manufacturing Date	**: APR-14**	**Expiry Date**	**: MAR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 17/04/14**	**Date of completion**	**: 01/05/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate shoul be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easil with the possible exception of a fe large particles which dissolve slowly
03	Extractable Volume	10.2mL	Not less than nominal volume and no more than 115% of the nomina volume for ≤ 5 mL, or Not less tha nominal volume and not more tha 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	99.1%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	3 Particles/container of≥10µm 0.67 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater tha 10 µm and not more than 600 pe container equal to or greater tha 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.61	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By: s47F		Review s47F	
Name :		Name:(	
Date:05/05/14	Date:05/05/14	Date:05/05/14	Date:05/05/14

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/298-01**	
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984062**	**A.R. NO.**	**: FP/S-01/14/139**
Manufacturing Date	**: APR-14**	**Expiry Date**	**: MAR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 16/04/14**	**Date of completion**	**: 01/05/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.1mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL.
04	Assay of Sodium Chloride	98.5%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL.	Less than 0.25 EU/mL.
06	Particulate Contamination	7 Particles/container of≥10µm 0.67 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.63	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By	s47F		
Name			
Date:05/05/14	Date:05/05/14	Date:05/05/14	Date:05/05/14

s47G

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-01**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984061**	**A.R. NO.**	**: FP/S-01/14/138**
Manufacturing Date	**: APR-14**	**Expiry Date**	**: MAR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 16/04/14**	**Date of completion**	**: 01/05/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.2mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	98.5%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	3 Particles/container of≥10µm 0 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.63	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

s47F

Prepared By:			
Name :			
Date:05/05/14	Date:05/05/14	Date:05/05/14	Date:05/05/14

s47G

s47G

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-01**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984059**	**A.R. NO.**	**: FP/S-01/14/133**
Manufacturing Date	**: APR-14**	**Expiry Date**	**: MAR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 11/04/14**	**Date of completion**	**: 25/04/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.1mL.	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL. or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL.
04	Assay of Sodium Chloride	98.5%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL.	Less than 0.25 EU/mL.
06	Particulate Contamination	47 Particles/container of≥10µm 7 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.75	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By	s47F	Reviewed By	s47F
Name		Name:	
Date: 5/5/14	Date: 5/5/14	Date: 05/05/14	Date: 5/5/14

s47G

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-01**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984058**	**A.R. NO.**	**: FP/S-01/14/132**
Manufacturing Date	**: APR-14**	**Expiry Date**	**: MAR-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 11/04/14**	**Date of completion**	**: 25/04/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.1mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	99.1%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	45 Particles/container of≥10µm 3 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.72	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report:The product complies with the prescribed standard of the quality as per specification.

Prepared By	s47F	Review	s47F
Name		Name:	
Date:05/05/14	Date:05/05/14	Date:05/05/14	Date:05/05/14

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Q01019/F-20-01/010412 **CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

DEPARTMENT	**: Quality Control**	**Reference Specification No: FP/SPEC/298-01**	
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984051**	**A.R. NO.**	**: FP/S-01/14/103**
Manufacturing Date	**: MAR-14**	**Expiry Date**	**: FEB-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 17/03/14**	**Date of completion**	**: 01/04/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.2mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5ml.
04	Assay of Sodium Chloride	100.2%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/ml.
06	Particulate Contamination	16 Particles/container of≥10µm 5 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.81	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report: The product complies with the prescribed standard of the quality as per specification.

s47F

s47F

Prepared By:		Reviev	
Name :		Name:	
Date:05/05/14	Date:05/05/14	Date:05/05/14	Date:05/05/14

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-01**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984050**	**A.R. NO.**	**: FP/S-01/14/102**
Manufacturing Date	**: MAR-14**	**Expiry Date**	**: FEB-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 16/03/14**	**Date of completion**	**: 30/03/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	 (A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	 (A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.1mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	100.2%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	21 Particles/container of≥10µm 5 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.68	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report: The product complies with the prescribed standard of the quality as per specification.

Prepared By: s47F		Reviewed By: s47F	
Name :		Name:	
Date:14/05/14	Date:14/05/14	Date:14/05/14	Date:14/05/14

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT : Quality Control **Reference Specification No: FP/SPEC/298-01**

TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)

.Batch No.	**: 1T2984048**	**A.R. NO.**	**: FP/S-01/14/100**
Manufacturing Date	**: MAR-14**	**Expiry Date**	**: FEB-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 14/03/14**	**Date of completion**	**: 28/03/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.1mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5 mL
04	Assay of Sodium Chloride	100.2%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	71 Particles/container of≥10µm 25 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.78	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report: The product complies with the prescribed standard of the quality as per specification.

Prepared By: s47F		Reviev s47F	
Name :		Name:	
Date:02/04/14	Date:02/04/14	Date:02/04/14	Date:02/04/14

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-01**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984047**	**A.R. NO.**	**: FP/S-01/14/099**
Manufacturing Date	**: MAR-14**	**Expiry Date**	**: FEB-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 13/03/14**	**Date of completion**	**: 27/03/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.2mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5 mL
04	Assay of Sodium Chloride	99.5%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	43 Particles/container of≥10µm 5 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.75	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report: The product complies with the prescribed standard of the quality as per specification.

Prepared By: s47F		Revie s47F	
Name :		Name	
Date:02/04/14	Date:02/04/14	Date:02/04/14	Date:02/04/14

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-01**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984036**	**A.R. NO.**	**: FP/S-01/14/055**
Manufacturing Date	**: FEB-14**	**Expiry Date**	**: JAN-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 13/02/14**	**Date of completion**	**: 27/02/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.2mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5 mL
04	Assay of Sodium Chloride	100.2%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	94 Particles/container of≥10µm 39 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.61	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Storage:Store below 25°C

Report: The product complies with the prescribed standard of the quality as per specification.

Prepared By s47F		Reviewed s47F	
Name		Name:	
DATE:28/02/14	DATE:28/02/14	DATE: 01/03/14	DATE: 01/03/14

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Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-01**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1T2984032**	**A.R. NO.**	**: FP/S-01/14/048**
Manufacturing Date	**: FEB-14**	**Expiry Date**	**: JAN-17**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 125Nos.**
Testing Date	**: 10/02/14**	**Date of completion**	**: 25/02/14**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	(A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	(A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	10.2mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5 mL
04	Assay of Sodium Chloride	100.2%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25 EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	347 Particles/container of≥10µm 39 Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.72	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Storage:Store below 25°C

Report: The product complies with the prescribed standard of the quality as per specification.

Prepared By	s47F		
Name			
DATE:28/02/14	DATE:28/02/14	DATE: 01/03/14	DATE :01.3.14

s47G

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-00**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1TW2983003**	**A.R. NO.**	**: FP/S-01/13/398**
Manufacturing Date	**: NOV-13**	**Expiry Date**	**: OCT-16**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 80 Nos.**
Testing Date	**: 25/11/13**	**Date of completion**	**: 11/12/13**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	 (A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	 (A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	20.3mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	99.0%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	17Particles/container of≥10µm 1Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.78	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report: The product complies with the prescribed standard of the quality as per specification.

s47F

Prepared By:			
Name :			
DATE:28/03/14	DATE:28/03/14	DATE:28/03/14	DATE:28/03/14

MARCK BIOSCIENCES LTD.

Q01019/F-20-01/010412

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

DEPARTMENT	**: Quality Control**	**Reference Specification No:**	**FP/SPEC/298-00**
TITLE : SODIUM CHLORIDE FOR INJECTION -MS 0.9%W/V (SODIUM CHLORIDE INJECTION BP)			
.Batch No.	**: 1TW2983002**	**A.R. NO.**	**: FP/S-01/13/397**
Manufacturing Date	**: NOV-13**	**Expiry Date**	**: OCT-16**
Batch Size	**: 1000 Litre**	**Quantity sampled**	**: 80 Nos.**
Testing Date	**: 25/11/13**	**Date of completion**	**: 11/12/13**

Sr. No.	Test	Observation	Specification
01	Appearance	A clear, colourless solution.	A clear, colourless solution
02	Identification (A) Sodium Salts (B) Chlorides	 (A) (a) A dense white precipitate is formed. (b) No precipitate is formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	 (A) (a) A dense white precipitate should be formed. (b) No precipitate should be formed. (B) The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
03	Extractable Volume	20.4mL	Not less than nominal volume and not more than 115% of the nominal volume for ≤ 5 mL or Not less than nominal volume and not more than 110% of the nominal volume for > 5mL
04	Assay of Sodium Chloride	99.0%	Between 96.0% to 104.0%
05	Bacterial Endotoxins	<0.25EU/mL	Less than 0.25 EU/mL
06	Particulate Contamination	11Particles/container of≥10µm 1Particles/container of ≥25µm	Average particles not more than 6000 per container equal to or greater than 10 µm and not more than 600 per container equal to or greater than 25µm
07	Sterility	Sterile	Must be sterile
ADDITIONAL TESTS AS PER IP			
08	pH	5.87	Between 4.5 to 7.0
09	Heavy Metals	<0.3ppm	Not more than 0.3 ppm
ADDITIONAL TEST AS PER USP			
10	Iron	<2ppm	Not more than 2 ppm

Report: The product complies with the prescribed standard of the quality as per specification.

Prepared By	s47F	Revie	s47F
Name		Name	
DATE:28/03/14	DATE:28/03/14	DATE:28/03/14	DATE:28/03/14

s47G

Australian Government

Department of Health

Therapeutic Goods Administration

URGENT MEDICINE RECALL*

LEVEL: Wholesale

CLASS: Class I

REFERENCE: RC-2014-RN-01098-1

DATE AGREED: 10/10/2014

PRODUCT: **Sodium Chloride For Injection – MS 0.9% W/V, 50 X 5ML Ampoules**

Batch Number: 1F2983003

AUST R Number: 199991

SPONSOR: s47G

PHONE: s47G

REASON: s47G, following advice from the Therapeutic Goods Administration that Batch Number 1F2983003 of Sodium Chloride for Injection-MS 0.9% w/v 5mL ampoules has failed the test for sterility, is recalling all units which are with the contracted distributor. No affected units have been supplied by the contracted distributor. No other batches or pack sizes of this product are affected by this recall.

PROPOSED ACTION: The contracted distributor is asked to inspect their stocks and quarantine all units from the above batch number. s47G will arrange for the affected stock to be recovered.

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product Distribution: 1 contracted distributor in VIC

Product export status: Unknown

This issue was first identified by the Sponsor

*For further details about Recall Actions, please refer to http://tga.gov.au/safety/recalls-about.htm

Australian Government

Department of Health
Therapeutic Goods Administration

URGENT MEDICINE RECALL*

LEVEL: Retail CLASS: Class II

REFERENCE: RC-2015-RN-00513-1 DATE AGREED: 16/06/15

PRODUCT: **Paclitaxel Suspension (Abraxane) 207.5mg in 0.9% Sodium Chloride (Compounded Patient Specific Product)**

Batch Number: 15F11QM00119

Manufacturing date: 11/06/2015

Expiry Date: 13/06/2015

SPONSOR: s47G

PHONE: s47G – Customer Service

REASON: s47G has decided to recall this product as it has been determined that the partially used vial of Paclitaxel Suspension used to manufacture this product has possibly been incorrectly stored at room temperature rather than at a refrigerated temperature. Consequently the shelf life of the product cannot be guaranteed.

PROPOSED ACTION: s47G is sending the pharmacy a letter describing the issue and recall action. The pharmacy was previously contacted via telephone to alert them of the issue and ensure that the medicine was not administered.

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product Distribution: 1 pharmacy in QLD

Product export status: Unknown

This issue was first identified by the Sponsor

*For further details about Recall Actions, please refer to http://tga.gov.au/safety/recalls-about.htm