Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Laboratory Report

LB Reference: Project 2992
RCB reference: RC-036280

Re: *Ivervid 12 Ivermectin Tablets IP 12 mg*

Background

On Wednesday, 18 December 2024, Laboratories Branch (LB) Chemistry received a Request for Analysis form from s22 of the TGA Product Import Compliance Section (PICS).On Monday, 23 December 2024 LB Chemistry received the following sample.

- One, clear, plastic, tamper-evident, security bag bearing seal number *'A260653525'*. This bag contained two, blister trays labelled as '*Ivervid 12 Ivermectin Tablets IP 12 mg'*. Batch number '*TI-1230001'* and expiry date '*04/2027'* were also included on the blister tray.

The sample was assigned TGA sample number **2412004166** upon receipt.

According to the request for analysis, PICS obtained the sample from Australian Border Force. It is suspected to contain less than the labelled content of ivermectin.

PICS has requested LB Chemistry to investigate the amount of ivermectin in the sample.

Examination and Analysis

The sample was visually examined, photographed[1] and analysed. A '*Certificate of Analysis'* for the sample (D25-1159710 refers) is provided with this report. The results of the examination and analysis of the sample are reviewed below.

A photograph of the sample is provided in **Appendix 1** of this report.

(i) Visual examination

The sample consisted of twenty, white, round, biconvex tablets, debossed with a break-line on one face. Ten tablets were contained in each labelled blister tray. The average tablet weight (based on 10 tablets) was 109.3 mg.

Labelling details for the blister trays included 'Manufactured by: *Fortune Healthcare Product Pvt. Ltd.'* and indicated that each tablet contained 12 mg of Ivermectin.

[1] The photographs are located in TRIM container E24-585415 TRIM record D24-5425477.

(ii) Testing

Analysis was conducted on 10 individual tablets, tested separately.

Confirmation of the presence of ivermectin and its content in the sample was determined by analysing each tablet in accordance with the assay test outlined in the *USP*[2] *- Ivermectin Tablets* monograph.

Ivermectin was identified in the sample. The average content in the sample was 84.4% of the labelled content, with the variation between the 10 tablets ranging from 81.8% to 88.1%.

This sample would not meet the requirements of the USP or the IP[3] as the content is below 90.0% of the labelled amount.

Conclusion

Ivermectin was identified in the sample of '*Ivervid 12 Ivermectin Tablets IP 12 mg'* (TGA sample number **2412004166**). The content of ivermectin in the sample was 84.4% of the labelled content.

Signed electronically by

s22

20/03/2025

Authorised by:

s22

Principle Chemist, LB Chemistry

Appendix 1: Photograph of the sample

[2] United States Pharmacopeia
[3] Indian Pharmacopoeia

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Certificate of Analysis

A sample of therapeutic goods, bearing TGA sample number 2412004166 has been examined and analysed

The sample was submitted by s22 [redacted] for s22 [redacted]

Results are applicable to the sample tested, as received by the TGA Laboratories Branch.

The goods were represented to be:

ARTG Number: N/A

Name: Ivervid 12 Ivermectin Tablets

Sponsor: NOT AVAILABLE

Batch Number: TI-1230001

Expiry Date: 30-April-2027

Dosage Form: Tablet

TEST	RESULT	REQUIREMENT
TGA Seal Number	A260653525	
Sample Appearance		
	White, round, biconvex tablets, debossed with a break-line on one face. The average tablet weight (based on 10 tablets) was 109.3 mg. The tablets were contained in labelled, aluminium blister trays (10 blister trays each containing 10 tablets). The blister trays were presented in a sealed 'Tamper Evident Security Bag'	
Content of Ivermectin by UPLC (USP)	84.4 %	90.0 to 110.0 %
Identification of Ivermectin by UPLC (USP)	Present	Present
Uniformity of dosage units - content uniformity	Acceptance Value (AV) = 19.4 (85.0, 88.1, 82.2, 85.2, 81.8, 84.8, 82.3, 85.8, 86.9, 82.2 %LC)	AV = 15.0 or less

Abbreviations: UPLC = ultra performance liquid chromatography; USP = United States Pharmacopeia

This Certificate has been signed and issued electronically by the nominated analyst

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Email: info@tga.gov.au https://www.tga.gov.au

TGA Health Safety Regulation

Project Name: Chemistry\System25_2025_01
Sample Set Name: Ivermectin s22 11022024

LIMS Number:
Sample Set Id: 1463
Sample Set Start Date: 11/02/2025 12:18:48 PM AEDT
Print Date: 12/02/2025

Analyst s22

System Suitability

Processed Channel Descr. DAD.0.0.S PDA 245.0 nm (DAD: Spectrum)

System Suitability (Duration)
Peak Name: Ivermectin A

	Inj Id	Result Id	Sample Name	Label	RT (min)	k'	Area (µV*sec)	Height (µV)	Symmetry Factor	N (Plates)	Resolution
1	1251	2105	Ivermectin Std 1	S101	1.22	4.53	661052	186833	1.0581	2666	2.2
2	1253	2106	Ivermectin Std 1	S101	1.23	4.55	658164	189557	1.0639	2796	2.3
3	1277	2107	Ivermectin Std 1	S102	1.24	4.60	664346	213374	1.0667	3562	2.5
4	1279	2108	Ivermectin Std 1	S102	1.24	4.60	663071	213089	1.0647	3546	2.5
5	1297	2109	Ivermectin Std 1	S103	1.24	4.60	660398	211688	1.0707	3534	2.5
6	1299	2110	Ivermectin Std 1	S103	1.24	4.60	658035	211435	1.0768	3569	2.5
7	1318	2111	Ivermectin Std 1	S104	1.24	4.59	662915	211261	1.0821	3499	2.5
8	1320	2112	Ivermectin Std 1	S104	1.24	4.59	659688	209922	1.0877	3511	2.5
9	1338	2113	Ivermectin Std 1	S105	1.24	4.59	657282	208216	1.0783	3432	2.5
10	1340	2114	Ivermectin Std 1	S105	1.24	4.59	660397	209575	1.0761	3482	2.5
11	1358	2115	Ivermectin Std 1	S106	1.24	4.59	657244	207939	1.0852	3420	2.5
12	1360	2116	Ivermectin Std 1	S106	1.24	4.59	662783	209613	1.0800	3460	2.5
13	1378	2117	Ivermectin Std 1	S107	1.24	4.59	662301	209279	1.0939	3464	2.5
14	1380	2118	Ivermectin Std 1	S107	1.24	4.59	659036	208336	1.0938	3468	2.5
15	1393	2119	Ivermectin Std 1	S108	1.24	4.59	661441	208373	1.0832	3423	2.5
16	1395	2120	Ivermectin Std 1	S108	1.24	4.59	656342	206827	1.0916	3411	2.5
Mean					1.23	4.59	660281		1.08	3390	2.4
% RSD					0.34	0.42	0.37				

System Suitability (Duration)
Peak Name: Ivermectin B

	Inj Id	Result Id	Sample Name	Label	RT (min)	k'	Area (µV*sec)	Height (µV)	Symmetry Factor	N (Plates)
1	1251	2105	Ivermectin Std 1	S101	1.02	3.63	15212	4913	1.0519	2381
2	1253	2106	Ivermectin Std 1	S101	1.03	3.65	15179	4955	1.0558	2448
3	1277	2107	Ivermectin Std 1	S102	1.04	3.68	15470	5346	1.0580	2774
4	1279	2108	Ivermectin Std 1	S102	1.04	3.68	15438	5334	1.0720	2763
5	1297	2109	Ivermectin Std 1	S103	1.04	3.68	15352	5297	1.0747	2758
6	1299	2110	Ivermectin Std 1	S103	1.04	3.68	15346	5303	1.0596	2782
7	1318	2111	Ivermectin Std 1	S104	1.03	3.68	15394	5295	1.0661	2754
8	1320	2112	Ivermectin Std 1	S104	1.04	3.68	15334	5264	1.0639	2746
9	1338	2113	Ivermectin Std 1	S105	1.03	3.68	15251	5225	1.0755	2726
10	1340	2114	Ivermectin Std 1	S105	1.03	3.68	15354	5253	1.0665	2715
11	1358	2115	Ivermectin Std 1	S106	1.03	3.68	15285	5223	1.0753	2718
12	1360	2116	Ivermectin Std 1	S106	1.04	3.68	15419	5260	1.0698	2700
13	1378	2117	Ivermectin Std 1	S107	1.03	3.68	15363	5251	1.0703	2725
14	1380	2118	Ivermectin Std 1	S107	1.03	3.68	15281	5227	1.0695	2729

Project Name: Chemistry\System25_2025_01
Sample Set Name: Ivermectin s22 11022024

Analyst s22

LIMS Number:
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Print Date: 12/02/2025

System Suitability

System Suitability (Duration)
Peak Name: Ivermectin B

	Inj Id	Result Id	Sample Name	Label	RT (min)	k'	Area (µV*sec)	Height (µV)	Symmetry Factor	N (Plates)
15	1393	2119	Ivermectin Std 1	S108	1.03	3.68	15322	5222	1.0783	2688
16	1395	2120	Ivermectin Std 1	S108	1.03	3.68	15260	5200	1.0743	2706
Mean					1.03	3.68	15329		1.07	2695
% RSD					0.31	0.40	0.53			

Total Ivermectin Std 1 = 675610

Standard Correlation (Analytical Standard)
Peak Name: Ivermectin A

	Inj Id	Result Id	Sample Name	Label	RT (min)	k'	Area (µV*sec)	Height (µV)	Symmetry Factor	N (Plates)
1	1257	2161	Ivermectin Std 2	C001	1.23	4.56	703628	207039	1.06	2935
2	1259	2162	Ivermectin Std 2	C001	1.23	4.57	705299	211176	1.06	3056
Mean					1.23	4.56	704464		1.06	2995
% RSD					0.09	0.11	0.17			

Standard Correlation (Analytical Standard)
Peak Name: Ivermectin B

	Inj Id	Result Id	Sample Name	Label	RT (min)	k'	Area (µV*sec)	Height (µV)	Symmetry Factor	N (Plates)
1	1257	2161	Ivermectin Std 2	C001	1.03	3.66	16206	5352	1.06	2511
2	1259	2162	Ivermectin Std 2	C001	1.03	3.66	16266	5419	1.06	2560
Mean					1.03	3.66	16236		1.06	2535
% RSD					0.08	0.10	0.26			

Standard Correlation (Analytical Standard)
Peak Name: Total Ivermectin (A+B)

	Inj Id	Result Id	Sample Name	Label	RT (min)	Area (µV*sec)	Height (µV)	% Deviation
1	1257	2161	Ivermectin Std 2	C001	1.23	719834	212391	-0.38
2	1259	2162	Ivermectin Std 2	C001	1.23	721565	216594	-0.14
Mean					1.23	720700		-0.26
% RSD					0.09	0.17		

System Suitability Requirements:

%RSD (Rt) NMT 1.0%: Complies / Fails

%RSD (Response): NMT 2.0% Complies / Fails

Symmetry Factor: 0.8<As<1.5 Complies / Fails

Standard Correlation: < 2.0% Abs. Complies / Fails

Capacity Factor (K') for Ivermectin B (Component H2B1b) NLT 3: PASS
Column Efficiency for Ivermectin A (Component H2B1a) NLT 1500: PASS
Tailing facrot for Ivermectin A (Component H2B1a) NMT 2: PASS
RSD for Total Ivermecting for replicate injections NMT 2.0% PASS (Refer summary report)

Standard Correlation Confirmation:
Standard 1 Response = 675610, Mass = 7.05 mg
Standard 2 Response = 720700, Mass = 7.54 mg
Standard Correlation = 100 - 100[(720700/675610) X (7.05/7.54)] = -0.26%
Standard Correlation Complies

Project Name: Chemistry\System25_2025_01
Sample Set Name: Ivermectin s22 11022024

Analyst s22

LIMS Number:
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Print Date: 12/02/2025

System Suitability

Error Log

System Suitability Sum table group contains information that doesn't match the data being reported.

Project Name: Chemistry\System25_2025_01
Sample Set Name: Ivermectin s22 11022024

Analyst s22

LIMS Number:
Sample Set Id: 1463
Sample Set Start Date: 11/02/2025 12:18:48 PM AEDT
Print Date: 12/02/2025

Results Summary Report

Results Summary Tablet (peak area)
Peak Name: Ivermectin A

	Name	Sample Name	Injection	RT	Area	Sample Wt.	Dilution	K'	Sym	USP N (Plates)
1	Ivermectin A	Ivermectin Std 1	1	1.222	661052	1.00	25.00	4.53	1.06	2672
2	Ivermectin A	Ivermectin Std 1	2	1.226	658164	1.00	25.00	4.55	1.06	2803
3	Ivermectin A	Ivermectin Std 2	1	1.229	703628	1.00	25.00	4.56	1.06	2934
4	Ivermectin A	Ivermectin Std 2	2	1.231	705299	1.00	25.00	4.57	1.06	3053
s22										
11	Ivermectin A	Ivermectin Std 1	1	1.237	664346	1.00	25.00	4.60	1.07	3555
12	Ivermectin A	Ivermectin Std 1	2	1.237	663071	1.00	25.00	4.60	1.06	3620
s22										
19	Ivermectin A	Ivermectin Std 1	1	1.237	660398	1.00	25.00	4.60	1.07	3605
20	Ivermectin A	Ivermectin Std 1	2	1.237	658035	1.00	25.00	4.60	1.08	3554
s22										
27	Ivermectin A	Ivermectin Std 1	1	1.236	662915	1.00	25.00	4.59	1.08	3524
28	Ivermectin A	Ivermectin Std 1	2	1.236	659688	1.00	25.00	4.59	1.09	3482
s22										
31	Ivermectin A	2412004166_1	1	1.238	552267	1.00	50.00	4.60	1.09	3584
32	Ivermectin A	2412004166_1	2	1.239	550718	1.00	50.00	4.60	1.08	3662
33	Ivermectin A	2412004166_2	1	1.238	571133	1.00	50.00	4.60	1.08	3638
34	Ivermectin A	2412004166_2	2	1.238	572897	1.00	50.00	4.60	1.08	3602
35	Ivermectin A	Ivermectin Std 1	1	1.236	657282	1.00	25.00	4.59	1.08	3526
36	Ivermectin A	Ivermectin Std 1	2	1.236	660397	1.00	25.00	4.59	1.08	3503
37	Ivermectin A	2412004166_3	1	1.238	531187	1.00	50.00	4.60	1.08	3622
38	Ivermectin A	2412004166_3	2	1.238	535809	1.00	50.00	4.60	1.08	3571

Project Name: Chemistry\System25_2025_01
Sample Set Name: Ivermectin s22 11022024

Analyst s22

LIMS Number:
Sample Set Id: 1463
Sample Set Start Date: 11/02/2025 12:18:48 PM AEDT
Print Date: 12/02/2025

Results Summary Report

Results Summary Tablet (peak area)
Peak Name: Ivermectin A

	Name	Sample Name	Injection	RT	Area	Sample Wt.	Dilution	K'	Sym	USP N (Plates)
39	Ivermectin A	2412004166_4	1	1.238	552892	1.00	50.00	4.60	1.09	3615
40	Ivermectin A	2412004166_4	2	1.238	553727	1.00	50.00	4.60	1.09	3601
41	Ivermectin A	2412004166_5	1	1.238	530642	1.00	50.00	4.60	1.08	3599
42	Ivermectin A	2412004166_5	2	1.238	530872	1.00	50.00	4.60	1.09	3554
43	Ivermectin A	Ivermectin Std 1	1	1.236	657244	1.00	25.00	4.59	1.09	3508
44	Ivermectin A	Ivermectin Std 1	2	1.236	662783	1.00	25.00	4.59	1.08	3483
45	Ivermectin A	2412004166_6	1	1.238	550902	1.00	50.00	4.60	1.09	3594
46	Ivermectin A	2412004166_6	2	1.238	550612	1.00	50.00	4.60	1.08	3601
47	Ivermectin A	2412004166_7	1	1.238	532947	1.00	50.00	4.60	1.08	3595
48	Ivermectin A	2412004166_7	2	1.238	535478	1.00	50.00	4.60	1.08	3622
49	Ivermectin A	2412004166_8	1	1.238	557549	1.00	50.00	4.60	1.08	3620
50	Ivermectin A	2412004166_8	2	1.238	556961	1.00	50.00	4.60	1.09	3544
51	Ivermectin A	Ivermectin Std 1	1	1.236	662301	1.00	25.00	4.59	1.09	3448
52	Ivermectin A	Ivermectin Std 1	2	1.236	659036	1.00	25.00	4.59	1.09	3453
53	Ivermectin A	2412004166_9	1	1.238	563561	1.00	50.00	4.60	1.09	3591
54	Ivermectin A	2412004166_9	2	1.238	564891	1.00	50.00	4.60	1.09	3580
55	Ivermectin A	2412004166_10	1	1.238	532542	1.00	50.00	4.60	1.09	3558
56	Ivermectin A	2412004166_10	2	1.238	534208	1.00	50.00	4.60	1.10	3527
57	Ivermectin A	Ivermectin Std 1	1	1.236	661441	1.00	25.00	4.59	1.08	3469
58	Ivermectin A	Ivermectin Std 1	2	1.236	656342	1.00	25.00	4.59	1.09	3469

s22

Results Summary Table (peak area)
Peak Name: Ivermectin B

	Name	Sample Name	Injection	RT	Area	Sample Wt.	Dilution	K'	Sym	USP N (Plates)
1	Ivermectin B	Ivermectin Std 1	1	1.024	15212	1.00	25.00	3.63	1.05	2371
2	Ivermectin B	Ivermectin Std 1	2	1.027	15179	1.00	25.00	3.65	1.06	2429
3	Ivermectin B	Ivermectin Std 2	1	1.029	16206	1.00	25.00	3.66	1.06	2519
4	Ivermectin B	Ivermectin Std 2	2	1.031	16266	1.00	25.00	3.66	1.06	2596

s22

11	Ivermectin B	Ivermectin Std 1	1	1.035	15470	1.00	25.00	3.68	1.06	2878
12	Ivermectin B	Ivermectin Std 1	2	1.035	15438	1.00	25.00	3.68	1.07	2871

s22

Project Name: Chemistry\System25_2025_01
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LIMS Number:
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Sample Set Start Date: 11/02/2025 12:18:48 PM AEDT
Print Date: 12/02/2025

Analyst s22

Results Summary Report

Results Summary Table (peak area)
Peak Name: Ivermectin B

	Name	Sample Name	Injection	RT	Area	Sample Wt.	Dilution	K'	Sym	USP N (Plates)
s22										
19	Ivermectin B	Ivermectin Std 1	1	1.035	15352	1.00	25.00	3.68	1.07	2863
20	Ivermectin B	Ivermectin Std 1	2	1.035	15346	1.00	25.00	3.68	1.06	2788
s22										
27	Ivermectin B	Ivermectin Std 1	1	1.035	15394	1.00	25.00	3.68	1.07	2747
28	Ivermectin B	Ivermectin Std 1	2	1.035	15334	1.00	25.00	3.68	1.06	2764
s22										
31	Ivermectin B	2412004166_1	1	1.043	1664	1.00	50.00	3.72	1.07	2360
32	Ivermectin B	2412004166_1	2	1.043	1643	1.00	50.00	3.72	1.06	2360
33	Ivermectin B	2412004166_2	1	1.043	1725	1.00	50.00	3.72	1.06	2367
34	Ivermectin B	2412004166_2	2	1.043	1725	1.00	50.00	3.72	1.07	2360
35	Ivermectin B	Ivermectin Std 1	1	1.035	15251	1.00	25.00	3.68	1.08	2795
36	Ivermectin B	Ivermectin Std 1	2	1.035	15354	1.00	25.00	3.68	1.07	2823
37	Ivermectin B	2412004166_3	1	1.043	1604	1.00	50.00	3.72	1.06	2345
38	Ivermectin B	2412004166_3	2	1.043	1610	1.00	50.00	3.72	1.07	2356
39	Ivermectin B	2412004166_4	1	1.043	1662	1.00	50.00	3.72	1.06	2331
40	Ivermectin B	2412004166_4	2	1.043	1655	1.00	50.00	3.72	1.07	2354
41	Ivermectin B	2412004166_5	1	1.043	1604	1.00	50.00	3.72	1.07	2310
42	Ivermectin B	2412004166_5	2	1.043	1596	1.00	50.00	3.72	1.07	2347
43	Ivermectin B	Ivermectin Std 1	1	1.035	15285	1.00	25.00	3.68	1.08	2773
44	Ivermectin B	Ivermectin Std 1	2	1.035	15419	1.00	25.00	3.68	1.07	2807
45	Ivermectin B	2412004166_6	1	1.043	1671	1.00	50.00	3.72	1.07	2327
46	Ivermectin B	2412004166_6	2	1.042	1665	1.00	50.00	3.72	1.07	2359
47	Ivermectin B	2412004166_7	1	1.042	1595	1.00	50.00	3.72	1.08	2336
48	Ivermectin B	2412004166_7	2	1.043	1589	1.00	50.00	3.72	1.06	2346
49	Ivermectin B	2412004166_8	1	1.042	1655	1.00	50.00	3.72	1.07	2352
50	Ivermectin B	2412004166_8	2	1.043	1662	1.00	50.00	3.72	1.07	2354
51	Ivermectin B	Ivermectin Std 1	1	1.035	15363	1.00	25.00	3.68	1.07	2708
52	Ivermectin B	Ivermectin Std 1	2	1.035	15281	1.00	25.00	3.68	1.07	2712
53	Ivermectin B	2412004166_9	1	1.042	1666	1.00	50.00	3.72	1.06	2334
54	Ivermectin B	2412004166_9	2	1.042	1674	1.00	50.00	3.72	1.06	2323
55	Ivermectin B	2412004166_10	1	1.043	1596	1.00	50.00	3.72	1.07	2351
56	Ivermectin B	2412004166_10	2	1.043	1615	1.00	50.00	3.72	1.07	2341
57	Ivermectin B	Ivermectin Std 1	1	1.035	15322	1.00	25.00	3.68	1.08	2793

Project Name: Chemistry\System25_2025_01
Sample Set Name: Ivermectin [redacted] 11022024

Analyst [redacted]

LIMS Number:
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Results Summary Report

Results Summary Table (peak area)
Peak Name: Ivermectin B

	Name	Sample Name	Injection	RT	Area	Sample Wt.	Dilution	K'	Sym	USP N (Plates)
58	Ivermectin B	Ivermectin Std 1	2	1.035	15260	1.00	25.00	3.68	1.07	2735
[redacted]										

Results Summary Table (peak area)
Peak Name: Total Ivermectin (A+B)

	SampleName	Peak Name	Area	SampleWeight	Dilution	PercentLabelClaim
1	Ivermectin Std 1	Total Ivermectin (A+B)	676264	1.00	25.00	24.90
2	Ivermectin Std 1	Total Ivermectin (A+B)	673343	1.00	25.00	24.90
3	Ivermectin Std 2	Total Ivermectin (A+B)	719834	1.00	25.00	663.26
4	Ivermectin Std 2	Total Ivermectin (A+B)	721565	1.00	25.00	664.86
5	Ivermectin Std 1	Total Ivermectin (A+B)	679816	1.00	25.00	24.90
6	Ivermectin Std 1	Total Ivermectin (A+B)	678509	1.00	25.00	24.90
7	Ivermectin Std 1	Total Ivermectin (A+B)	675750	1.00	25.00	24.90
8	Ivermectin Std 1	Total Ivermectin (A+B)	673381	1.00	25.00	24.90
9	Ivermectin Std 1	Total Ivermectin (A+B)	678310	1.00	25.00	24.90
10	Ivermectin Std 1	Total Ivermectin (A+B)	675023	1.00	25.00	24.90
11	Ivermectin Std 1	Total Ivermectin (A+B)	672533	1.00	25.00	24.90
12	Ivermectin Std 1	Total Ivermectin (A+B)	675751	1.00	25.00	24.90
13	Ivermectin Std 1	Total Ivermectin (A+B)	672529	1.00	25.00	24.90
14	Ivermectin Std 1	Total Ivermectin (A+B)	678202	1.00	25.00	24.90
15	Ivermectin Std 1	Total Ivermectin (A+B)	677663	1.00	25.00	24.90
16	Ivermectin Std 1	Total Ivermectin (A+B)	674317	1.00	25.00	24.90
17	Ivermectin Std 1	Total Ivermectin (A+B)	676762	1.00	25.00	24.90
18	Ivermectin Std 1	Total Ivermectin (A+B)	671603	1.00	25.00	24.90

Results Summary Table (peak area)
Peak Name: Total Ivermectin (A+B)

	SampleName	Peak Name	Area	SampleWeight	Dilution	PercentLabelClaim	Average
[redacted]							[redacted]

Project Name: Chemistry\System25_2025_01
Sample Set Name: Ivermectin [redacted] 11022024

Analyst [redacted]

LIMS Number:
Sample Set Id: 1463
Sample Set Start Date: 11/02/2025 12:18:48 PM AEDT
Print Date: 12/02/2025

Results Summary Report

Results Summary Table (peak area)
Peak Name: Total Ivermectin (A+B)

	SampleName	Peak Name	Area	SampleWeight	Dilution	PercentLabelClaim	[redacted]
[redacted]							
21	2412004166_1	Total Ivermectin (A+B)	553931	1.00	50.00	85.07	84.95
22	2412004166_1	Total Ivermectin (A+B)	552361	1.00	50.00	84.83	
23	2412004166_2	Total Ivermectin (A+B)	572859	1.00	50.00	87.97	88.11
24	2412004166_2	Total Ivermectin (A+B)	574622	1.00	50.00	88.24	
25	2412004166_3	Total Ivermectin (A+B)	532791	1.00	50.00	81.82	82.18
26	2412004166_3	Total Ivermectin (A+B)	537418	1.00	50.00	82.53	
27	2412004166_4	Total Ivermectin (A+B)	554554	1.00	50.00	85.16	85.23
28	2412004166_4	Total Ivermectin (A+B)	555383	1.00	50.00	85.29	
29	2412004166_5	Total Ivermectin (A+B)	532247	1.00	50.00	81.74	81.76
30	2412004166_5	Total Ivermectin (A+B)	532468	1.00	50.00	81.77	
31	2412004166_6	Total Ivermectin (A+B)	552573	1.00	50.00	84.86	84.84
32	2412004166_6	Total Ivermectin (A+B)	552276	1.00	50.00	84.81	
33	2412004166_7	Total Ivermectin (A+B)	534542	1.00	50.00	82.09	82.29
34	2412004166_7	Total Ivermectin (A+B)	537066	1.00	50.00	82.48	
35	2412004166_8	Total Ivermectin (A+B)	559204	1.00	50.00	85.88	85.84
36	2412004166_8	Total Ivermectin (A+B)	558623	1.00	50.00	85.79	
37	2412004166_9	Total Ivermectin (A+B)	565227	1.00	50.00	86.80	86.91
38	2412004166_9	Total Ivermectin (A+B)	566566	1.00	50.00	87.01	
39	2412004166_10	Total Ivermectin (A+B)	534138	1.00	50.00	82.03	82.16
40	2412004166_10	Total Ivermectin (A+B)	535822	1.00	50.00	82.29	

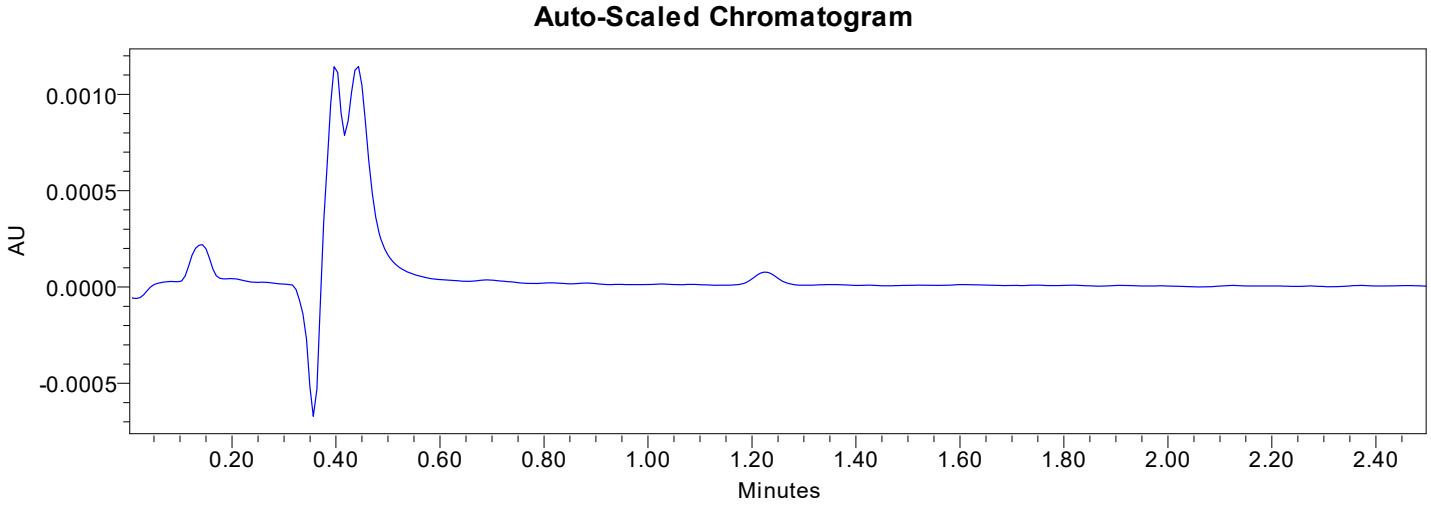
[redacted]

Project Name: Chemistry\System25_2025_01
Sample Set Name: Ivermectin s22 11022024

Sample Set Id: 1463
Sample Set Start Date: 11/02/2025 12:18:48 PM AEDT
Print Date: 12/02/2025

Analyst s22

Example Chromatograms



SampleName: Blank; Sample Type: Unknown; Date Acquired: 11/02/2025 4:32:38 PM AEDT; Vial: 1:A,1
Injection Id: 1405; Result Id 2184; Result Set Id ; Channel: DAD.0.0.S PDA 245.0 nm (DAD: Spectrum)

System Suitability Separation Results

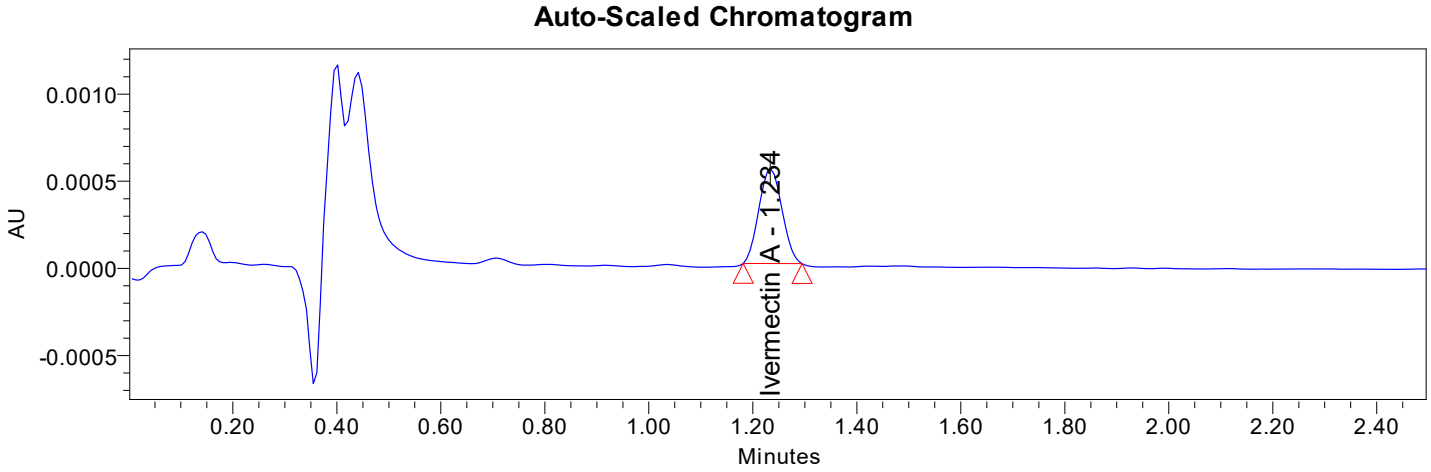
	Name	RT	USP Resolution	USP Tailing	K Prime	s/n
1	Ivermectin B	1.020				
2	Ivermectin A	1.230				
3	Total Ivermectin (A+B)					

Project Name: Chemistry\System25_2025_01
Sample Set Name: Ivermectin s22 11022024

Sample Set Id: 1463
Sample Set Start Date: 11/02/2025 12:18:48 PM AEDT
Print Date: 12/02/2025

Analyst s22

Example Chromatograms



SampleName: Ivermectin Sensitivity sol; Sample Type: Unknown; Date Acquired: 11/02/2025 4:21:05 PM AEDT; Vial: 1:A,2; Injection Id: 1398; Result Id 2180; Result Set Id ; Channel: DAD.0.0.S PDA 245.0 nm (DAD: Spectrum)

System Suitability Separation Results

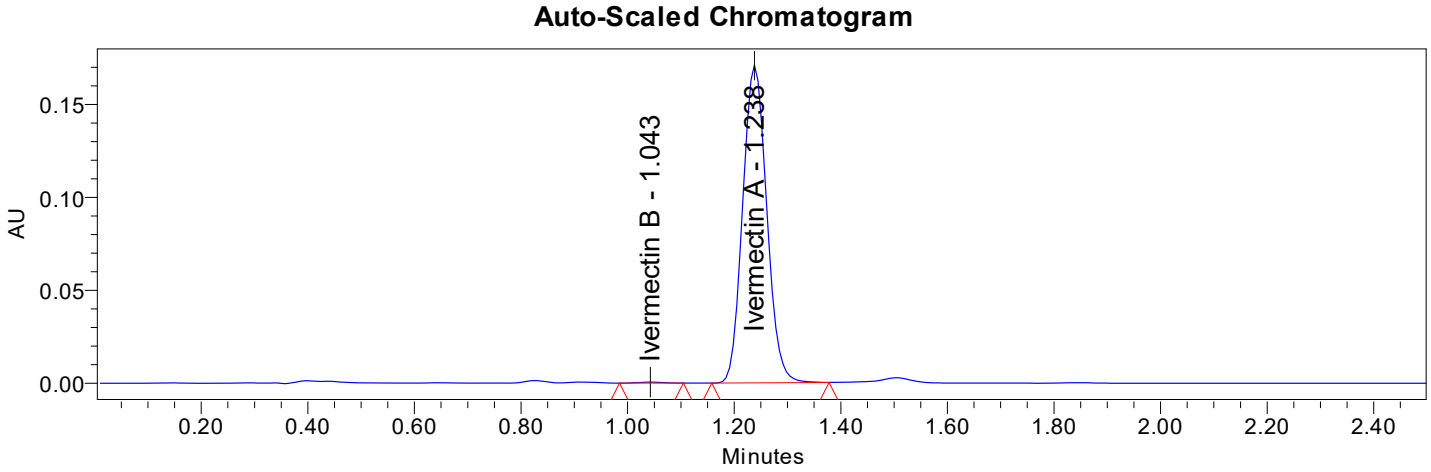
	Name	RT	USP Resolution	USP Tailing	K Prime	s/n
1	Ivermectin B	1.020				
2	Ivermectin A	1.234		1.07	4.58	115.18

Project Name: Chemistry\System25_2025_01
Sample Set Name: Ivermectin s22 11022024

Sample Set Id: 1463
Sample Set Start Date: 11/02/2025 12:18:48 PM AEDT
Print Date: 12/02/2025

Analyst s22

Example Chromatograms



SampleName: 2412004166_10; Sample Type: Unknown; Date Acquired: 11/02/2025 4:09:28 PM AEDT
Vial: 1:C,2; Injection Id: 1390; Result Id 2160; Result Set Id 2100; Channel: DAD.0.0.S PDA 245.0 nm (DAD: Spectrum)

s22

Project Name: Chemistry\System25_2025_01
Sample Set Name: Ivermectin s22 11022024

Sample Set Id: 1463
Sample Set Start Date: 11/02/2025 12:18:48 PM AEDT

Analyst s22

Print Date: 12/02/2025

Example Chromatograms

System Suitability Separation Results

	Name	RT	USP Resolution	USP Tailing	K Prime	s/n
1	Ivermectin B	1.035		1.07	3.68	15.14
2	Ivermectin A	1.236	2.443195	1.09	4.59	602.32
3	Ivermectin B	1.052		1.02	3.76	7.31
4	Ivermectin A	1.238	2.190586	1.09	4.60	996.72
5	Ivermectin B	1.043		1.07	3.72	1.97
6	Ivermectin A	1.238	2.304565	1.10	4.60	655.04

Project Name: Chemistry\System25_2025_01
Sample Set Name: Ivermectin s22 11022024

Analyst s22

System Name System 25
Sample Set Id: 1463
Sample Set Start Date: 11/02/2025 12:18:48 PM AEDT
Print Date: 12/02/2025

Run and Method Summary Report

Column Description: LC0267 - Phenomenex, Luna Omega Polar C18, 1.6µm, 2.1 × 100mm.

Sample Set Summary Table

	Inj Id	Sample Name	Label	Sample Type	Date Acquired	Acq Method Set	Vial	Inj. #	Inj Vol (ul)	Run Time (Minutes)	Sample Weight (mg)	Dilution	AverageUnitWeight	SaltCorrection	LabelClaim
1	1251	Ivermectin Std 1	S101	Standard	11/02/2025 12:37:24 PM AEDT	Ivermectin Assay USP	1:A,3	1	1.0	3.00	1.00	25.0000	1.00000	1.00000	1.00000
2	1253	Ivermectin Std 1	S101	Standard	11/02/2025 12:41:40 PM AEDT	Ivermectin Assay USP	1:A,3	2	1.0	3.00	1.00	25.0000	1.00000	1.00000	1.00000
3	1257	Ivermectin Std 2	C001	Control	11/02/2025 12:46:05 PM AEDT	Ivermectin Assay USP	1:A,4	1	1.0	2.50	1.00	25.0000	1.00000	1.00000	1.00000
4	1259	Ivermectin Std 2	C001	Control	11/02/2025 12:49:51 PM AEDT	Ivermectin Assay USP	1:A,4	2	1.0	2.50	1.00	25.0000	1.00000	1.00000	1.00000
s22															
11	1277	Ivermectin Std 1	S102	Standard	11/02/2025 1:16:44 PM AEDT	Ivermectin Assay USP	1:A,3	1	1.0	2.50	1.00	25.0000	1.00000	1.00000	1.00000
12	1279	Ivermectin Std 1	S102	Standard	11/02/2025 1:20:29 PM AEDT	Ivermectin Assay USP	1:A,3	2	1.0	2.50	1.00	25.0000	1.00000	1.00000	1.00000
s22															
19	1297	Ivermectin Std 1	S103	Standard	11/02/2025 1:47:26 PM AEDT	Ivermectin Assay USP	1:A,3	1	1.0	2.50	1.00	25.0000	1.00000	1.00000	1.00000
20	1299	Ivermectin Std 1	S103	Standard	11/02/2025 1:51:12 PM AEDT	Ivermectin Assay USP	1:A,3	2	1.0	2.50	1.00	25.0000	1.00000	1.00000	1.00000
s22															

Project Name: Chemistry\System25_2025_01
Sample Set Name: Ivermectin [redacted] 11022024

Analyst [redacted]

System Name System 25
Sample Set Id: 1463
Sample Set Start Date: 11/02/2025 12:18:48 PM AEDT
Print Date: 12/02/2025

Run and Method Summary Report

Sample Set Summary Table

	Inj Id	Sample Name	Label	Sample Type	Date Acquired	Acq Method Set	Vial	Inj. #	Inj Vol (ul)	Run Time (Minutes)	Sample Weight (mg)	Dilution	AverageUnitWeight	SaltCorrection	LabelClaim
[redacted]															
27	1318	Ivermectin Std 1	S104	Standard	11/02/2025 2:18:13 PM AEDT	Ivermectin Assay USP	1:A,3	1	1.0	2.50	1.00	25.0000	1.00000	1.00000	1.00000
28	1320	Ivermectin Std 1	S104	Standard	11/02/2025 2:21:59 PM AEDT	Ivermectin Assay USP	1:A,3	2	1.0	2.50	1.00	25.0000	1.00000	1.00000	1.00000
[redacted]															
31	1328	2412004166_1	U201	Unknown	11/02/2025 2:33:34 PM AEDT	Ivermectin Assay USP	1:B,4	1	1.0	2.50	1.00	50.0000	1.00000	1.00000	12.00000
32	1330	2412004166_1	U201	Unknown	11/02/2025 2:37:20 PM AEDT	Ivermectin Assay USP	1:B,4	2	1.0	2.50	1.00	50.0000	1.00000	1.00000	12.00000
33	1333	2412004166_2	U202	Unknown	11/02/2025 2:41:16 PM AEDT	Ivermectin Assay USP	1:B,5	1	1.0	2.50	1.00	50.0000	1.00000	1.00000	12.00000
34	1335	2412004166_2	U202	Unknown	11/02/2025 2:45:02 PM AEDT	Ivermectin Assay USP	1:B,5	2	1.0	2.50	1.00	50.0000	1.00000	1.00000	12.00000
35	1338	Ivermectin Std 1	S105	Standard	11/02/2025 2:48:59 PM AEDT	Ivermectin Assay USP	1:A,3	1	1.0	2.50	1.00	25.0000	1.00000	1.00000	1.00000
36	1340	Ivermectin Std 1	S105	Standard	11/02/2025 2:52:45 PM AEDT	Ivermectin Assay USP	1:A,3	2	1.0	2.50	1.00	25.0000	1.00000	1.00000	1.00000
37	1343	2412004166_3	U203	Unknown	11/02/2025 2:56:40 PM AEDT	Ivermectin Assay USP	1:B,6	1	1.0	2.50	1.00	50.0000	1.00000	1.00000	12.00000
38	1345	2412004166_3	U203	Unknown	11/02/2025 3:00:26 PM AEDT	Ivermectin Assay USP	1:B,6	2	1.0	2.50	1.00	50.0000	1.00000	1.00000	12.00000
39	1348	2412004166_4	U204	Unknown	11/02/2025 3:04:21 PM AEDT	Ivermectin Assay USP	1:B,7	1	1.0	2.50	1.00	50.0000	1.00000	1.00000	12.00000
40	1350	2412004166_4	U204	Unknown	11/02/2025 3:08:05 PM AEDT	Ivermectin Assay USP	1:B,7	2	1.0	2.50	1.00	50.0000	1.00000	1.00000	12.00000
41	1353	2412004166_5	U205	Unknown	11/02/2025 3:12:00 PM AEDT	Ivermectin Assay USP	1:B,8	1	1.0	2.50	1.00	50.0000	1.00000	1.00000	12.00000
42	1355	2412004166_5	U205	Unknown	11/02/2025 3:15:46 PM AEDT	Ivermectin Assay USP	1:B,8	2	1.0	2.50	1.00	50.0000	1.00000	1.00000	12.00000
43	1358	Ivermectin Std 1	S106	Standard	11/02/2025 3:19:44 PM AEDT	Ivermectin Assay USP	1:A,3	1	1.0	2.50	1.00	25.0000	1.00000	1.00000	1.00000
44	1360	Ivermectin Std 1	S106	Standard	11/02/2025 3:23:29 PM AEDT	Ivermectin Assay USP	1:A,3	2	1.0	2.50	1.00	25.0000	1.00000	1.00000	1.00000
45	1363	2412004166_6	U206	Unknown	11/02/2025 3:27:22 PM AEDT	Ivermectin Assay USP	1:B,9	1	1.0	2.50	1.00	50.0000	1.00000	1.00000	12.00000
46	1365	2412004166_6	U206	Unknown	11/02/2025 3:31:08 PM AEDT	Ivermectin Assay USP	1:B,9	2	1.0	2.50	1.00	50.0000	1.00000	1.00000	12.00000
47	1368	2412004166_7	U207	Unknown	11/02/2025 3:35:02 PM AEDT	Ivermectin Assay USP	1:B,10	1	1.0	2.50	1.00	50.0000	1.00000	1.00000	12.00000
48	1370	2412004166_7	U207	Unknown	11/02/2025 3:38:46 PM AEDT	Ivermectin Assay USP	1:B,10	2	1.0	2.50	1.00	50.0000	1.00000	1.00000	12.00000
49	1373	2412004166_8	U208	Unknown	11/02/2025 3:42:42 PM AEDT	Ivermectin Assay USP	1:B,11	1	1.0	2.50	1.00	50.0000	1.00000	1.00000	12.00000
50	1375	2412004166_8	U208	Unknown	11/02/2025 3:46:28 PM AEDT	Ivermectin Assay USP	1:B,11	2	1.0	2.50	1.00	50.0000	1.00000	1.00000	12.00000
51	1378	Ivermectin Std 1	S107	Standard	11/02/2025 3:50:22 PM AEDT	Ivermectin Assay USP	1:A,3	1	1.0	2.50	1.00	25.0000	1.00000	1.00000	1.00000
52	1380	Ivermectin Std 1	S107	Standard	11/02/2025 3:54:08 PM AEDT	Ivermectin Assay USP	1:A,3	2	1.0	2.50	1.00	25.0000	1.00000	1.00000	1.00000
53	1383	2412004166_9	U209	Unknown	11/02/2025 3:58:02 PM AEDT	Ivermectin Assay USP	1:C,1	1	1.0	2.50	1.00	50.0000	1.00000	1.00000	12.00000
54	1385	2412004166_9	U209	Unknown	11/02/2025 4:01:48 PM AEDT	Ivermectin Assay USP	1:C,1	2	1.0	2.50	1.00	50.0000	1.00000	1.00000	12.00000
55	1388	2412004166_10	U210	Unknown	11/02/2025 4:05:42 PM AEDT	Ivermectin Assay USP	1:C,2	1	1.0	2.50	1.00	50.0000	1.00000	1.00000	12.00000

Project Name: Chemistry\System25_2025_01
Sample Set Name: Ivermectin [redacted] 11022024

Analyst [redacted]

System Name System 25
Sample Set Id: 1463
Sample Set Start Date: 11/02/2025 12:18:48 PM AEDT
Print Date: 12/02/2025

Run and Method Summary Report

Sample Set Summary Table

	Inj Id	Sample Name	Label	Sample Type	Date Acquired	Acq Method Set	Vial	Inj. #	Inj Vol (ul)	Run Time (Minutes)	Sample Weight (mg)	Dilution	AverageUnitWeight	SaltCorrection	LabelClaim
56	1390	2412004166_10	U210	Unknown	11/02/2025 4:09:28 PM AEDT	Ivermectin Assay USP	1:C,2	2	1.0	2.50	1.00	50.0000	1.00000	1.00000	12.00000
57	1393	Ivermectin Std 1	S108	Standard	11/02/2025 4:13:23 PM AEDT	Ivermectin Assay USP	1:A,3	1	1.0	2.50	1.00	25.0000	1.00000	1.00000	1.00000
58	1395	Ivermectin Std 1	S108	Standard	11/02/2025 4:17:09 PM AEDT	Ivermectin Assay USP	1:A,3	2	1.0	2.50	1.00	25.0000	1.00000	1.00000	1.00000

Instrument Method: Ivermectin Assay USP

Stored: 10/02/2025 1:49:45 PM AEDT

Method Information

Method Comments
Method Modified User [redacted]
Method Locked No
Method Id 1181
Old Id
Method Version 2
Method Edit User
Source S/W Info Empower 3 Software Build 3471 SPs Installed: Service Release 5 DB ID: 3107713112

AgilentLC Instrument Setup

Quat. Pump G7104C

Flow 0.750 (mL/min)
Use Solvent Types Yes
Low Pressure Limit 0.00 (bar)
High Pressure Limit 800.00 (bar)
Max. Flow Ramp Up 100.000 (mL/min²)
Primary Channel Automatic

Max. Flow Ramp Down 100.000 (mL/min²)

Project Name: Chemistry\System25_2025_01
Sample Set Name: Ivermectin [redacted] 11022024

Analyst [redacted]

System Name System 25
Sample Set Id: 1463
Sample Set Start Date: 11/02/2025 12:18:48 PM AEDT
Print Date: 12/02/2025

Run and Method Summary Report

Solvent Composition

	Channel	Ch. 1 Solv.	Name 1	Used	Percent (%)
1	A	100.0 % (Methanol/ACN 1:1) in Water V.01		Yes	100.00
2	B	100.0 % Acetonitrile V.03		Yes	0.00
3	C	100.0 % Acetonitrile V.03		Yes	0.00
4	D	100.0 % Water V.03		Yes	0.00

Timetable

	Time (min)	A (%)	B (%)	C (%)	D (%)	Flow (mL/min)	Pressure (bar)
1	10.00	---	---	---	---	0.750	800.00
2	20.00	100.00	0.00	0.00	0.00	0.000	800.00

Quat. Pump - Pump0 - Stroke
Automatic Stroke Calculation Yes

Quat. Pump - Pump0 - Emulation Mode
Emulation Enabled No

Quat. Pump - Pump0 - Mixer Selection
Selected Mixer Do not use Mixer

Quat. Pump - Pump0 - Blend Assist
Enabled No

Quat. Pump - Pump0 - Stop Time
Stoptime Mode No limit

Quat. Pump - Pump0 - Post Time
Posttime Mode Off

Sampler G7129C

Sampler - Sampler0 - Auxiliary
Draw Speed 200 (µL/min)
Eject Speed 400 (µL/min)
Wait Time After Draw 1.2 (s)

Project Name: Chemistry\System25_2025_01
Sample Set Name: Ivermectin [redacted] 11022024

Analyst [redacted]

System Name System 25
Sample Set Id: 1463
Sample Set Start Date: 11/02/2025 12:18:48 PM AEDT
Print Date: 12/02/2025

Run and Method Summary Report

Needle Height Offset 0.0 (mm)

Sampler - Sampler0 - Injection

Injection Mode	Injection with needle wash
Injection Volume	1.00 (µL)

Sampler - Injection - Needle Wash

Needle Wash Location	Flush Port
Wash Time	3 (s)

Sampler - Sampler0 - High throughput

Sample Flush-Out Factor	5.0
Injection Valve to Bypass for Delay Volume Reduction	No

Sampler - High throughput - Overlapped Injection

Overlapped Injection Mode	Off

Sampler - Sampler0 - Stop Time

Stoptime Mode	As pump/No limit

Sampler - Sampler0 - Post Time

Posttime Mode	Off

Column Comp. G7116A

Valve Position	Position 1 (Port 1 -> 1')
Position Switch After Run	Do not switch

Column Comp. - Column Comp.0 - Left Temperature Control

Temperature Control Mode	Temperature Set
Temperature	30.0 (°C)

Column Comp. - Left Temperature Control - Enable Analysis Left Temperature

Enable Analysis Left Temperature On	Yes
Enable Analysis Left Temperature Value	0.8 (°C)
Left Temp. Equilibration Time	0.0 (min)

Column Comp. - Column Comp.0 - Right Temperature Control

Right temperature Control Mode	Temperature Set

Project Name: Chemistry\System25_2025_01
Sample Set Name: Ivermectin s22 11022024

Analyst s22

System Name System 25
Sample Set Id: 1463
Sample Set Start Date: 11/02/2025 12:18:48 PM AEDT
Print Date: 12/02/2025

Run and Method Summary Report

Right temperature 30.0 (°C)

Column Comp. - Right Temperature Control - Enable Analysis Right Temperature

Enable Analysis Right Temperature On Yes
Enable Analysis Right Temperature Value 0.8 (°C)
Right Temp. Equilibration Time 0.0 (min)

Column Comp. - Column Comp.0 - Enforce column for run

Enforce column for run enabled No

Column Comp. - Column Comp.0 - Stop Time

Stoptime Mode As pump/injector

Column Comp. - Column Comp.0 - Post Time

Posttime Mode Off

Column Comp. - Column Comp.0 - Timetable

DAD G7117C

Peakwidth > 0.1 min (2 s response time) (2.5 Hz)
UV Lamp Required Yes

DAD - DAD0 - Analog Output

Analog Zero Offset 5 (%)
Analog Attenuation 1000 (mAU)

DAD - DAD0 - Signals

Signal table-DAD0

	Acquire	Signal
1	No	Signal A
2	No	Signal B
3	No	Signal C
4	No	Signal D
5	No	Signal E
6	No	Signal F

	Acquire	Signal
7	No	Signal G
8	No	Signal H

Project Name: Chemistry\System25_2025_01
Sample Set Name: Ivermectin [redacted] 11022024

Analyst [redacted]

System Name System 25
Sample Set Id: 1463
Sample Set Start Date: 11/02/2025 12:18:48 PM AEDT
Print Date: 12/02/2025

Run and Method Summary Report

DAD - DAD0 - Prepare Mode
Margin for negative Absorbance 100 (mAU)

DAD - DAD0 - Autobalance
Autobalance Prerun Yes
Autobalance Postrun No

DAD - DAD0 - Spectrum
Spectrum Range WL from 190 (nm)
Spectrum Range WL to 400 (nm)
Spectrum Step 2.0 (nm)
Spectrum Store All

DAD - DAD0 - Stoptime
Stoptime Mode As pump/injector

DAD - DAD0 - Posttime
Posttime Mode Off

DAD - DAD0 - Timetable

Injector Preference Value :
Injector Selected ALS

Sampler G7129C

Auxiliary Channels

Auxiliary Channels - - PUMP.0.0.Pressure
PUMP.0.0.Pressure disabled

Auxiliary Channels - - PUMP.0.1.Flow
PUMP.0.1.Flow disabled

Auxiliary Channels - - PUMP.0.2.SolventRatioA
PUMP.0.2.SolventRatioA disabled

Auxiliary Channels - - PUMP.0.3.SolventRatioB
PUMP.0.3.SolventRatioB disabled

Project Name: Chemistry\System25_2025_01
Sample Set Name: Ivermectin [redacted] 11022024

Analyst [redacted]

System Name System 25
Sample Set Id: 1463
Sample Set Start Date: 11/02/2025 12:18:48 PM AEDT
Print Date: 12/02/2025

Run and Method Summary Report

Auxiliary Channels - - PUMP.0.4.SolventRatioC
PUMP.0.4.SolventRatioC disabled

Auxiliary Channels - - PUMP.0.5.SolventRatioD
PUMP.0.5.SolventRatioD disabled

Auxiliary Channels - - PUMP.0.6.Tuning
PUMP.0.6.Tuning disabled

Auxiliary Channels - - SAMPLER.0.0.Temperature
SAMPLER.0.0.Temperature disabled

Auxiliary Channels - - COLCOMP.0.0.LeftTemperature
COLCOMP.0.0.LeftTemperature disabled

Auxiliary Channels - - COLCOMP.0.1.RightTemperature
COLCOMP.0.1.RightTemperature disabled

Auxiliary Channels - - DAD.0.0.BoardTemperature
DAD.0.0.BoardTemperature disabled

Auxiliary Channels - - DAD.0.1.OpticalUnitTemperature
DAD.0.1.OpticalUnitTemperature disabled

Auxiliary Channels - - DAD.0.2.UVLampAnodeVoltage
DAD.0.2.UVLampAnodeVoltage disabled

General Settings

General Settings - - Fraction Start Location Specified
Fraction Start Location Specified False

General Settings - - Start Location
Start Location 1

General Settings - - Shutdown after Run
Shutdown after Run False

Revision History

Project Name: Chemistry\System25_2025_01
Sample Set Name: Ivermectin s22 11022024

Analyst s22

System Name System 25
Sample Set Id: 1463
Sample Set Start Date: 11/02/2025 12:18:48 PM AEDT
Print Date: 12/02/2025

Run and Method Summary Report

This method contains 2 items in the revision history.

s22 s22

Analyst – s22

TGA Sample No.	Strength
s22	s22
2412004166	Ivermectin 12 mg/tablet

Substance assayed: Ivermectin	**Sequence date:** 11/02/2025

Analysis type: Uniformity of content - Test A - Stage:

Technique: UHPLC

System/Instrument number: 25

Method reference: Ivermectin Tablets USP

Method modifications: Yes Approved by: s22

System suitability: Complies

RESULTS				
Sample LIMS	**Content (%LC)**	**Mean (%LC)**	**Requirements Source**	**Results**
s22				
2412004166	Tablet 1 84.95% Tablet 2 88.11% Tablet 3 82.18% Tablet 4 85.23% Tablet 5 81.76% Tablet 6 84.84% Tablet 7 82.29% Tablet 8 85.84% Tablet 9 86.91% Tablet 10 82.16%	84.4%	Assay 90 -110% Uniformity of Content: 85 – 115% of Mean (71.87 – 97.1%) s22 17/3	Assay: Fail Uniformity of Content: Pass

Identified as: Ivermectin

Calculations: s22

s22

s22

Attachments: Empower report: D25-630124

Reference Weights

Balance LIMS No: 4003

Std.	Reference Code No	Reference Name	Potency	Expiry date	Wt. of the scoop and standard	Wt. of the scoop	Wt. of the standard
S1	6755	Ivermectin	88.3%	~~31/07/2025~~ 24/02/2026	7.22 mg	0.17 mg	7.05 mg
S2	6755	Ivermectin	88.3%	~~31/07/2025~~ 24/02/2026	7.80 mg	0.26 mg	7.54 mg

s22 25/02/2025

Certificates of Analysis Checked: Yes

Comments: **Other:**

Salt Correction calculation: N/A

Reference Preparation/Dilutions

Std.	Preparation Details	Date prepared	Solution name in Sequence
S1	Wt. in 25 mL made to volume with MeOH	11/02/2025	Ivermectin Std 1
S2	Wt. in 25 mL made to volume with MeOH	11/02/2025	Ivermectin Std 2
S3	Sensitivity solution: 1 mL S1 → 100mL, 2mL → 10mL with MeOH	11/02/2025	Ivermectin sensitivity solution

Sample Weights

Balance LIMS No: 32650

LIMS No.	Replicate	Wt. of the scoop and sample	Wt. of the scoop	Wt. of the sample	Average unit weight	# Pooled
s22						
2412004166	Tablet 1	-	-	110.35 mg	N/A	N/A
	Tablet 2	-	-	109.44 mg	N/A	N/A
	Tablet 3	-	-	108.28 mg	N/A	N/A
	Tablet 4	-	-	111.54 mg	N/A	N/A
	Tablet 5	-	-	110.15 mg	N/A	N/A
	Tablet 6	-	-	112.22 mg	N/A	N/A
	Tablet 7	-	-	105.50 mg	N/A	N/A
	Tablet 8	-	-	107.22 mg	N/A	N/A
	Tablet 9	-	-	110.42 mg	N/A	N/A
	Tablet 10	-	-	107.88 mg	N/A	N/A

Sample Preparation/Dilutions

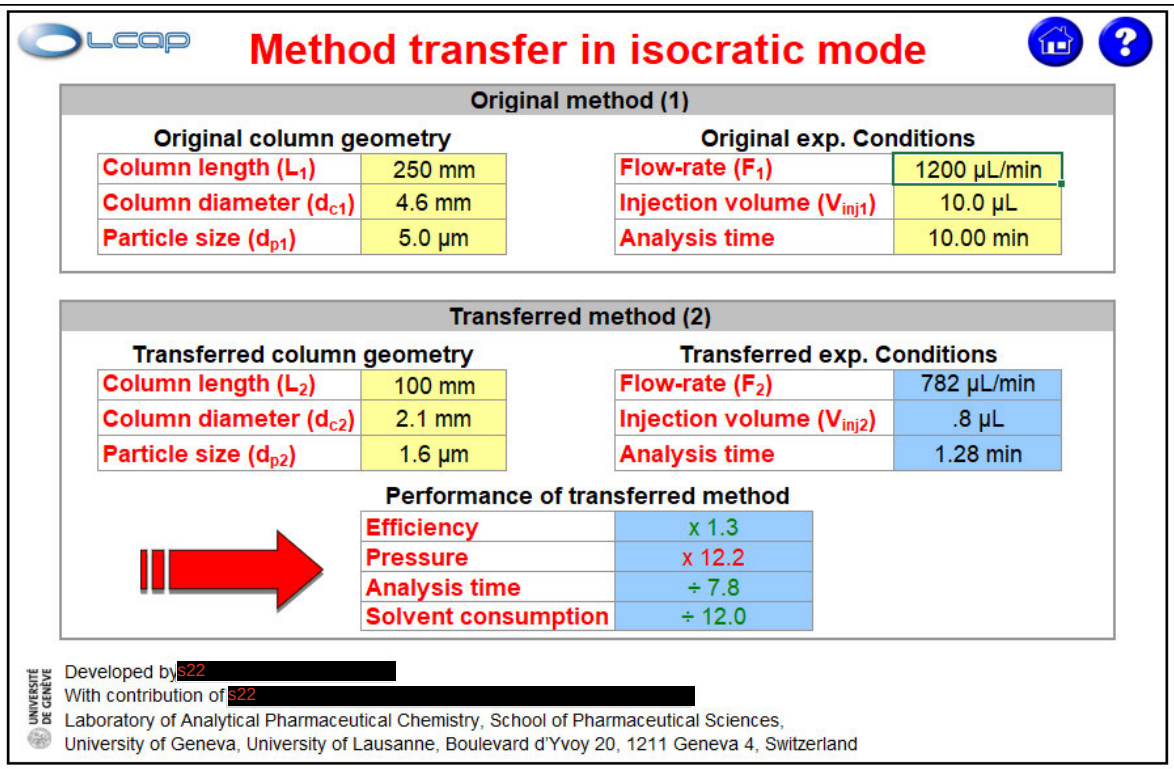
LIMS No.	Replicate	Preparation Details	Solution name in Sequence
s22			
2412004166	Tablet 1	Following procedure was used to prepare all 10 replicates: 1 tablet in 50 mL VF, 10 mL H2O sonicated for 10 mins. 30 mL MeOH sonicate 5 mins. Made to volume with MeOH.	2412004166_1
	Tablet 2		2412004166_2
	Tablet 3		2412004166_3
	Tablet 4		2412004166_4
	Tablet 5		2412004166_5
	Tablet 6		2412004166_6
	Tablet 7		2412004166_7
	Tablet 8		2412004166_8
	Tablet 9		2412004166_9
	Tablet 10		2412004166_10

Method modifications:

Method Converted from HPLC to UPLC:

Ivermectin USP method:
Column: 4.6 mm x 25 cm 5 µm L1
Injection volume 10 µL
Mobile Phase: Acetonitrile, MeOH & Water (53:35:12)

Modified Method:
Column: 2.1 mm x 10 cm 1.6 µm C18
Injection volume 1 µL
Mobile Phase: Acetonitrile, MeOH & Water (52:34:14)



Method transfer in isocratic mode

Original method (1)

Original column geometry		Original exp. Conditions	
Column length (L_1)	250 mm	Flow-rate (F_1)	1200 µL/min
Column diameter (d_{c1})	4.6 mm	Injection volume (V_{inj1})	10.0 µL
Particle size (d_{p1})	5.0 µm	Analysis time	10.00 min

Transferred method (2)

Transferred column geometry		Transferred exp. Conditions	
Column length (L_2)	100 mm	Flow-rate (F_2)	782 µL/min
Column diameter (d_{c2})	2.1 mm	Injection volume (V_{inj2})	.8 µL
Particle size (d_{p2})	1.6 µm	Analysis time	1.28 min

Performance of transferred method

Efficiency	x 1.3
Pressure	x 12.2
Analysis time	÷ 7.8
Solvent consumption	÷ 12.0

Flow rate was kept at 0.75 ml/min to avoid the pressure increasing too much. Flow rate change is within USP permissible range of ±50%.

Reagents and/or Mobile Phase preparation:

Mobile Phase preparation:

06/02/2025
ACN: MeOH: H_2O (53:35:12)
530 mL ACN + 350 mL MeOH + 120 mL H_2O.

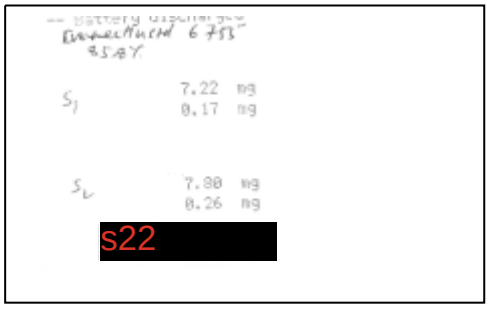
After some test injections mobile Phase was adjusted to meet the method requirements:

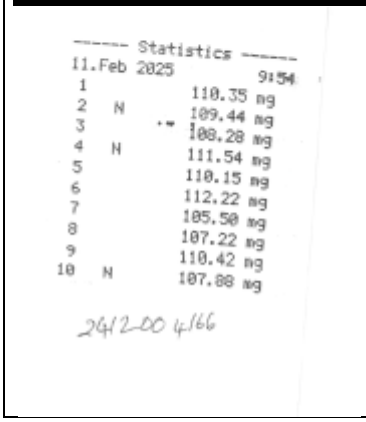
10/02/2025
ACN: MeOH: H_2O (52:34:14)
520 mL ACN + 340 mL MeOH + 140 mL H_2O.

Reagents:
Acetonitrile – Brand: Merck – Lot#: I1357230429
Methanol – Brand Merck – Lot#: I1326307408
Equipment:
Mili-Q LIMS#: 33536

Comments and Balance Printouts:

s22





Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Laboratories Branch

Q-Pulse Document Number	Chem-Form-2
Title	Uniformity of Dosage Units - Content Uniformity
Author	s22
Owner	s22
Approver	[redacted]
Revision #	3
Date Authorised	1/07/2024

Uniformity of Dosage Units - Mass Variation

Sample Name:			
TGAL No:		Bal. LIMS #	
Analyst:		Date:	
Batch No:		Exp:	
Active:		Overage (% of l.c.):	
Pharmaceutical form:		Average Content (%):	
Comments:			

Unit weight (mg)	Unit content (%)	Unit content (%)	Individual Pass/Fail

Average wt (10): #DIV/0!

Average content of first 10 units:	#DIV/0!
SD (10):	#DIV/0!
Reference value-10 units (M):	#DIV/0!

Acceptance Value (10): #DIV/0! #DIV/0!

Average wt (30):

Average content of all 30 units:	
SD (30):	
Reference value-30 units (M):	

Acceptance Value (30):

Requirement: The Acceptance Value (AV) of the first 10 dosage units is less than or equal to 15. If AV is greater than15, test a further 20 units. The AV of all 30 units is less than 15 and no individual unit is less than 0.75M or greater than 1.25M.

RESULT **PASS** ☐ **FAIL** ☐

Signature of Analyst: Date:

Checked by Official Analyst: Date:

Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Laboratories Branch

Q-Pulse Document Number	Chem-Form-2
Title	Uniformity of Dosage Units - Content Uniformity
Author	s22
Owner	s22
Approver	s22
Revision #	3
Date Authorised	1/07/2024

Sample Name:			
TGAL No:		Bal. LIMS #	
Analyst:		Date:	
Batch No:		Exp:	
Active:		Overage (% of l.c.):	
Pharmaceutical form:		Average Content (%):	
Comments:			

Unit Full (mg)	Unit Empty (mg)	Unit Fill Wt (mg)	Unit content (%)	Unit content (%)	Individual Pass/Fail

Average wt (10): #DIV/0!

Average content of first 10 units:	#DIV/0!
SD (10):	#DIV/0!
Reference value-10 units (M):	#DIV/0!

Acceptance Value (10): #DIV/0! #DIV/0!

Average wt (30): #DIV/0!

Average content of all 30 units:	
SD (30):	
Reference value-30 units (M):	

Acceptance Value (30):

Requirement: The Acceptance Value (AV) of the first 10 dosage units is less than or equal to 15. If AV is greater than15, test a further 20 units. The AV of all 30 units is less than 15 and no individual unit is less than 0.75M or greater than 1.25M.

RESULT **PASS** ☐ **FAIL** ☐

Signature of Analyst: Date:

Checked by Official Analyst: Date:

Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Laboratories Branch

Q-Pulse Document Number	Chem-Form-2
Title	Uniformity of Dosage Units - Content Uniformity
Author	s22
Owner	s22
Approver	s22
Revision #	3
Date Authorised	1/07/2024

Uniformity of Dosage Units - Content Uniformity

Sample Name:	Ivervid 12 Ivermectin Tablets		
TGAL No:	2412004166	Bal. LIMS #	32650
Analyst:	s22	Date:	11/02/25
Batch No:	TI-1230001	Exp:	30/04/2027
Active:	Ivermectin	Overage (% of l.c.):	
Pharmaceutical form:	Tablet		
Comments:			

	Unit content (%)	Individual Pass/Fail
1	85.0	
2	88.1	
3	82.2	
4	85.2	
5	81.8	
6	84.8	
7	82.3	
8	85.8	
9	86.9	
10	82.2	

Average content of first 10 units:	84.4			
SD (10):	2.23	Acceptance Value (10):	19.42	FAIL
Reference value-10 units (M):	98.5			
Average content of all 30 units:				
SD (30):		Acceptance Value (30):		
Reference value-30 units (M):				

Requirement: The Acceptance Value (AV) of the first 10 dosage units is less than or equal to 15. If AV is greater than15, test a further 20 units. The AV of all 30 units is less than 15 and no individual unit is less than 0.75M or greater than 1.25M.

RESULT **PASS** ☐ **FAIL** ☑

Signature of Analyst: s22 Date: 12/02/2025

Checked by Official Analyst: s22 Date: 17/03/2025

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Laboratories Branch

Q-Pulse Document Number	Chem-Form-2
Title	Uniformity of Dosage Units - Content Uniformity
Author	s22 [redacted]
Owner	s22 [redacted]
Approver	s22 [redacted]
Revision #	3
Date Authorised	1/07/2024

Uniformity of Dosage Units - Mass Variation

Sample Name:	Validation Data From: el://R15%2f660283?db=A7&open		
TGAL No:		Bal. LIMS #:	
Analyst:		Date:	
Batch No:		Exp:	
Active:		Overage (% of l.c.):	
Pharmaceutical form:	Tablet	Average Content (%):	100.0
Comments:			

	Unit weight (mg)	Unit content (%)	Unit content (%)	Individual Pass/Fail
1	285.0	114.0	115.0	PASS
2	215.0	86.0	86.8	PASS
3	250.0	100.0	100.9	PASS
4	250.0	100.0	100.9	PASS
5	250.0	100.0	100.9	PASS
6	250.0	100.0	100.9	PASS
7	250.0	100.0	100.9	PASS
8	250.0	100.0	100.9	PASS
9	250.0	100.0	100.9	PASS
10	250.0	100.0	100.9	PASS
11	250.0		100.9	PASS
12	185.0		74.6	FAIL
13	250.0		100.9	PASS
14	250.0		100.9	PASS
15	250.0		100.9	PASS
16	250.0		100.9	PASS
17	250.0		100.9	PASS
18	250.0		100.9	PASS
19	250.0		100.9	PASS
20	250.0		100.9	PASS
21	250.0		100.9	PASS
22	250.0		100.9	PASS
23	250.0		100.9	PASS
24	250.0		100.9	PASS
25	250.0		100.9	PASS
26	250.0		100.9	PASS
27	250.0		100.9	PASS
28	250.0		100.9	PASS
29	250.0		100.9	PASS
30	250.0		100.9	PASS

Average wt (10):	250.0				
	Average content of first 10 units:		100.0		
		SD (10):	6.60	Acceptance Value (10):	15.84 FAIL
	Reference value-10 units (M):		100.0		
Average wt (30):	247.8				
	Average content of all 30 units:		100.0		
		SD (30):	6.06	Acceptance Value (30):	12.11 PASS
	Reference value-30 units (M):		100.0		

Requirement: The Acceptance Value (AV) of the first 10 dosage units is less than or equal to 15. If AV is greater than15, test a further 20 units. The AV of all 30 units is less than 15 and no individual unit is less than 0.75M or greater than 1.25M.

RESULT **PASS** ☐ **FAIL** ☐

Signature of Analyst: Date:

Checked by Official Analyst: Date:

Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Laboratories Branch

Q-Pulse Document Number	Chem-Form-2
Title	Uniformity of Dosage Units - Content Uniformity
Author	s22
Owner	[redacted]
Approver	s22
Revision #	3
Date Authorised	1/07/2024

Sample Name:	Validation Data From: el://R15%2f660283?db=A7&open		
TGAL No:		Bal. LIMS #	
Analyst:		Date:	
Batch No:		Exp:	
Active:		Overage (% of l.c.):	
Pharmaceutical form:	Capsule	Average Content (%):	100.0
Comments:			

	Unit Full (mg)	Unit Empty (mg)	Unit Fill Wt (mg)	Unit content (%)	Unit content (%)	Individual Pass/Fail
1	335.0	50.0	285.0	114.0	115.0	PASS
2	265.0	50.0	215.0	86.0	86.8	PASS
3	300.0	50.0	250.0	100.0	100.9	PASS
4	300.0	50.0	250.0	100.0	100.9	PASS
5	300.0	50.0	250.0	100.0	100.9	PASS
6	300.0	50.0	250.0	100.0	100.9	PASS
7	300.0	50.0	250.0	100.0	100.9	PASS
8	300.0	50.0	250.0	100.0	100.9	PASS
9	300.0	50.0	250.0	100.0	100.9	PASS
10	300.0	50.0	250.0	100.0	100.9	PASS
11	300.0	50.0	250.0		100.9	PASS
12	235.0	50.0	185.0		74.6	FAIL
13	300.0	50.0	250.0		100.9	PASS
14	300.0	50.0	250.0		100.9	PASS
15	300.0	50.0	250.0		100.9	PASS
16	300.0	50.0	250.0		100.9	PASS
17	300.0	50.0	250.0		100.9	PASS
18	300.0	50.0	250.0		100.9	PASS
19	300.0	50.0	250.0		100.9	PASS
20	300.0	50.0	250.0		100.9	PASS
21	300.0	50.0	250.0		100.9	PASS
22	300.0	50.0	250.0		100.9	PASS
23	300.0	50.0	250.0		100.9	PASS
24	300.0	50.0	250.0		100.9	PASS
25	300.0	50.0	250.0		100.9	PASS
26	300.0	50.0	250.0		100.9	PASS
27	300.0	50.0	250.0		100.9	PASS
28	300.0	50.0	250.0		100.9	PASS
29	300.0	50.0	250.0		100.9	PASS
30	300.0	50.0	250.0		100.9	PASS

Average wt (10): 250.0

Average content of first 10 units:	100.0
SD (10):	6.60
Reference value-10 units (M):	100.0

Acceptance Value (10): 15.84 FAIL

Average wt (30): 247.8

Average content of all 30 units:	100.0
SD (30):	6.06
Reference value-30 units (M):	100.0

Acceptance Value (30): 12.11 PASS

Requirement: The Acceptance Value (AV) of the first 10 dosage units is less than or equal to 15. If AV is greater than15, test a further 20 units. The AV of all 30 units is less than 15 and no individual unit is less than 0.75M or greater than 1.25M.

RESULT **PASS** ☐ **FAIL** ☐

Signature of Analyst: Date:

Checked by Official Analyst: Date:

Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Laboratories Branch

Q-Pulse Document Number	Chem-Form-2
Title	Uniformity of Dosage Units - Content Uniformity
Author	s22 [redacted]
Owner	s22 [redacted]
Approver	[redacted]
Revision #	3
Date Authorised	1/07/2024

Uniformity of Dosage Units - Content Uniformity

Sample Name:	Validation Data From: el://R15%2f660283?db=A7&open		
TGAL No:		Bal. LIMS #	
Analyst:		Date:	
Batch No:		Exp:	
Active:		Overage (% of l.c.):	
Pharmaceutical form:	Capsule		
Comments:			

	Unit content (%)	Individual Pass/Fail
1	115.0	PASS
2	85.0	PASS
3	100.0	PASS
4	100.0	PASS
5	100.0	PASS
6	100.0	PASS
7	100.0	PASS
8	100.0	PASS
9	100.0	PASS
10	100.0	PASS
11	100.0	PASS
12	74.0	FAIL
13	100.0	PASS
14	100.0	PASS
15	100.0	PASS
16	100.0	PASS
17	100.0	PASS
18	100.0	PASS
19	100.0	PASS
20	100.0	PASS
21	100.0	PASS
22	100.0	PASS
23	100.0	PASS
24	100.0	PASS
25	100.0	PASS
26	100.0	PASS
27	100.0	PASS
28	100.0	PASS
29	100.0	PASS
30	100.0	PASS

Average content of first 10 units:	100.0
SD (10):	7.07
Reference value-10 units (M):	100.0

Acceptance Value (10): 16.97 FAIL

Average content of all 30 units:	99.1
SD (30):	6.17
Reference value-30 units (M):	99.1

Acceptance Value (30): 12.34 PASS

Requirement: The Acceptance Value (AV) of the first 10 dosage units is less than or equal to 15. If AV is greater than15, test a further 20 units. The AV of all 30 units is less than 15 and no individual unit is less than 0.75M or greater than 1.25M.

RESULT **PASS** ☐ **FAIL** ☐

Signature of Analyst: Date:

Checked by Official Analyst: Date:

From: s22
To:
Cc:
Subject: RC-036280 - Ivervid-12 [SEC=OFFICIAL]
Date: Thursday, 20 March 2025 3:01:00 PM
Attachments: image001.png

Good Afternoon

Please see the report relating to the laboratory analysis for the above investigation: D25-690325

Links to the Certificate of Analysis and photographs are located within the report.

If you have any questions about our findings, please contact me.

Regards,

s22
Senior Chemist / Assistant Director - Chemistry Section
Laboratories Branch

Medical Devices & Product Quality Division | Health Products Regulation Group
Australian Government Department of Health and Aged Care
s22
Location: Level 1, 1 Tindal Lane, Fairbairn, ACT
PO Box 100, Woden ACT 2606, Australia

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Certificate of Responsible Analyst

A sample of therapeutic goods, bearing TGA sample number 2206002093 has been examined and analysed

The sample was submitted by s22 - TGA RCB Product and Import Compliance Section

Results are applicable to the sample tested, as received by the TGA Laboratories Branch.

The goods were represented to be:

ARTG Number: N/A

Name: Ivervid-12 Ivermectin 12mg

Sponsor: NOT AVAILABLE

Batch Number: TI-620004

Expiry Date: 31-December-2024

Dosage Form: Tablet

TEST	RESULT	REQUIREMENT
Sample Appearance		
Ten, white, circular, convex tablets, debossed with a break line on one side. The average tablet weight (based on 4 tablets) was 108.63mg. Tablets in labelled aluminium blister tray. Sample was received wrapped in bubble wrap in a plastic Ziplock bag sealed with Australian Border Force seal '078624'. Ziplock bag was received in a sealed 'Tamper Evident Security Bag'.		
Content of Ivermectin by UPLC (USP)	87.7 %	90.0 to 110.0 %
Identification of Ivermectin by UPLC (USP)	Present	Present
Drug Screen by UPLC/PDA (UPLCD01)	No undeclared pharmaceuticals detected	No undeclared pharmaceutical active ingredient detected.
TGA Seal Number	A340463994	

Abbreviations: ; UPLC/PDA = ultra performance liquid chromatography/ photodiode array detector; USP = United States Pharmacopeia; UPLC = ultra performance liquid chromatography

This Certificate has been signed and issued electronically by the Responsible Analyst nominated under subregulation 25(3)(c) of the *Therapeutic Goods Regulations 1990*

Phone: 1800 020 653 Email: info@tga.gov.au https://www.tga.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Laboratory Report

LB Reference: Project 2647
RIES reference: RC-018899

Re: Ivervid 12, Ivermectin Tablets 12 mg

Background

On Friday, 17 June 2022, Laboratories Branch (LB) Chemistry received the following sample from s22 of the TGA Product and Import Compliance Section (PICS) along with a Request for Analysis from s22 of PICS, dated Monday, 16 June 2022:

- One, clear, plastic, tamper-evident, security bag bearing seal number '*A340463994*'. The security bag contained a resealable plastic bag bearing an Australian Border Force seal, number *078624*. This bag contained one, foil blister tray labelled as '*Ivervid 12, Ivermectin Tablets USP 12 mg'*. Batch number and expiry details of '*TI-620004'* and '*12/2024'* respectively, were also included on the blister tray.

The sample was assigned TGA sample number **2206002093** upon receipt.

According to the request for analysis, PICS obtained the sample from Australian Border Force. It is suspected to contain less than the labelled content of ivermectin.

PICS has requested LB Chemistry to check the amount of ivermectin in the sample and to screen for the presence of other active pharmaceutical ingredients.

Examination and Analysis

The sample was visually examined, photographed[1] and analysed. A '*Certificate of Responsible Analyst'* for the sample (D22-5820676 refers) is provided with this report. The results of the examination and analysis of the sample are reviewed below.

A photograph of the sample is provided in **Appendix 1** of this report.

(i) Visual examination

The sample consisted of ten, round, white, biconvex tablets with a debossed break bar on one face. The tablets were contained in a single, labelled, foil, blister tray. The average tablet weight (based on 4 tablets) was 108.6 mg.

Labelling details for the blister trays and carton included '*Manufactured by Fortune Health Care.'* with address details.

[1] The photographs are located in TRIM container E22-581692 : TRIM records D22-5648818 and D22-5648866 (web alert photo)

(ii) Testing

Analysis was conducted on 4 individual tablets, tested separately.

Confirmation of the presence of ivermectin and its content in the sample, was determined by analysing each tablet in accordance with the assay test outlined in the Ivermectin Tablets USP[2] monograph. Ivermectin was identified in the sample. Its content in the sample was 87.7% of the labelled content, with the variation between the 4 tablets ranging from 83.8% to 90.8%. Under the requirements of the USP, this sample would be considered unacceptable as the content is below 90.0% of the labelled amount.

The sample was also screened for other active pharmaceutical ingredients by in-house UPLC/PDA[3] drug screen method. No undeclared, active pharmaceutical ingredients were detected in the sample.

Conclusions

Ivermectin was identified in the sample of '*Ivervid 12, Ivermectin Tablets USP 12 mg'* (TGA sample number **2206002093**). The content of ivermectin in the sample was 87.7% of the labelled content.

No undeclared, active pharmaceutical ingredients were detected in the sample.

Electronically signed

s22 [redacted]
LB Chemistry

s22 [redacted]
Principal Chemist, LB Chemistry

23rd August 2022

Appendix 1: Photograph of the sample

[2] United States Pharmacopeia
[3] Ultra-High Performance Liquid Chromatography with Photodiode Array detection

Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Laboratories Branch

Owner: s22	**Number:** Chem-Form-29
Author: s22	**Version:** 1
Active: 15/06/2021	**Review:** <QPulse_DocReviewDate>
Title: Uniformity of content by UPLC HPLC - Worksheet	

SAMPLE NAME: Ivervid-12 **STRENGTH:** 12mg

TGA Sample No. 2206002093 **SUBSTANCE ASSAYED**: Ivermectin

METHOD REFERENCE: USP 43 – Ivermectin Tablets

Method modifications (detailed overleaf) approved by…s22 11/07…… System No. 25

SYSTEM SUITABILITY (mean of results for standard solution) – H_2B_{1a} / H_2B_{1b}

Area/height 3925054 (Summed Components) %RSD Area/height 0.75

Retention Time 18.78 / 14.98 (RRT =0.8) %RSD RT 0.23 / 0.19

Efficiency (N) 12395 / 12035 Asymmetry (f) 0.99 / 1.03

Standard Precision 2.46* Resolution 6.2

RESULTS

	1st	2nd	Mean		1st	2nd	Mean
Sample 1	83.90	83.78	83.84	Sample 6	-	-	
Sample 2	90.77	90.80	90.79	Sample 7	-	-	
Sample 3	85.96	85.85	85.91	Sample 8	-	-	
Sample 4	90.20	90.27	90.24	Sample 9	-	-	
Sample 5	-	-		Sample 10	-	-	

Mean Result 87.69 **Relative Standard Deviation** 3.33%

85 – 115% of mean 74.54 – 100.84

CALCULATIONS

Example Calculations for % Label Claim: Sample 2206002093 Tablet 1 Injection 1

$$\left(\frac{3344448}{3925054}\right) \times \left(\frac{6.436\ mg}{25\ mL}\right) \times 91.8\% \times \frac{50\ mL}{12\ mg} = 83.90\%$$

ATTACHMENTS: Analysts Notes: D22-5643864 , Uniformity of Content Empower Reports: D22-5643886, Standard Balance Printouts: D22-5647563 , 2206002093 Balance Printouts: D22-5647651

REQUIREMENTS (Source: USP Ivermectin Tablets) 90 – 110% of label claim (based on Ivermectin H_2B_{1a} & H_2B_{1b} components)

IDENTIFIED AS: Ivermectin

RESULT **PASS** ☐ **FAIL** ☒

Signature of Analyst: Electronically signed by s22 Date: 29/06/22

Checked by Official Analyst……*Electronically signed* – s22 ….. Date…*11/07/2022*……

REFERENCE WEIGHTS

Balance LIMS No 4004

	S1	S2	S3	S4	S5	S6
Reference Code No	6370	6370	6370			
Reference Name	Ivermectin	Ivermectin	Ivermectin			
Potency	91.8%	91.8%	91.8%			
Expiry date	31/12/21	31/12/20	31/12/20			
Wt Std + scoop	6.531mg	6.537mg	6.535mg			
Wt scoop	0.095mg	0.173mg	0.111mg			
Wt standard	6.436mg	6.364mg	6.423mg			
Date Prepared	21/06/22	21/06/22	24/06/22			

REFERENCE PREPARATION/DILUTIONS

Certificates of Analysis Checked ☒

S1 Wt. in 25mL VF + 2.5mL H_2O made to volume with MeOH
S2 Wt. in 25mL VF + 2.5mL H_2O made to volume with MeOH
S3 Wt. in 25mL VF + 2.5mL H_2O made to volume with MeOH
S4 .....
S5 .....
S6 .....

Standard amount = 0.236 mg/mL

SAMPLE WEIGHTS

Balance LIMS No 32650

	Mass of tablet
Sample 1	108.11 mg
Sample 2	108.52 mg
Sample 3	108.68 mg
Sample 4	109.20 mg
Sample 5	-
Sample 6	-
Sample 7	-
Sample 8	-
Sample 9	-
Sample 10	-

SAMPLE PREPARATION/DILUTIONS

One tablet in 50mL VF flask 5mL H_2O sonicated for 10 minutes. Filled 3 quarters full with MeOH sonicate for 5 minutes. Made to volume with MeOH. Filtered Through 0.45 µm glass filter.

Theoretical sample concentration = 0.24 mg/mL

METHOD MODIFICATIONS

Single tablets used to investigate uniformity of dosage units, as opposed to the whole tablet assay outlined in the monograph. Volumes were scaled accordingly.
*The standard precision was recalculated using the third standard and found to be acceptable, 0.3% against standard 2 and 0.7% against standard 3. See page 27 of empower reports pdf. s22 6/07

Result Summary Report

*Integration incorrect see correct area Page 11

Result Summary Table (peak area)
Peak Name: Ivermectin A

	Sample Name	RT	Area (µV*sec)	Sample Wt (divider)	Dilution (multiplier)	k'	Sym.	N (Plates)	Resolution	Wave length
1	Sensitivity Solution	18.84	*3626	1.0000	12500.0000	7.56	1.04	21727		DAD.0.0
2	Sensitivity Solution	18.83	*4516	1.0000	12500.0000	7.56	1.00	19432		DAD.0.0
3	Ivermection Standard 1 0.25mg/mL	18.82	3789769	1.0000	25.0000	7.55	0.99	12503	6.28	DAD.0.0
4	Ivermection Standard 1 0.25mg/mL	18.82	3786061	1.0000	25.0000	7.55	0.99	12516	4.50	DAD.0.0
5	Ivermection Standard 2 0.25mg/mL	18.81	3666507	1.0000	25.0000	7.55	0.99	12487	6.28	DAD.0.0
6	Ivermection Standard 2 0.25mg/mL	18.81	3720904	1.0000	25.0000	7.55	1.00	12380	6.26	DAD.0.0
7	2206002093 - Tablet 1	18.81	3282944	1.0000	50.0000	7.55	1.00	12350	6.24	DAD.0.0
8	2206002093 - Tablet 1	18.80	3277472	1.0000	50.0000	7.55	1.00	12311	6.22	DAD.0.0
9	2206002093 - Tablet 2	18.79	3551447	1.0000	50.0000	7.54	1.00	12307	6.22	DAD.0.0
10	2206002093 - Tablet 2	18.80	3553097	1.0000	50.0000	7.54	1.00	12305	6.23	DAD.0.0
11	2206002093 - Tablet 3	18.80	3362715	1.0000	50.0000	7.55	1.00	12251	6.22	DAD.0.0
12	2206002093 - Tablet 3	18.80	3358421	1.0000	50.0000	7.54	1.00	12252	6.22	DAD.0.0
13	2206002093 - Tablet 4	18.80	3528877	1.0000	50.0000	7.54	1.00	12246	6.21	DAD.0.0
14	2206002093 - Tablet 4	18.80	3531318	1.0000	50.0000	7.54	1.00	12252	6.21	DAD.0.0
15	Ivermectin Standard 1 0.25mg/mL	18.80	3850025	1.0000	25.0000	7.54	0.99	12308	6.24	DAD.0.0
[redacted]										
24	Ivermectin Standard 1 0.25mg/mL	18.79	3852907	1.0000	25.0000	7.54	0.99	12263	6.22	DAD.0.0
[redacted]										
33	Ivermectin Standard 1 0.25mg/mL	18.80	3858323	1.0000	25.0000	7.55	0.99	12280	6.23	DAD.0.0
[redacted]										

Result Summary Report_Lr

Result Summary Table (peak area)
Peak Name: Ivermectin A

	Sample Name	RT	Area (µV*sec)	Sample Wt (divider)	Dilution (multiplier)	k'	Sym.	N (Plates)	Resolution	Wave length
s22										
42	Ivermectin Standard 1 0.25mg/mL	18.80	3848091	1.0000	25.0000	7.55	0.99	12346	6.24	DAD.0.0
s22										
47	Ivermectin Standard 1 0.25mg/mL	18.72	3807513	1.0000	25.0000	7.51	0.99	12517	4.34	DAD.0.0
48	Ivermectin Standard 1 0.25mg/mL	18.71	3831297	1.0000	25.0000	7.50	0.99	12423	6.24	DAD.0.0
s22										

Result Summary Table (peak area)
Peak Name: Ivermectin B

	Sample Name	RT	Area (µV*sec)	Sample Wt (divider)	Dilution (multiplier)	k'	Sym.	N (Plates)	Wave length
1	Ivermection Standard 1 0.25mg/mL	15.00	96840	1.0000	25.0000	5.82	1.05	12109	DAD.0.0
2	Ivermection Standard 1 0.25mg/mL	15.00	97120	1.0000	25.0000	5.82	1.05	12096	DAD.0.0
3	Ivermection Standard 2 0.25mg/mL	14.99	94460	1.0000	25.0000	5.81	1.04	12099	DAD.0.0
4	Ivermection Standard 2 0.25mg/mL	14.99	93866	1.0000	25.0000	5.82	1.04	12098	DAD.0.0
5	2206002093 - Tablet 1	14.99	61504	1.0000	50.0000	5.82	1.07	11960	DAD.0.0
6	2206002093 - Tablet 1	14.99	61937	1.0000	50.0000	5.81	1.08	11879	DAD.0.0
7	2206002093 - Tablet 2	14.98	66489	1.0000	50.0000	5.81	1.08	11886	DAD.0.0
8	2206002093 - Tablet 2	14.99	66167	1.0000	50.0000	5.81	1.07	11932	DAD.0.0
9	2206002093 - Tablet 3	14.99	63631	1.0000	50.0000	5.81	1.08	11875	DAD.0.0
10	2206002093 - Tablet 3	14.99	63526	1.0000	50.0000	5.81	1.06	11901	DAD.0.0
11	2206002093 - Tablet 4	14.99	66442	1.0000	50.0000	5.81	1.08	11827	DAD.0.0
12	2206002093 - Tablet 4	14.99	66652	1.0000	50.0000	5.81	1.08	11839	DAD.0.0
13	Ivermectin Standard 1 0.25mg/mL	14.99	96186	1.0000	25.0000	5.81	1.03	12043	DAD.0.0
s22									
22	Ivermectin Standard 1 0.25mg/mL	14.98	96538	1.0000	25.0000	5.81	1.02	11966	DAD.0.0
s22									

Result Summary Report_Lr

Result Summary Table (peak area)
Peak Name: Ivermectin B

	Sample Name	RT	Area (µV*sec)	Sample Wt (divider)	Dilution (multiplier)	k'	Sym.	N (Plates)	Wave length
s22									
31	Ivermectin Standard 1 0.25mg/mL	14.99	96858	1.0000	25.0000	5.81	1.02	11958	DAD.0.0
s22									
40	Ivermectin Standard 1 0.25mg/mL	14.99	97591	1.0000	25.0000	5.81	1.04	11965	DAD.0.0
s22									
45	Ivermectin Standard 1 0.25mg/mL	14.94	97346	1.0000	25.0000	5.79	1.03	12118	DAD.0.0
46	Ivermectin Standard 1 0.25mg/mL	14.93	97969	1.0000	25.0000	5.79	1.03	12024	DAD.0.0
s22									

Result Summary Table (peak area)
Peak Name: Ivermectin Total (A+B)

	Sample Name	RT	Area (µV*sec)	Sample Wt (divider)	Dilution (multiplier)	Wave length	%Label Claim
1	Sensitivity Solution	18.84	*~~3626~~	1.0000	12500.0000	DAD.0.0	272.94
2	Sensitivity Solution	18.83	* ~~4516~~	1.0000	12500.0000	DAD.0.0	324.83
3	Ivermection Standard 1 0.25mg/mL	18.82	3886609	1.0000	25.0000	DAD.0.0	23.63
4	Ivermection Standard 1 0.25mg/mL	18.82	3883181	1.0000	25.0000	DAD.0.0	23.63
5	Ivermection Standard 2 0.25mg/mL	18.81	3760967	1.0000	25.0000	DAD.0.0	566.13
6	Ivermection Standard 2 0.25mg/mL	18.81	3814770	1.0000	25.0000	DAD.0.0	574.22
7	2206002093 - Tablet 1	18.81	3344448	1.0000	50.0000	DAD.0.0	83.90
8	2206002093 - Tablet 1	18.80	3339409	1.0000	50.0000	DAD.0.0	83.78
9	2206002093 - Tablet 2	18.79	3617937	1.0000	50.0000	DAD.0.0	90.77
10	2206002093 - Tablet 2	18.80	3619264	1.0000	50.0000	DAD.0.0	90.80
11	2206002093 - Tablet 3	18.80	3426346	1.0000	50.0000	DAD.0.0	85.96
12	2206002093 - Tablet 3	18.80	3421947	1.0000	50.0000	DAD.0.0	85.85
13	2206002093 - Tablet 4	18.80	3595319	1.0000	50.0000	DAD.0.0	90.20
14	2206002093 - Tablet 4	18.80	3597970	1.0000	50.0000	DAD.0.0	90.27
15	Ivermectin Standard 1 0.25mg/mL	18.80	3946210	1.0000	25.0000	DAD.0.0	23.63
s22							

*Integration incorrect see correct area Page 11

Result Summary Report_Lr

Result Summary Table (peak area)
Peak Name: Ivermectin Total (A+B)

	Sample Name	RT	Area (µV*sec)	Sample Wt (divider)	Dilution (multiplier)	Wave length	%Label Claim
s22							
24	Ivermectin Standard 1 0.25mg/mL	18.79	3949445	1.0000	25.0000	DAD.0.0	23.63
s22							
33	Ivermectin Standard 1 0.25mg/mL	18.80	3955181	1.0000	25.0000	DAD.0.0	23.63
s22							
42	Ivermectin Standard 1 0.25mg/mL	18.80	3945682	1.0000	25.0000	DAD.0.0	23.63
s22							
47	Ivermectin Standard 1 0.25mg/mL	18.72	3904859	1.0000	25.0000	DAD.0.0	23.63
48	Ivermectin Standard 1 0.25mg/mL	18.71	3929266	1.0000	25.0000	DAD.0.0	23.63
s22							

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_s22

LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST
Print Date: 27/06/2022

Analyst s22

System Suitability

System Suitability (Duration)
Ivermectin Total (A+B)

	Inj Id	Result Id	Sample Name	Label	RT (min)	K'	Area (µV*sec)	Height (µV)	Symmetry Factor	N (Plates)	Wave length
1	1113	1504	Ivermection Standard 1 0.25mg/mL	S101	18.82		3886609	150982			DAD.0.0
2	1118	1505	Ivermection Standard 1 0.25mg/mL	S101	18.82		3883181	151019			DAD.0.0
3	1160	1506	Ivermectin Standard 1 0.25mg/mL	S102	18.80		3946210	150680			DAD.0.0
4	1192	1507	Ivermectin Standard 1 0.25mg/mL	S103	18.79		3949445	150621			DAD.0.0
5	1224	1508	Ivermectin Standard 1 0.25mg/mL	S104	18.80		3955181	150890			DAD.0.0
6	1256	1509	Ivermectin Standard 1 0.25mg/mL	S105	18.80		3945682	151658			DAD.0.0
7	1274	1510	Ivermectin Standard 1 0.25mg/mL	S106	18.72		3904859	152805			DAD.0.0
8	1277	1511	Ivermectin Standard 1 0.25mg/mL	S106	18.71		3929266	152885			DAD.0.0
Mean					18.78		3925054				
% RSD					0.23		0.75				

System Suitability Requirements:

%RSD (Rt) NMT 1.0%: Complies / Fails

%RSD (Response): NMT 2.0% Complies / Fails

Symmetry Factor: 0.8<As<1.5 Complies / Fails

N/A

Standard Correlation (Analytical Standard)
Ivermectin Total (A+B)

	Inj Id	Result Id	Sample Name	Label	RT (min)	K'	Area (µV*sec)	Height (µV)	Symmetry Factor	N (Plates)	Wave length
1	1113	1504	Ivermection Standard 1 0.25mg/mL	S101	18.82		3886609	150982			DAD.0.0
2	1118	1505	Ivermection Standard 1 0.25mg/mL	S101	18.82		3883181	151019			DAD.0.0
3	1160	1506	Ivermectin Standard 1 0.25mg/mL	S102	18.80		3946210	150680			DAD.0.0
4	1192	1507	Ivermectin Standard 1 0.25mg/mL	S103	18.79		3949445	150621			DAD.0.0
5	1224	1508	Ivermectin Standard 1 0.25mg/mL	S104	18.80		3955181	150890			DAD.0.0
6	1256	1509	Ivermectin Standard 1 0.25mg/mL	S105	18.80		3945682	151658			DAD.0.0
7	1274	1510	Ivermectin Standard 1 0.25mg/mL	S106	18.72		3904859	152805			DAD.0.0
8	1277	1511	Ivermectin Standard 1 0.25mg/mL	S106	18.71		3929266	152885			DAD.0.0
Mean					18.78		3925054				
% RSD					0.23		0.75				

Standard Correlation (Check Standard)
Ivermectin Total (A+B)
Sample Name: Ivermection Standard 2 0.25mg/mL

	Inj Id	Result Id	Sample Name	Label	RT (min)	K'	Area (µV*sec)	Height (µV)	Symmetry Factor	N (Plates)	Wave length
1	1124	1553	Ivermection Standard 2 0.25mg/mL	C101	18.81		3760967	146309			DAD.0.0
2	1128	1554	Ivermection Standard 2 0.25mg/mL	C101	18.81		3814770	146181			DAD.0.0
Mean					18.81		3787869				
% RSD					0.01		1.00				

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_s22

LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST
Print Date: 27/06/2022

Analyst s22

System Suitability

Standard Correlation (Check Standard)
Ivermectin Total (A+B)
Sample Name: Ivermection Standard 2 0.25mg/mL

	Correlation
1	466.125
2	474.224
Mean	470.17
% RSD	1.2

System Suitability Requirement:

Standard Correlation: <2.0% Complies / Fails

Standard correlation:

(3925054/3787869) × (6.364/6.436) × 100 - 100 = 2.46

Standard correlation is above the acceptable criteria a third std was made and all three standards were rerun to check the std correlation. Standard check seen on page 27.

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_s22

Analyst s22

LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST
Print Date: 27/06/2022

System Suitability

System Suitability (Duration)
Ivermectin A

	Inj Id	Result Id	Sample Name	Label	RT (min)	k'	Area (µV*sec)	Height (µV)	Symmetry Factor	N (Plates)	Wave length
1	1113	1504	Ivermection Standard 1 0.25mg/mL	S101	18.82	7.55	3789769	146314	0.99	12503	DAD.0.0
2	1118	1505	Ivermection Standard 1 0.25mg/mL	S101	18.82	7.55	3786061	146341	0.99	12516	DAD.0.0
3	1160	1506	Ivermectin Standard 1 0.25mg/mL	S102	18.80	7.54	3850025	146041	0.99	12308	DAD.0.0
4	1192	1507	Ivermectin Standard 1 0.25mg/mL	S103	18.79	7.54	3852907	145982	0.99	12263	DAD.0.0
5	1224	1508	Ivermectin Standard 1 0.25mg/mL	S104	18.80	7.55	3858323	146239	0.99	12280	DAD.0.0
6	1256	1509	Ivermectin Standard 1 0.25mg/mL	S105	18.80	7.55	3848091	146974	0.99	12346	DAD.0.0
7	1274	1510	Ivermectin Standard 1 0.25mg/mL	S106	18.72	7.51	3807513	148080	0.99	12517	DAD.0.0
8	1277	1511	Ivermectin Standard 1 0.25mg/mL	S106	18.71	7.50	3831297	148156	0.99	12423	DAD.0.0
Mean					18.78	7.54	3827998		0.99	12395	
% RSD					0.23	0.26	0.77				

System Suitability Requirements:

%RSD (Rt) NMT 1.0%: Complies / Fails

%RSD (Response): NMT 2.0% Complies / Fails

Symmetry Factor: 0.8<As<1.5 Complies / Fails

Standard Correlation (Analytical Standard)
Ivermectin Total A

	Inj Id	Result Id	Sample Name	Label	RT (min)	k'	Area (µV*sec)	Height (µV)	Symmetry Factor	N (Plates)	Wave length
1	1113	1504	Ivermection Standard 1 0.25mg/mL	S101	18.82	7.55	3789769	146314	0.99	12503	DAD.0.0
2	1118	1505	Ivermection Standard 1 0.25mg/mL	S101	18.82	7.55	3786061	146341	0.99	12516	DAD.0.0
3	1160	1506	Ivermectin Standard 1 0.25mg/mL	S102	18.80	7.54	3850025	146041	0.99	12308	DAD.0.0
4	1192	1507	Ivermectin Standard 1 0.25mg/mL	S103	18.79	7.54	3852907	145982	0.99	12263	DAD.0.0
5	1224	1508	Ivermectin Standard 1 0.25mg/mL	S104	18.80	7.55	3858323	146239	0.99	12280	DAD.0.0
6	1256	1509	Ivermectin Standard 1 0.25mg/mL	S105	18.80	7.55	3848091	146974	0.99	12346	DAD.0.0
7	1274	1510	Ivermectin Standard 1 0.25mg/mL	S106	18.72	7.51	3807513	148080	0.99	12517	DAD.0.0
8	1277	1511	Ivermectin Standard 1 0.25mg/mL	S106	18.71	7.50	3831297	148156	0.99	12423	DAD.0.0
Mean					18.78	7.54	3827998		0.99	12395	
% RSD					0.23	0.26	0.77				

Standard Correlation (Check Standard)
Ivermectin A
Sample Name: Ivermection Standard 2 0.25mg/mL

	Inj Id	Result Id	Sample Name	Label	RT (min)	k'	Area (µV*sec)	Height (µV)	Symmetry Factor	N (Plates)	Wave length
1	1124	1553	Ivermection Standard 2 0.25mg/mL	C101	18.81	7.55	3666507	141755	0.99	12487	DAD.0.0
2	1128	1554	Ivermection Standard 2 0.25mg/mL	C101	18.81	7.55	3720904	141647	1.00	12380	DAD.0.0
Mean					18.81	7.55	3693706		1.00	12434	
% RSD					0.01	0.01	1.04				

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_s22

LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST
Print Date: 27/06/2022

Analyst s22

System Suitability

Standard Correlation (Check Standard)
Ivermectin A
Sample Name: Ivermection Standard 2 0.25mg/mL

	Correlation
1	100.000
2	100.000
Mean	100.00
% RSD	0.0

System Suitability Requirement:

Standard Correlation: <2.0% Complies / Fails

Standard Correlation:

(3827998/3693706) × (6.364/6.436) × 100 - 100 = 2.47

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_s22

LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST
Print Date: 27/06/2022

Analyst s22

System Suitability

System Suitability (Duration)
Ivermectin B

	Inj Id	Result Id	Sample Name	Label	RT (min)	k'	Area (µV*sec)	Height (µV)	Symmetry Factor	N (Plates)	Wave length
1	1113	1504	Ivermection Standard 1 0.25mg/mL	S101	15.00	5.82	96840	4668	1.05	12109	DAD.0.0
2	1118	1505	Ivermection Standard 1 0.25mg/mL	S101	15.00	5.82	97120	4677	1.05	12096	DAD.0.0
3	1160	1506	Ivermectin Standard 1 0.25mg/mL	S102	14.99	5.81	96186	4639	1.03	12043	DAD.0.0
4	1192	1507	Ivermectin Standard 1 0.25mg/mL	S103	14.98	5.81	96538	4640	1.02	11966	DAD.0.0
5	1224	1508	Ivermectin Standard 1 0.25mg/mL	S104	14.99	5.81	96858	4651	1.02	11958	DAD.0.0
6	1256	1509	Ivermectin Standard 1 0.25mg/mL	S105	14.99	5.81	97591	4684	1.04	11965	DAD.0.0
7	1274	1510	Ivermectin Standard 1 0.25mg/mL	S106	14.94	5.79	97346	4726	1.03	12118	DAD.0.0
8	1277	1511	Ivermectin Standard 1 0.25mg/mL	S106	14.93	5.79	97969	4729	1.03	12024	DAD.0.0
Mean					14.98	5.81	97056		1.03	12035	
% RSD					0.19	0.23	0.59				

System Suitability Requirements:

%RSD (Rt) NMT 1.0%: Complies / Fails

%RSD (Response): NMT 2.0% Complies / Fails

Symmetry Factor: 0.8<As<1.5 Complies / Fails

Standard Correlation (Analytical Standard)
Ivermectin Total B
Sample Name: Ivermection Standard 1 0.25mg/mL

	Inj Id	Result Id	Sample Name	Label	RT (min)	k'	Area (µV*sec)	Height (µV)	Symmetry Factor	N (Plates)	Wave length
1	1113	1504	Ivermection Standard 1 0.25mg/mL	S101	15.00	5.82	96840	4668	1.05	12109	DAD.0.0
2	1118	1505	Ivermection Standard 1 0.25mg/mL	S101	15.00	5.82	97120	4677	1.05	12096	DAD.0.0
Mean					15.00	5.82	96980		1.05	12102	
% RSD					0.01	0.01	0.20				

Standard Correlation (Analytical Standard)
Ivermectin Total B
Sample Name: Ivermectin Standard 1 0.25mg/mL

	Inj Id	Result Id	Sample Name	Label	RT (min)	k'	Area (µV*sec)	Height (µV)	Symmetry Factor	N (Plates)	Wave length
1	1160	1506	Ivermectin Standard 1 0.25mg/mL	S102	14.99	5.81	96186	4639	1.03	12043	DAD.0.0
2	1192	1507	Ivermectin Standard 1 0.25mg/mL	S103	14.98	5.81	96538	4640	1.02	11966	DAD.0.0
3	1224	1508	Ivermectin Standard 1 0.25mg/mL	S104	14.99	5.81	96858	4651	1.02	11958	DAD.0.0
4	1256	1509	Ivermectin Standard 1 0.25mg/mL	S105	14.99	5.81	97591	4684	1.04	11965	DAD.0.0
5	1274	1510	Ivermectin Standard 1 0.25mg/mL	S106	14.94	5.79	97346	4726	1.03	12118	DAD.0.0
6	1277	1511	Ivermectin Standard 1 0.25mg/mL	S106	14.93	5.79	97969	4729	1.03	12024	DAD.0.0
Mean					14.97	5.80	97081		1.03	12012	
% RSD					0.20	0.23	0.69				

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_s22

Analyst s22

LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST
Print Date: 27/06/2022

System Suitability

Standard Correlation (Check Standard)
Ivermectin B
Sample Name: Ivermection Standard 2 0.25mg/mL

	Inj Id	Result Id	Sample Name	Label	RT (min)	k'	Area (µV*sec)	Height (µV)	Symmetry Factor	N (Plates)	Wave length
1	1124	1553	Ivermection Standard 2 0.25mg/mL	C101	14.99	5.81	94460	4554	1.04	12099	DAD.0.0
2	1128	1554	Ivermection Standard 2 0.25mg/mL	C101	14.99	5.82	93866	4533	1.04	12098	DAD.0.0
Mean					14.99	5.82	94163		1.04	12098	
% RSD					0.01	0.01	0.45				

Standard Correlation (Check Standard) Ivermectin B Sample Name: Ivermection Standard 2 0.25mg/mL

	Correlation
1	100.000
2	100.000
Mean	100.00
% RSD	0.0

System Suitability Requirement:

Standard Correlation: <2.0% Complies / Fails

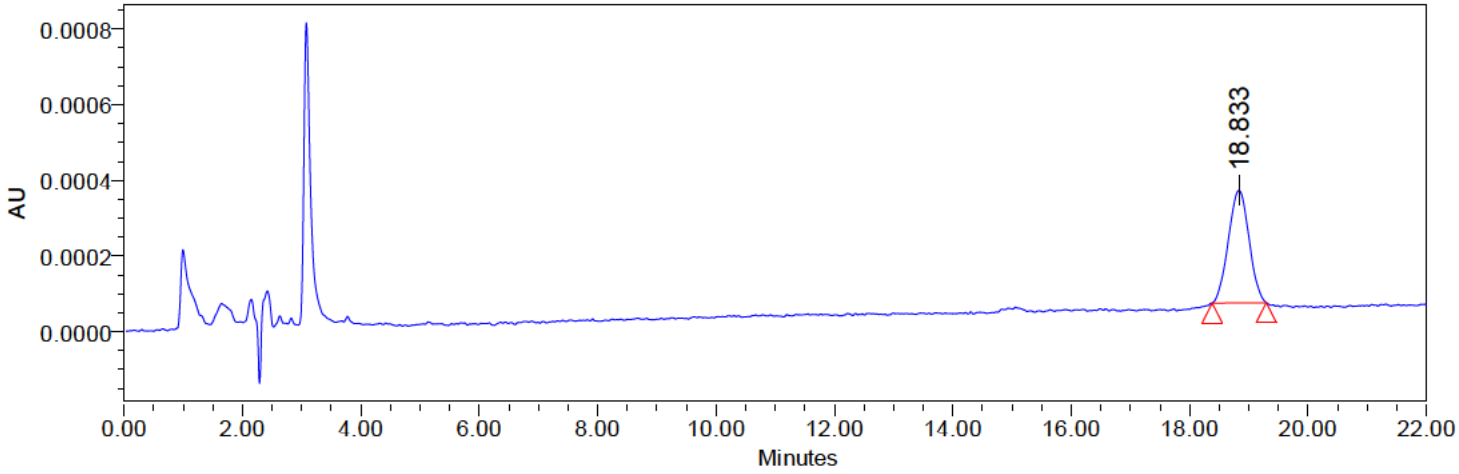
Standard Correlation:

(97056/97081) × (6.364/6.436) × 100 - 100 = 1.14

Sensitivity Solution Report

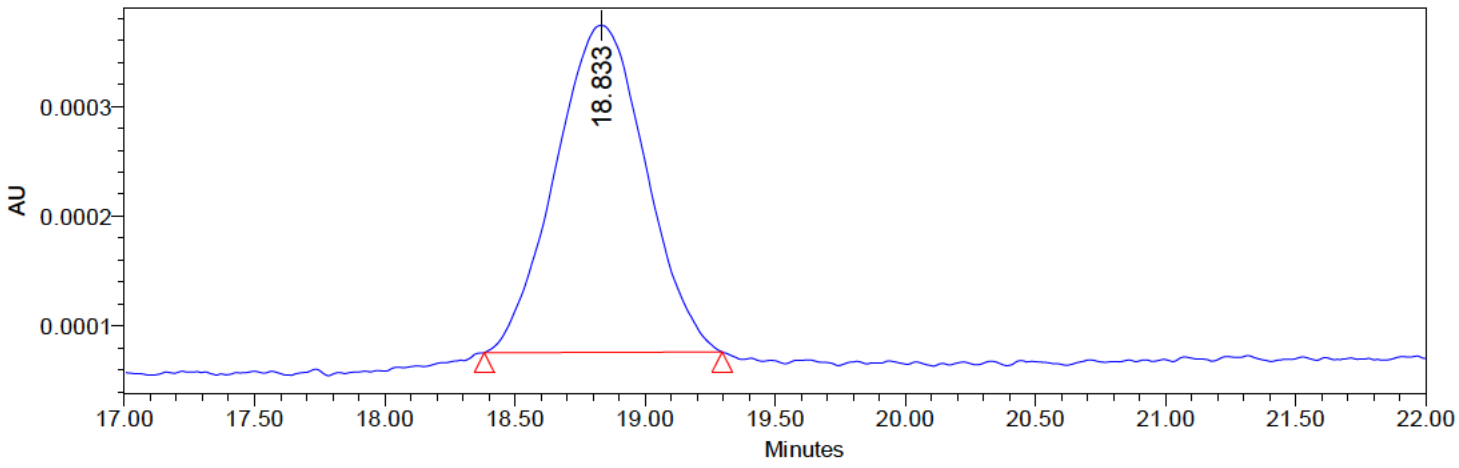
SampleName Sensitivity Solution (0.2%)

Auto-Scaled Chromatogram



Date Acq 22/06/2022 12:40:04 PM AEST; Vial 1:A,2; Inj 1; Inj Vol 10.00; Wavelength DAD.0.0

Zoomed Chromatogram - 1



Date Acq 22/06/2022 12:40:04 PM AEST; Vial 1:A,2; Inj 1; Inj Vol 10.00; Wavelength DAD.0.0

	Injection	RT	Area	% Area	Symmetry	Signal_to_Noise_Ratio	N (Plates)
1	1	18.83	7199	100.00	1.01	34.63	13398
2	2	18.83	7356	100.00	0.98	43.45	13192
Mean			7277				

Sensitivity Solution (0.2%) Requirements:

Singal to Noise Ratio: >10 Complies / Fails

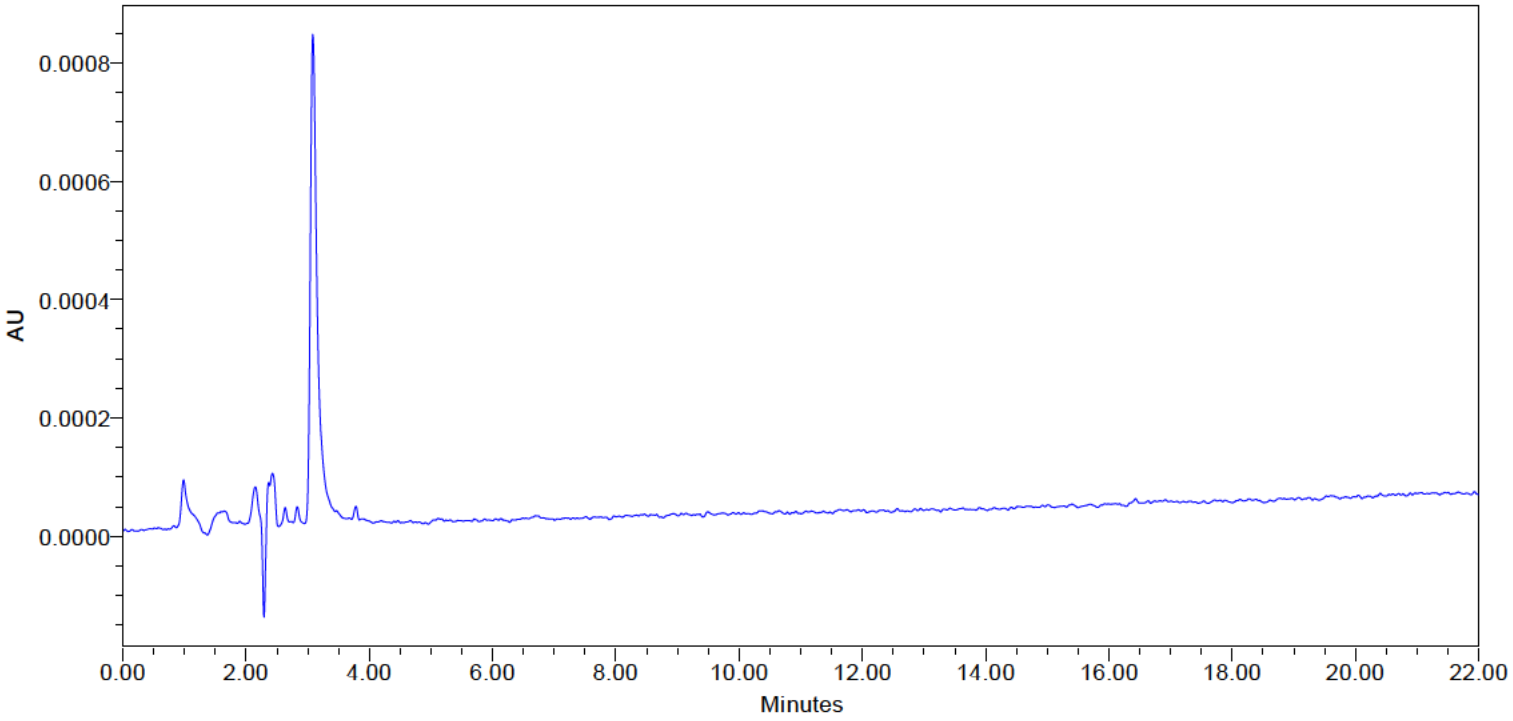
Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_s22

LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST
Print Date: 28/06/2022

Analyst s22

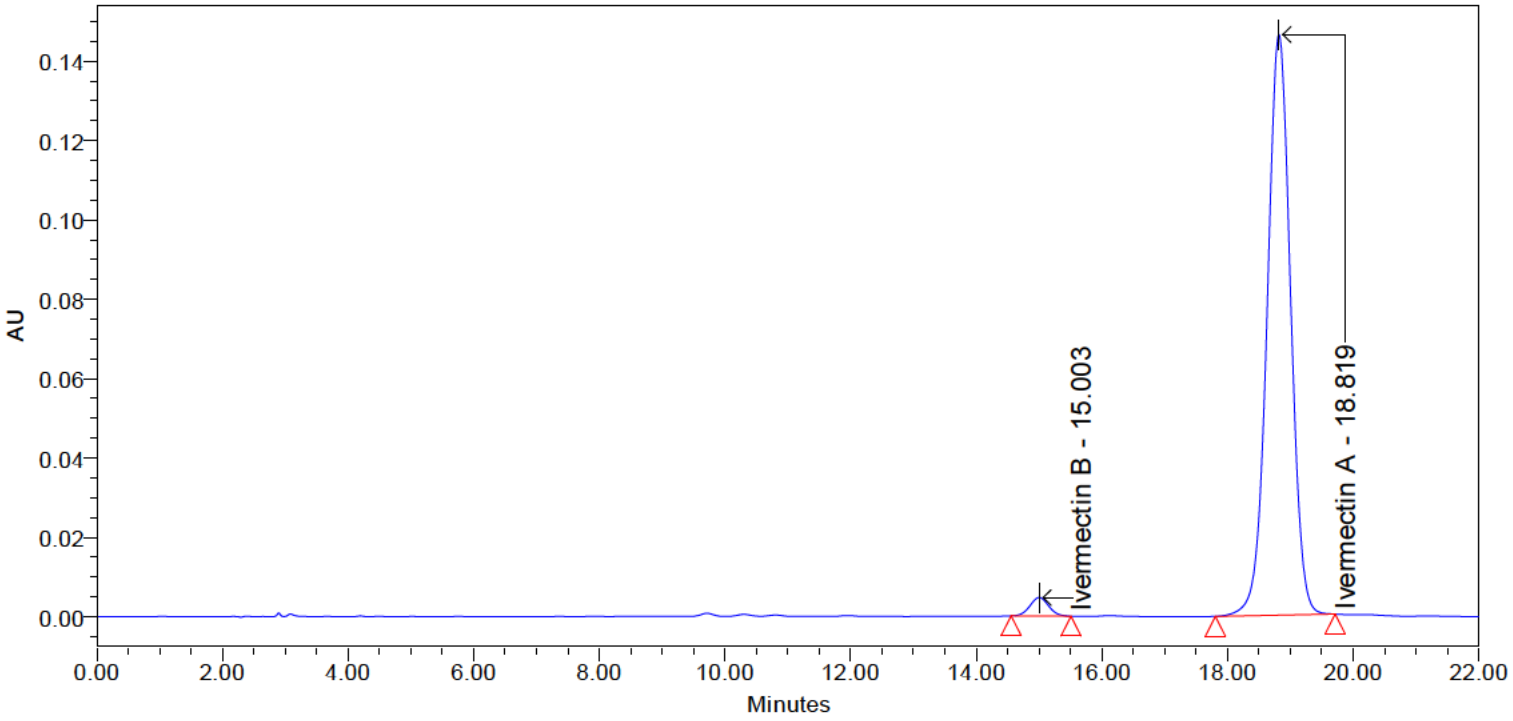
Example Chromatograms

Auto-Scaled Chromatogram



SampleName: Blank; Sample Type: Unknown; Date Acquired: 22/06/2022 12:16:34 PM AEST; Vial: 1:A,1; Injection Id: 1102; Result Id 1548; Inj Vol: 10; Wavelength: DAD.0.0

Auto-Scaled Chromatogram



SampleName: Ivermection Standard 1 0.25mg/mL; Sample Type: Standard; Date Acquired: 22/06/2022 1:26:57 PM AEST; Vial: 1:A,3; Injection Id: 1113; Result Id 1504; Inj Vol: 10; Wavelength: DAD.0.0

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_s22

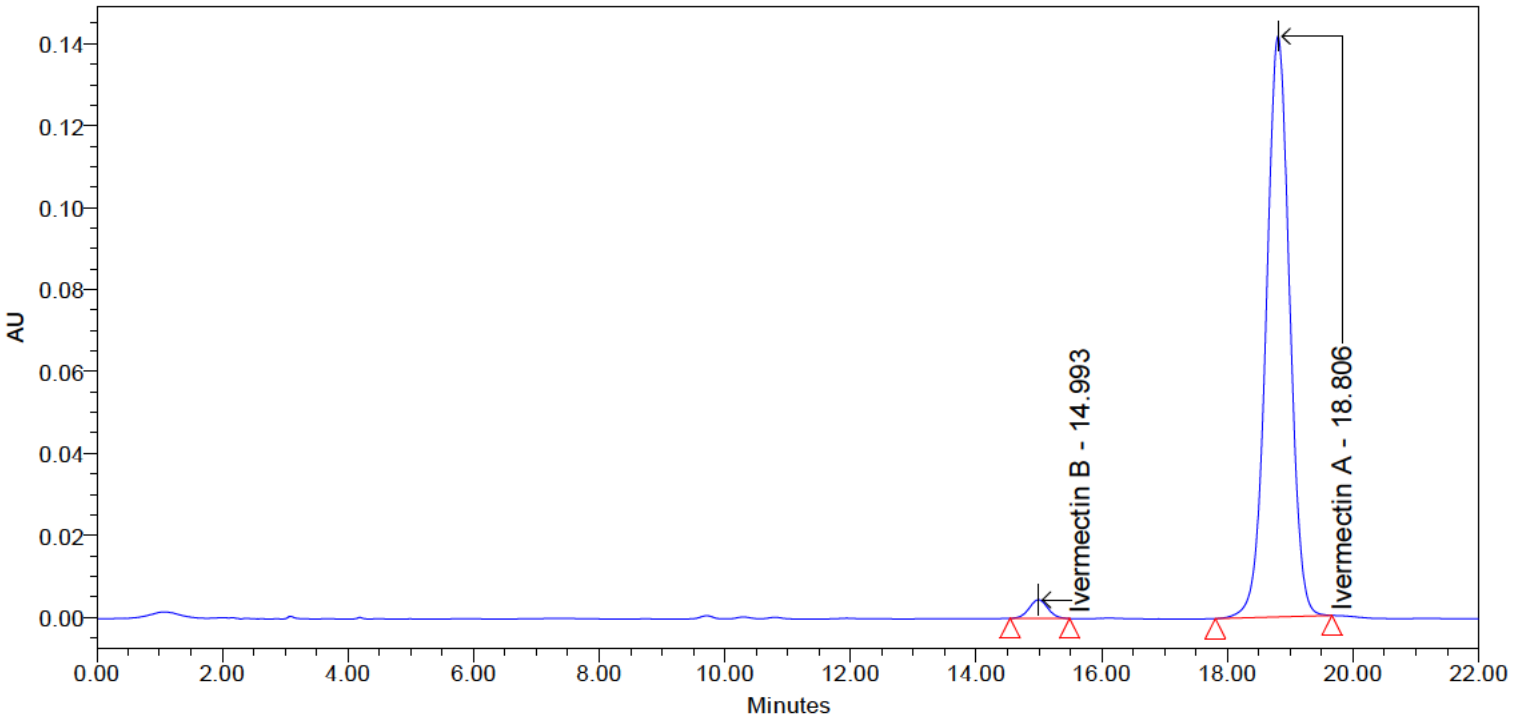
LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST

Analyst s22

Print Date: 28/06/2022

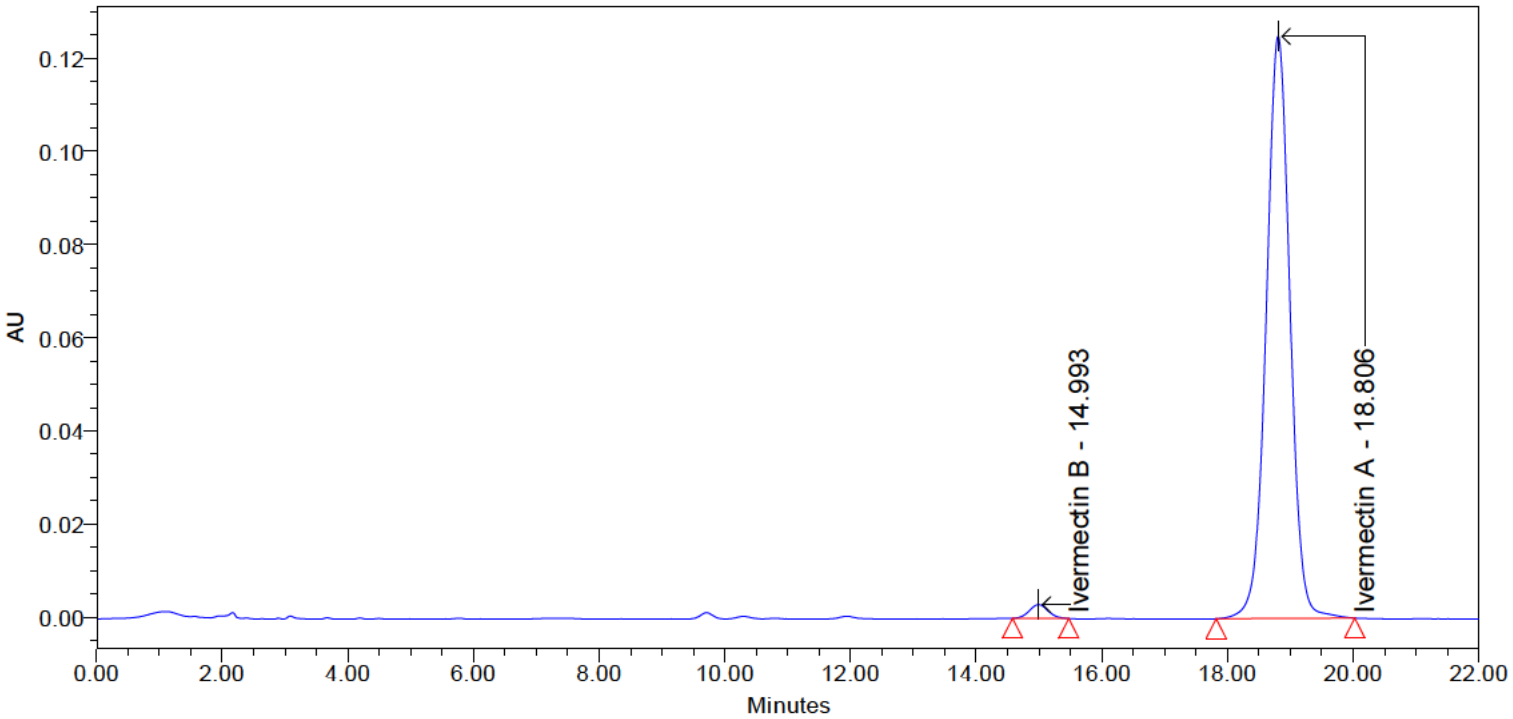
Example Chromatograms

Auto-Scaled Chromatogram



SampleName: Ivermection Standard 2 0.25mg/mL; Sample Type: Control; Date Acquired: 22/06/2022 2:13:46 PM AEST; Vial: 1:A,4; Injection Id: 1124; Result Id 1553; Inj Vol: 10; Wavelength: DAD.0.0

Auto-Scaled Chromatogram



SampleName: 2206002093 - Tablet 1; Sample Type: Unknown; Date Acquired: 22/06/2022 3:00:35 PM AEST; Vial: 1:A,5; Injection Id: 1132; Result Id 1512; Inj Vol: 10; Wavelength: DAD.0.0

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_s22

Analyst s22

LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST
Print Date: 28/06/2022

Example Chromatograms

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_s22

LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST
Print Date: 29/06/2022

Analyst s22

Run and Method Summary Report

Column Description: LC0278 - Phenomenex, Luna C18(2), 5µm, 4.6 × 250mm.

	Injection Id	Date Acquired	SampleName	Vial	Injection Volume (ul)	Sample Weight	Dilution
1	1090	22/06/2022 10:42:54 AM AEST	Blank	1:A,1	10.00	1.00000	1.00000
2	1093	22/06/2022 11:06:26 AM AEST	Sensitivity Solution	1:A,2	10.00	1.00000	1.00000
3	1095	22/06/2022 11:29:47 AM AEST	Sensitivity Solution	1:A,2	10.00	1.00000	1.00000
4	1102	22/06/2022 12:16:34 PM AEST	Blank	1:A,1	10.00	1.00000	1.00000
5	1102	22/06/2022 12:16:34 PM AEST	Blank	1:A,1	10.00	1.00000	1.00000
6	1106	22/06/2022 12:40:04 PM AEST	Sensitivity Solution	1:A,2	10.00	1.00000	12500.00000
7	1106	22/06/2022 12:40:04 PM AEST	Sensitivity Solution	1:A,2	10.00	1.00000	12500.00000
8	1109	22/06/2022 1:03:25 PM AEST	Sensitivity Solution	1:A,2	10.00	1.00000	12500.00000
9	1109	22/06/2022 1:03:25 PM AEST	Sensitivity Solution	1:A,2	10.00	1.00000	12500.00000
10	1113	22/06/2022 1:26:57 PM AEST	Ivermection Standard 1 0.25mg/mL	1:A,3	10.00	1.00000	25.00000
11	1113	22/06/2022 1:26:57 PM AEST	Ivermection Standard 1 0.25mg/mL	1:A,3	10.00	1.00000	25.00000
12	1118	22/06/2022 1:50:16 PM AEST	Ivermection Standard 1 0.25mg/mL	1:A,3	10.00	1.00000	25.00000
13	1118	22/06/2022 1:50:16 PM AEST	Ivermection Standard 1 0.25mg/mL	1:A,3	10.00	1.00000	25.00000
14	1124	22/06/2022 2:13:46 PM AEST	Ivermection Standard 2 0.25mg/mL	1:A,4	10.00	1.00000	25.00000
15	1124	22/06/2022 2:13:46 PM AEST	Ivermection Standard 2 0.25mg/mL	1:A,4	10.00	1.00000	25.00000
16	1128	22/06/2022 2:37:05 PM AEST	Ivermection Standard 2 0.25mg/mL	1:A,4	10.00	1.00000	25.00000
17	1128	22/06/2022 2:37:05 PM AEST	Ivermection Standard 2 0.25mg/mL	1:A,4	10.00	1.00000	25.00000
18	1132	22/06/2022 3:00:35 PM AEST	2206002093 - Tablet 1	1:A,5	10.00	1.00000	50.00000
19	1132	22/06/2022 3:00:35 PM AEST	2206002093 - Tablet 1	1:A,5	10.00	1.00000	50.00000
20	1135	22/06/2022 3:23:54 PM AEST	2206002093 - Tablet 1	1:A,5	10.00	1.00000	50.00000
21	1135	22/06/2022 3:23:54 PM AEST	2206002093 - Tablet 1	1:A,5	10.00	1.00000	50.00000
22	1139	22/06/2022 3:47:24 PM AEST	2206002093 - Tablet 2	1:A,6	10.00	1.00000	50.00000
23	1139	22/06/2022 3:47:24 PM AEST	2206002093 - Tablet 2	1:A,6	10.00	1.00000	50.00000
24	1142	22/06/2022 4:10:42 PM AEST	2206002093 - Tablet 2	1:A,6	10.00	1.00000	50.00000
25	1142	22/06/2022 4:10:42 PM AEST	2206002093 - Tablet 2	1:A,6	10.00	1.00000	50.00000
26	1146	22/06/2022 4:34:11 PM AEST	2206002093 - Tablet 3	1:A,7	10.00	1.00000	50.00000
27	1146	22/06/2022 4:34:11 PM AEST	2206002093 - Tablet 3	1:A,7	10.00	1.00000	50.00000
28	1149	22/06/2022 4:57:31 PM AEST	2206002093 - Tablet 3	1:A,7	10.00	1.00000	50.00000
29	1149	22/06/2022 4:57:31 PM AEST	2206002093 - Tablet 3	1:A,7	10.00	1.00000	50.00000
30	1153	22/06/2022 5:21:02 PM AEST	2206002093 - Tablet 4	1:A,8	10.00	1.00000	50.00000
31	1153	22/06/2022 5:21:02 PM AEST	2206002093 - Tablet 4	1:A,8	10.00	1.00000	50.00000
32	1156	22/06/2022 5:44:20 PM AEST	2206002093 - Tablet 4	1:A,8	10.00	1.00000	50.00000
33	1156	22/06/2022 5:44:20 PM AEST	2206002093 - Tablet 4	1:A,8	10.00	1.00000	50.00000
34	1160	22/06/2022 6:07:51 PM AEST	Ivermectin Standard 1 0.25mg/mL	1:A,3	10.00	1.00000	25.00000
35	1160	22/06/2022 6:07:51 PM AEST	Ivermectin Standard 1 0.25mg/mL	1:A,3	10.00	1.00000	25.00000

s22

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_[redacted]

LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST
Print Date: 29/06/2022

Analyst [redacted]

Run and Method Summary Report

	Injection Id	Date Acquired	SampleName	Vial	Injection Volume (ul)	Sample Weight	Dilution
[redacted]							
52	1192	22/06/2022 9:38:58 PM AEST	Ivermectin Standard 1 0.25mg/mL	1:A,3	10.00	1.00000	25.00000
53	1192	22/06/2022 9:38:58 PM AEST	Ivermectin Standard 1 0.25mg/mL	1:A,3	10.00	1.00000	25.00000
[redacted]							
70	1224	23/06/2022 1:09:52 AM AEST	Ivermectin Standard 1 0.25mg/mL	1:A,3	10.00	1.00000	25.00000
71	1224	23/06/2022 1:09:52 AM AEST	Ivermectin Standard 1 0.25mg/mL	1:A,3	10.00	1.00000	25.00000
[redacted]							

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_[redacted]

LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST

Analyst [redacted]
Print Date: 29/06/2022

Run and Method Summary Report

	Injection Id	Date Acquired	SampleName	Vial	Injection Volume (ul)	Sample Weight	Dilution
[redacted]							
88	1256	23/06/2022 4:40:41 AM AEST	Ivermectin Standard 1 0.25mg/mL	1:A,3	10.00	1.00000	25.00000
89	1256	23/06/2022 4:40:41 AM AEST	Ivermectin Standard 1 0.25mg/mL	1:A,3	10.00	1.00000	25.00000
[redacted]							
98	1274	23/06/2022 6:37:55 AM AEST	Ivermectin Standard 1 0.25mg/mL	1:A,3	10.00	1.00000	25.00000
99	1274	23/06/2022 6:37:55 AM AEST	Ivermectin Standard 1 0.25mg/mL	1:A,3	10.00	1.00000	25.00000
100	1277	23/06/2022 7:01:15 AM AEST	Ivermectin Standard 1 0.25mg/mL	1:A,3	10.00	1.00000	25.00000
101	1277	23/06/2022 7:01:15 AM AEST	Ivermectin Standard 1 0.25mg/mL	1:A,3	10.00	1.00000	25.00000
102	1281	23/06/2022 7:24:50 AM AEST	Blank MeOH	1:A,1	10.00	1.00000	1.00000
103	1281	23/06/2022 7:24:50 AM AEST	Blank MeOH	1:A,1	10.00	1.00000	1.00000
104	1284	23/06/2022 7:48:13 AM AEST	Blank MeOH	1:A,1	10.00	1.00000	1.00000
105	1284	23/06/2022 7:48:13 AM AEST	Blank MeOH	1:A,1	10.00	1.00000	1.00000

	AverageUnitWeight	Label
1	1.00000	
2	1.00000	
3	1.00000	
4	1.00000	B101
5	1.00000	B101
6	1.00000	V101
7	1.00000	V101
8	1.00000	V101
9	1.00000	V101
10	1.00000	S101
11	1.00000	S101
12	1.00000	S101
13	1.00000	S101
14	1.00000	C101

	AverageUnitWeight	Label
15	1.00000	C101
16	1.00000	C101
17	1.00000	C101
18	1.00000	U101
19	1.00000	U101
20	1.00000	U101
21	1.00000	U101
22	1.00000	U102
23	1.00000	U102
24	1.00000	U102
25	1.00000	U102
26	1.00000	U103
27	1.00000	U103
28	1.00000	U103

	AverageUnitWeight	Label
29	1.00000	U103
30	1.00000	U104
31	1.00000	U104
32	1.00000	U104
33	1.00000	U104
34	1.00000	S102
35	1.00000	S102

[redacted]

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_[redacted]

LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST
Print Date: 29/06/2022

Analyst [redacted]

Run and Method Summary Report

	AverageUnitWeight	Label
[redacted]		
52	1.00000	S103
53	1.00000	S103
[redacted]		
70	1.00000	S104
71	1.00000	S104
[redacted]		

	AverageUnitWeight	Label
[redacted]		
88	1.00000	S105
89	1.00000	S105
[redacted]		
98	1.00000	S106
99	1.00000	S106
100	1.00000	S106
101	1.00000	S106
102	1.00000	B102
103	1.00000	B102
104	1.00000	B102
105	1.00000	B102

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_s22

LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST
Print Date: 29/06/2022

Analyst s22

Run and Method Summary Report

Instrument Method: Ivermectin Assay_s22

Stored: 21/06/2022 5:13:31 PM AEST

Method Information

Method Comments	
Method Modified User	s22
Method Locked	No
Method Id	1043
Old Id	
Method Version	3
Method Edit User	
Source S/W Info	Empower 3 Software Build 3471 SPs Installed: Service Release 5 DB ID: 3107713112

AgilentLC Instrument Setup

Quat. Pump G7104C

Flow	1.200 (mL/min)
Use Solvent Types	Yes
Low Pressure Limit	0.00 (psi)
High Pressure Limit	11603.02 (psi)
Max. Flow Ramp Up	100.000 (mL/min²)
Primary Channel	Automatic

Max. Flow Ramp Down 100.000 (mL/min²)

Solvent Composition

	Channel	Ch. 1 Solv.	Name 1	Used	Percent (%)
1	A	100.0 % Organic in Aqueous V.03	ACN:MeOH:H2O	Yes	100.00
2	B			No	
3	C			No	
4	D			No	

Quat. Pump - Pump0 - Stroke

Automatic Stroke Calculation Yes

Quat. Pump - Pump0 - Emulation Mode

Emulation Enabled No

Quat. Pump - Pump0 - Mixer Selection

Selected Mixer Do not use Mixer

Quat. Pump - Pump0 - Blend Assist

Enabled No

Quat. Pump - Pump0 - Stop Time

Stoptime Mode No limit

Quat. Pump - Pump0 - Post Time

Posttime Mode Off

Sampler G7129C

Sampler - Sampler0 - Auxiliary

Draw Speed	200 (µL/min)
Eject Speed	400 (µL/min)
Wait Time After Draw	1.2 (s)
Needle Height Offset	0.0 (mm)

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_s22

LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST

Analyst s22

Print Date: 29/06/2022

Run and Method Summary Report

Sampler - Sampler0 - Injection

Injection Mode	Injection with needle wash
Injection Volume	10.00 (µL)

Sampler - Injection - Needle Wash

Needle Wash Location	Flush Port
Wash Time	3 (s)

Sampler - Sampler0 - High throughput

Sample Flush-Out Factor	5.0
Injection Valve to Bypass for Delay Volume Reduction	No

Sampler - High throughput - Overlapped Injection

Overlapped Injection Mode	Off

Sampler - Sampler0 - Stop Time

Stoptime Mode	As pump/No limit

Sampler - Sampler0 - Post Time

Posttime Mode	Off

Column Comp. G7116A

Valve Position	Position 1 (Port 1 -> 1')
Position Switch After Run	Do not switch

Column Comp. - Column Comp.0 - Left Temperature Control

Temperature Control Mode	Temperature Set
Temperature	30.0 (°C)

Column Comp. - Left Temperature Control - Enable Analysis Left Temperature

Enable Analysis Left Temperature On	Yes
Enable Analysis Left Temperature Value	0.8 (°C)
Left Temp. Equilibration Time	0.0 (min)

Column Comp. - Column Comp.0 - Right Temperature Control

Right temperature Control Mode	Temperature Set
Right temperature	30.0 (°C)

Column Comp. - Right Temperature Control - Enable Analysis Right Temperature

Enable Analysis Right Temperature On	Yes
Enable Analysis Right Temperature Value	0.8 (°C)
Right Temp. Equilibration Time	0.0 (min)

Column Comp. - Column Comp.0 - Enforce column for run

Enforce column for run enabled	No

Column Comp. - Column Comp.0 - Stop Time

Stoptime Mode	As pump/injector

Column Comp. - Column Comp.0 - Post Time

Posttime Mode	Off

Column Comp. - Column Comp.0 - Timetable

DAD G7117C

Peakwidth	> 0.1 min (2 s response time) (2.5 Hz)
UV Lamp Required	Yes

DAD - DAD0 - Analog Output

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_s22

LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST
Print Date: 29/06/2022

Analyst s22

Run and Method Summary Report

Analog Zero Offset 5 (%)
Analog Attenuation 1000 (mAU)

DAD - DAD0 - Signals

Signal table-DAD0

	Acquire	Signal	Wavelength (nm)	Bandwidth (nm)	Use Ref.	Ref Wavel. (nm)	Ref Bandw. (nm)
1	Yes	Signal A	245	4	Yes	360	100
2	No	Signal B					
3	No	Signal C					
4	No	Signal D					
5	No	Signal E					
6	No	Signal F					
7	No	Signal G					
8	No	Signal H					

DAD - DAD0 - Prepare Mode

Margin for negative Absorbance 100 (mAU)

DAD - DAD0 - Autobalance

Autobalance Prerun Yes
Autobalance Postrun No

DAD - DAD0 - Spectrum

Spectrum Store None

DAD - DAD0 - Stoptime

Stoptime Mode As pump/injector

DAD - DAD0 - Posttime

Posttime Mode Off

DAD - DAD0 - Timetable

Injector Preference Value :

Injector Selected ALS

Sampler G7129C

Auxiliary Channels

Auxiliary Channels - - PUMP.0.0.Pressure

PUMP.0.0.Pressure disabled

Auxiliary Channels - - PUMP.0.1.Flow

PUMP.0.1.Flow disabled

Auxiliary Channels - - PUMP.0.2.SolventRatioA

PUMP.0.2.SolventRatioA disabled

Auxiliary Channels - - PUMP.0.3.SolventRatioB

PUMP.0.3.SolventRatioB disabled

Auxiliary Channels - - PUMP.0.4.SolventRatioC

PUMP.0.4.SolventRatioC disabled

Auxiliary Channels - - PUMP.0.5.SolventRatioD

PUMP.0.5.SolventRatioD disabled

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_s22

LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST
Print Date: 29/06/2022

Analyst s22

Run and Method Summary Report

Auxiliary Channels - - PUMP.0.6.Tuning
PUMP.0.6.Tuning disabled

Auxiliary Channels - - SAMPLER.0.0.Temperature
SAMPLER.0.0.Temperature disabled

Auxiliary Channels - - COLCOMP.0.0.LeftTemperature
COLCOMP.0.0.LeftTemperature disabled

Auxiliary Channels - - COLCOMP.0.1.RightTemperature
COLCOMP.0.1.RightTemperature disabled

Auxiliary Channels - - DAD.0.0.BoardTemperature
DAD.0.0.BoardTemperature disabled

Auxiliary Channels - - DAD.0.1.OpticalUnitTemperature
DAD.0.1.OpticalUnitTemperature disabled

Auxiliary Channels - - DAD.0.2.UVLampAnodeVoltage
DAD.0.2.UVLampAnodeVoltage disabled

General Settings

General Settings - - Fraction Start Location Specified
Fraction Start Location Specified False

General Settings - - Start Location
Start Location 1

General Settings - - Shutdown after Run
Shutdown after Run False

Revision History
This method contains 5 items in the revision history.

Instrument Method: Ivermectin Assay_s22

Stored: 22/06/2022 11:49:04 AM AEST

Method Information

Method Comments	
Method Modified User	s22
Method Locked	No
Method Id	1099
Old Id	
Method Version	4
Method Edit User	
Source S/W Info	Empower 3 Software Build 3471 SPs Installed: Service Release 5 DB ID: 3107713112

AgilentLC Instrument Setup

Quat. Pump G7104C

Flow	1.200 (mL/min)
Use Solvent Types	Yes
Low Pressure Limit	0.00 (psi)
High Pressure Limit	11603.02 (psi)

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_s22

LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST
Print Date: 29/06/2022

Analyst s22

Run and Method Summary Report

Max. Flow Ramp Up 100.000 (mL/min²) | Max. Flow Ramp Down 100.000 (mL/min²)
Primary Channel Automatic

Solvent Composition

	Channel	Ch. 1 Solv.	Name 1	Used	Percent (%)
1	A	100.0 % Organic in Aqueous V.03	ACN:MeOH:H2O	Yes	100.00
2	B			No	
3	C			No	
4	D			No	

Quat. Pump - Pump0 - Stroke
Automatic Stroke Calculation Yes

Quat. Pump - Pump0 - Emulation Mode
Emulation Enabled No

Quat. Pump - Pump0 - Mixer Selection
Selected Mixer Do not use Mixer

Quat. Pump - Pump0 - Blend Assist
Enabled No

Quat. Pump - Pump0 - Stop Time
Stoptime Mode No limit

Quat. Pump - Pump0 - Post Time
Posttime Mode Off

Sampler G7129C

Sampler - Sampler0 - Auxiliary
Draw Speed 200 (µL/min)
Eject Speed 400 (µL/min)
Wait Time After Draw 1.2 (s)
Needle Height Offset 0.0 (mm)

Sampler - Sampler0 - Injection
Injection Mode Injection with needle wash
Injection Volume 10.00 (µL)

Sampler - Injection - Needle Wash
Needle Wash Location Flush Port
Wash Time 3 (s)

Sampler - Sampler0 - High throughput
Sample Flush-Out Factor 5.0
Injection Valve to Bypass for Delay Volume Reduction No

Sampler - High throughput - Overlapped Injection
Overlapped Injection Mode Off

Sampler - Sampler0 - Stop Time
Stoptime Mode As pump/No limit

Sampler - Sampler0 - Post Time
Posttime Mode Off

Column Comp. G7116A

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_s22

LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST

Analyst s22

Print Date: 29/06/2022

Run and Method Summary Report

Valve Position Position 1 (Port 1 -> 1')
Position Switch After Run Do not switch

Column Comp. - Column Comp.0 - Left Temperature Control

Temperature Control Mode Temperature Set
Temperature 30.0 (°C)

Column Comp. - Left Temperature Control - Enable Analysis Left Temperature

Enable Analysis Left Temperature On Yes
Enable Analysis Left Temperature Value 0.8 (°C)
Left Temp. Equilibration Time 0.0 (min)

Column Comp. - Column Comp.0 - Right Temperature Control

Right temperature Control Mode Temperature Set
Right temperature 30.0 (°C)

Column Comp. - Right Temperature Control - Enable Analysis Right Temperature

Enable Analysis Right Temperature On Yes
Enable Analysis Right Temperature Value 0.8 (°C)
Right Temp. Equilibration Time 0.0 (min)

Column Comp. - Column Comp.0 - Enforce column for run

Enforce column for run enabled No

Column Comp. - Column Comp.0 - Stop Time

Stoptime Mode As pump/injector

Column Comp. - Column Comp.0 - Post Time

Posttime Mode Off

Column Comp. - Column Comp.0 - Timetable

DAD G7117C

Peakwidth > 0.1 min (2 s response time) (2.5 Hz)
UV Lamp Required Yes

DAD - DAD0 - Analog Output

Analog Zero Offset 5 (%)
Analog Attenuation 1000 (mAU)

DAD - DAD0 - Signals

Signal table-DAD0

	Acquire	Signal	Wavelength (nm)	Bandwidth (nm)	Use Ref.	Ref Wavel. (nm)	Ref Bandw. (nm)
1	Yes	Signal A	245	4	Yes	360	100
2	No	Signal B					
3	No	Signal C					
4	No	Signal D					
5	No	Signal E					
6	No	Signal F					
7	No	Signal G					
8	No	Signal H					

DAD - DAD0 - Prepare Mode

Margin for negative Absorbance 100 (mAU)

DAD - DAD0 - Autobalance

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_s22

LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST
Print Date: 29/06/2022

Analyst s22

Run and Method Summary Report

Autobalance Prerun Yes
Autobalance Postrun No

DAD - DAD0 - Spectrum

Spectrum Range WL from 190 (nm)
Spectrum Range WL to 400 (nm)
Spectrum Step 2.0 (nm)
Spectrum Store All

DAD - DAD0 - Stoptime

Stoptime Mode As pump/injector

DAD - DAD0 - Posttime

Posttime Mode Off

DAD - DAD0 - Timetable

Injector Preference Value :

Injector Selected ALS

Sampler G7129C

Auxiliary Channels

Auxiliary Channels - - PUMP.0.0.Pressure

PUMP.0.0.Pressure disabled

Auxiliary Channels - - PUMP.0.1.Flow

PUMP.0.1.Flow disabled

Auxiliary Channels - - PUMP.0.2.SolventRatioA

PUMP.0.2.SolventRatioA disabled

Auxiliary Channels - - PUMP.0.3.SolventRatioB

PUMP.0.3.SolventRatioB disabled

Auxiliary Channels - - PUMP.0.4.SolventRatioC

PUMP.0.4.SolventRatioC disabled

Auxiliary Channels - - PUMP.0.5.SolventRatioD

PUMP.0.5.SolventRatioD disabled

Auxiliary Channels - - PUMP.0.6.Tuning

PUMP.0.6.Tuning disabled

Auxiliary Channels - - SAMPLER.0.0.Temperature

SAMPLER.0.0.Temperature disabled

Auxiliary Channels - - COLCOMP.0.0.LeftTemperature

COLCOMP.0.0.LeftTemperature disabled

Auxiliary Channels - - COLCOMP.0.1.RightTemperature

COLCOMP.0.1.RightTemperature disabled

Auxiliary Channels - - DAD.0.0.BoardTemperature

DAD.0.0.BoardTemperature disabled

Auxiliary Channels - - DAD.0.1.OpticalUnitTemperature

DAD.0.1.OpticalUnitTemperature disabled

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220622_IvermectinAssay_s22

LIMS Number:
Sample Set Id: 1088
Sample Set Start Date: 22/06/2022 10:21:06 AM AEST
Print Date: 29/06/2022

Analyst s22

Run and Method Summary Report

Auxiliary Channels - - DAD.0.2.UVLampAnodeVoltage

DAD.0.2.UVLampAnodeVoltage disabled

General Settings

General Settings - - Fraction Start Location Specified

Fraction Start Location Specified False

General Settings - - Start Location

Start Location 1

General Settings - - Shutdown after Run

Shutdown after Run False

Revision History

This method contains 6 items in the revision history.

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220624_IvermectinSTDCheck_s22_3

LIMS Number:
Sample Set Id: 1868
Sample Set Start Date: 27/06/2022 11:47:14 AM AEST
Print Date: 28/06/2022

Analyst s22

System Suitability

System Suitability (Duration)
Ivermectin Total (A+B)

	Inj Id	Result Id	Sample Name	Label	RT (min)	k'	Area (µV*sec)	Height (µV)	Symmetry Factor	N (Plates)	Wave length
1	1956	2039	Ivermectin STD 1 0.25 mg/mL	S101	18.28		3876366	153793			DAD.0.0
2	1959	2040	Ivermectin STD 1 0.25 mg/mL	S101	18.27		3882734	153684			DAD.0.0
Mean					18.28		3879550				
% RSD					0.03		0.12				

System Suitability Requirements:

%RSD (Rt) NMT 1.0%: Complies / Fails

%RSD (Response): NMT 2.0% Complies / Fails

Symmetry Factor: 0.8<As<1.5 Complies / Fails
N/A

Standard Correlation (Analytical Standard)
Ivermectin Total (A+B)

	Inj Id	Result Id	Sample Name	Label	RT (min)	k'	Area (µV*sec)	Height (µV)	Symmetry Factor	N (Plates)	Wave length
1	1956	2039	Ivermectin STD 1 0.25 mg/mL	S101	18.28		3876366	153793			DAD.0.0
2	1959	2040	Ivermectin STD 1 0.25 mg/mL	S101	18.27		3882734	153684			DAD.0.0
Mean					18.28		3879550				
% RSD					0.03		0.12				

Standard Correlation (Check Standard)
Ivermectin Total (A+B)
Sample Name: Ivermectin STD 2 0.25 mg/mL

	Inj Id	Result Id	Sample Name	Label	RT (min)	k'	Area (µV*sec)	Height (µV)	Symmetry Factor	N (Plates)	Wave length	Correlation
1	1963	2044	Ivermectin STD 2 0.25 mg/mL	C101	18.26		3790683	150421			DAD.0.0	477.291
2	1966	2045	Ivermectin STD 2 0.25 mg/mL	C101	18.26		3783587	150560			DAD.0.0	476.210
Mean					18.26		3787135					476.75
% RSD					0.01		0.13					0.2

Standard Correlation (Check Standard)
Ivermectin Total (A+B)
Sample Name: Ivermectin STD 3 0.25 mg/mL

	Inj Id	Result Id	Sample Name	Label	RT (min)	k'	Area (µV*sec)	Height (µV)	Symmetry Factor	N (Plates)	Wave length	Correlation
1	1970	2046	Ivermectin STD 3 0.25 mg/mL	C201	18.26		3841277	153112			DAD.0.0	484.996
2	1973	2047	Ivermectin STD 3 0.25 mg/mL	C201	18.24		3851256	152851			DAD.0.0	486.516
Mean					18.25		3846267					485.76
% RSD					0.08		0.18					0.2

System Suitability Requirement:

Standard Correlation: <2.0% Complies / Fails

Standard Correlation Standard 1 & Standard 2:
(3879550/3787135) x (6.364/6.436) x 100 - 100 = 0.29

Standard Correlation Standard 1 & Standard 3:
(3879550/3846267) x (6.424/6.436) x 100 - 100 = 0.68

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220624_IvermectinSTDCheck_s22_3

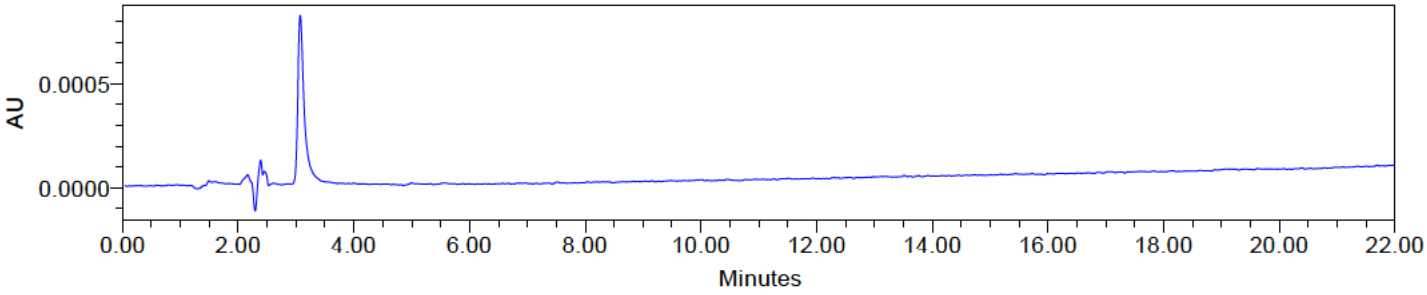
LIMS Number:
Sample Set Id: 1868
Sample Set Start Date: 27/06/2022 11:47:14 AM AEST

Analyst s22

Print Date: 30/06/2022

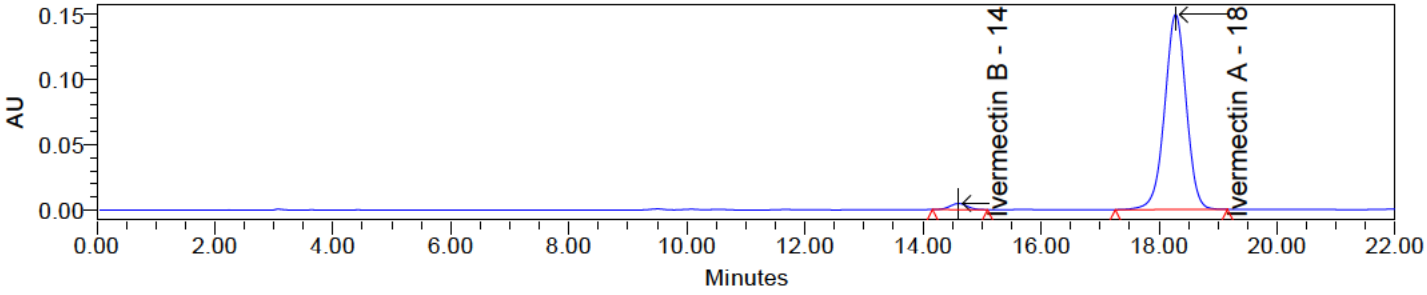
Example Chromatograms

Auto-Scaled Chromatogram



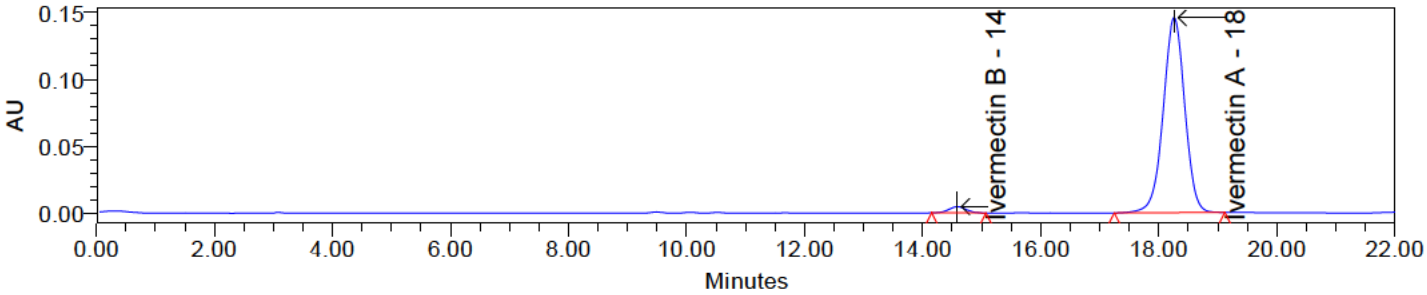
SampleName: Blank MeOH; Sample Type: Unknown; Date Acquired: 27/06/2022 11:48:29 AM AEST
Vial: 1:A,1; Injection Id: 1870; Result Id 2041; Inj Vol: 10; Wavelength: DAD.0.0

Auto-Scaled Chromatogram



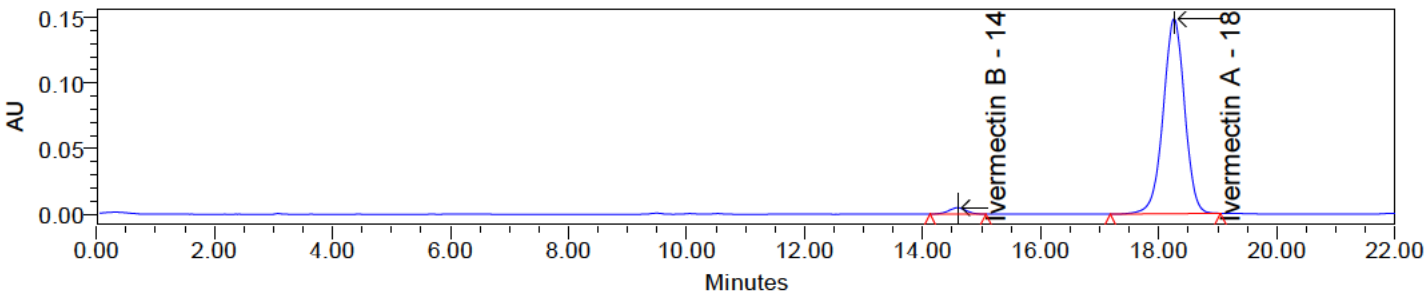
SampleName: Ivermectin STD 1 0.25 mg/mL; Sample Type: Standard; Date Acquired: 27/06/2022 12:35:25 PM AEST; Vial: 1:A,2; Injection Id: 1956; Result Id 2039; Inj Vol: 10; Wavelength: DAD.0.(

Auto-Scaled Chromatogram



SampleName: Ivermectin STD 2 0.25 mg/mL; Sample Type: Control; Date Acquired: 27/06/2022 1:22:18 PM AEST; Vial: 1:A,3; Injection Id: 1963; Result Id 2044; Inj Vol: 10; Wavelength: DAD.0.0

Auto-Scaled Chromatogram



SampleName: Ivermectin STD 3 0.25 mg/mL ; Sample Type: Control; Date Acquired: 27/06/2022 2:09:08 PM AEST; Vial: 1:A,4; Injection Id: 1970; Result Id 2046; Inj Vol: 10; Wavelength: DAD.0.0

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220624_IvermectinSTDCheck_[redacted]_3

LIMS Number:
Sample Set Id: 1868
Sample Set Start Date: 27/06/2022 11:47:14 AM AEST

Analyst [redacted]

Print Date: 29/06/2022

Run and Method Summary Report

Column Description: LC0278 - Phenomenex, Luna C18(2), 5µm, 4.6 × 250mm.

	Injection Id	Date Acquired	SampleName	Vial	Injection Volume (ul)	Sample Weight	Dilution
1	1870	27/06/2022 11:48:29 AM AEST	Blank MeOH	1:A,1	10.00	1.00000	1.00000
2	1870	27/06/2022 11:48:29 AM AEST	Blank MeOH	1:A,1	10.00	1.00000	1.00000
3	1940	27/06/2022 12:11:51 PM AEST	Blank MeOH	1:A,1	10.00	1.00000	1.00000
4	1940	27/06/2022 12:11:51 PM AEST	Blank MeOH	1:A,1	10.00	1.00000	1.00000
5	1956	27/06/2022 12:35:25 PM AEST	Ivermectin STD 1 0.25 mg/mL	1:A,2	10.00	1.00000	25.00000
6	1956	27/06/2022 12:35:25 PM AEST	Ivermectin STD 1 0.25 mg/mL	1:A,2	10.00	1.00000	25.00000
7	1959	27/06/2022 12:58:47 PM AEST	Ivermectin STD 1 0.25 mg/mL	1:A,2	10.00	1.00000	25.00000
8	1959	27/06/2022 12:58:47 PM AEST	Ivermectin STD 1 0.25 mg/mL	1:A,2	10.00	1.00000	25.00000
9	1963	27/06/2022 1:22:18 PM AEST	Ivermectin STD 2 0.25 mg/mL	1:A,3	10.00	1.00000	25.00000
10	1963	27/06/2022 1:22:18 PM AEST	Ivermectin STD 2 0.25 mg/mL	1:A,3	10.00	1.00000	25.00000
11	1966	27/06/2022 1:45:39 PM AEST	Ivermectin STD 2 0.25 mg/mL	1:A,3	10.00	1.00000	25.00000
12	1966	27/06/2022 1:45:39 PM AEST	Ivermectin STD 2 0.25 mg/mL	1:A,3	10.00	1.00000	25.00000
13	1970	27/06/2022 2:09:08 PM AEST	Ivermectin STD 3 0.25 mg/mL	1:A,4	10.00	1.00000	25.00000
14	1970	27/06/2022 2:09:08 PM AEST	Ivermectin STD 3 0.25 mg/mL	1:A,4	10.00	1.00000	25.00000
15	1973	27/06/2022 2:32:28 PM AEST	Ivermectin STD 3 0.25 mg/mL	1:A,4	10.00	1.00000	25.00000
16	1973	27/06/2022 2:32:28 PM AEST	Ivermectin STD 3 0.25 mg/mL	1:A,4	10.00	1.00000	25.00000
17	1977	27/06/2022 2:56:03 PM AEST	Blank MeOH	1:A,1	10.00	1.00000	1.00000
18	1977	27/06/2022 2:56:03 PM AEST	Blank MeOH	1:A,1	10.00	1.00000	1.00000

	AverageUnitWeight	Label
1	1.00000	B101
2	1.00000	B101
3	1.00000	B101
4	1.00000	B101
5	1.00000	S101
6	1.00000	S101
7	1.00000	S101
8	1.00000	S101
9	1.00000	C101
10	1.00000	C101
11	1.00000	C101
12	1.00000	C101
13	1.00000	C201
14	1.00000	C201
15	1.00000	C201
16	1.00000	C201
17	1.00000	B102

	AverageUnitWeight	Label
18	1.00000	B102

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220624_IvermectinSTDCheck_s22_3

LIMS Number:
Sample Set Id: 1868
Sample Set Start Date: 27/06/2022 11:47:14 AM AEST
Print Date: 29/06/2022

Analyst s22

Run and Method Summary Report

Instrument Method: Ivermectin Assay_s22

Stored: 22/06/2022 11:49:04 AM AEST

Method Information

Method Comments	
Method Modified User	s22
Method Locked	No
Method Id	1099
Old Id	
Method Version	4
Method Edit User	
Source S/W Info	Empower 3 Software Build 3471 SPs Installed: Service Release 5 DB ID: 3107713112

AgilentLC Instrument Setup

Quat. Pump G7104C

Flow	1.200 (mL/min)	Max. Flow Ramp Down	100.000 (mL/min²)
Use Solvent Types	Yes		
Low Pressure Limit	0.00 (psi)		
High Pressure Limit	11603.02 (psi)		
Max. Flow Ramp Up	100.000 (mL/min²)		
Primary Channel	Automatic		

Solvent Composition

	Channel	Ch. 1 Solv.	Name 1	Used	Percent (%)
1	A	100.0 % Organic in Aqueous V.03	ACN:MeOH:H2O	Yes	100.00
2	B			No	
3	C			No	
4	D			No	

Quat. Pump - Pump0 - Stroke

Automatic Stroke Calculation Yes

Quat. Pump - Pump0 - Emulation Mode

Emulation Enabled No

Quat. Pump - Pump0 - Mixer Selection

Selected Mixer Do not use Mixer

Quat. Pump - Pump0 - Blend Assist

Enabled No

Quat. Pump - Pump0 - Stop Time

Stoptime Mode No limit

Quat. Pump - Pump0 - Post Time

Posttime Mode Off

Sampler G7129C

Sampler - Sampler0 - Auxiliary

Draw Speed	200 (µL/min)
Eject Speed	400 (µL/min)
Wait Time After Draw	1.2 (s)
Needle Height Offset	0.0 (mm)

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220624_IvermectinSTDCheck_s22_3

LIMS Number:
Sample Set Id: 1868
Sample Set Start Date: 27/06/2022 11:47:14 AM AEST

Analyst s22

Print Date: 29/06/2022

Run and Method Summary Report

Sampler - Sampler0 - Injection

Injection Mode	Injection with needle wash
Injection Volume	10.00 (µL)

Sampler - Injection - Needle Wash

Needle Wash Location	Flush Port
Wash Time	3 (s)

Sampler - Sampler0 - High throughput

Sample Flush-Out Factor	5.0
Injection Valve to Bypass for Delay Volume Reduction	No

Sampler - High throughput - Overlapped Injection

Overlapped Injection Mode	Off

Sampler - Sampler0 - Stop Time

Stoptime Mode	As pump/No limit

Sampler - Sampler0 - Post Time

Posttime Mode	Off

Column Comp. G7116A

Valve Position	Position 1 (Port 1 -> 1')
Position Switch After Run	Do not switch

Column Comp. - Column Comp.0 - Left Temperature Control

Temperature Control Mode	Temperature Set
Temperature	30.0 (°C)

Column Comp. - Left Temperature Control - Enable Analysis Left Temperature

Enable Analysis Left Temperature On	Yes
Enable Analysis Left Temperature Value	0.8 (°C)
Left Temp. Equilibration Time	0.0 (min)

Column Comp. - Column Comp.0 - Right Temperature Control

Right temperature Control Mode	Temperature Set
Right temperature	30.0 (°C)

Column Comp. - Right Temperature Control - Enable Analysis Right Temperature

Enable Analysis Right Temperature On	Yes
Enable Analysis Right Temperature Value	0.8 (°C)
Right Temp. Equilibration Time	0.0 (min)

Column Comp. - Column Comp.0 - Enforce column for run

Enforce column for run enabled	No

Column Comp. - Column Comp.0 - Stop Time

Stoptime Mode	As pump/injector

Column Comp. - Column Comp.0 - Post Time

Posttime Mode	Off

Column Comp. - Column Comp.0 - Timetable

DAD G7117C

Peakwidth	> 0.1 min (2 s response time) (2.5 Hz)
UV Lamp Required	Yes

DAD - DAD0 - Analog Output

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220624_IvermectinSTDCheck_s22_3

LIMS Number:
Sample Set Id: 1868
Sample Set Start Date: 27/06/2022 11:47:14 AM AEST

Analyst s22

Print Date: 29/06/2022

Run and Method Summary Report

Analog Zero Offset 5 (%)
Analog Attenuation 1000 (mAU)

DAD - DAD0 - Signals

Signal table-DAD0

	Acquire	Signal	Wavelength (nm)	Bandwidth (nm)	Use Ref.	Ref Wavel. (nm)	Ref Bandw. (nm)
1	Yes	Signal A	245	4	Yes	360	100
2	No	Signal B					
3	No	Signal C					
4	No	Signal D					
5	No	Signal E					
6	No	Signal F					
7	No	Signal G					
8	No	Signal H					

DAD - DAD0 - Prepare Mode

Margin for negative Absorbance 100 (mAU)

DAD - DAD0 - Autobalance

Autobalance Prerun Yes
Autobalance Postrun No

DAD - DAD0 - Spectrum

Spectrum Range WL from 190 (nm)
Spectrum Range WL to 400 (nm)
Spectrum Step 2.0 (nm)
Spectrum Store All

DAD - DAD0 - Stoptime

Stoptime Mode As pump/injector

DAD - DAD0 - Posttime

Posttime Mode Off

DAD - DAD0 - Timetable

Injector Preference Value :

Injector Selected ALS

Sampler G7129C

Auxiliary Channels

Auxiliary Channels - - PUMP.0.0.Pressure

PUMP.0.0.Pressure disabled

Auxiliary Channels - - PUMP.0.1.Flow

PUMP.0.1.Flow disabled

Auxiliary Channels - - PUMP.0.2.SolventRatioA

PUMP.0.2.SolventRatioA disabled

Auxiliary Channels - - PUMP.0.3.SolventRatioB

PUMP.0.3.SolventRatioB disabled

Auxiliary Channels - - PUMP.0.4.SolventRatioC

Project Name: Chemistry\System25_2022_05
Sample Set Name: 220624_IvermectinSTDCheck_s22_3

LIMS Number:
Sample Set Id: 1868
Sample Set Start Date: 27/06/2022 11:47:14 AM AEST
Print Date: 29/06/2022

Analyst s22

Run and Method Summary Report

PUMP.0.4.SolventRatioC disabled

Auxiliary Channels - - PUMP.0.5.SolventRatioD

PUMP.0.5.SolventRatioD disabled

Auxiliary Channels - - PUMP.0.6.Tuning

PUMP.0.6.Tuning disabled

Auxiliary Channels - - SAMPLER.0.0.Temperature

SAMPLER.0.0.Temperature disabled

Auxiliary Channels - - COLCOMP.0.0.LeftTemperature

COLCOMP.0.0.LeftTemperature disabled

Auxiliary Channels - - COLCOMP.0.1.RightTemperature

COLCOMP.0.1.RightTemperature disabled

Auxiliary Channels - - DAD.0.0.BoardTemperature

DAD.0.0.BoardTemperature disabled

Auxiliary Channels - - DAD.0.1.OpticalUnitTemperature

DAD.0.1.OpticalUnitTemperature disabled

Auxiliary Channels - - DAD.0.2.UVLampAnodeVoltage

DAD.0.2.UVLampAnodeVoltage disabled

General Settings

General Settings - - Fraction Start Location Specified

Fraction Start Location Specified False

General Settings - - Start Location

Start Location 1

General Settings - - Shutdown after Run

Shutdown after Run False

Revision History

This method contains 6 items in the revision history.

From: s22 [redacted]
To:
Subject: RC-018899, Ivervid-12 [SEC=OFFICIAL]
Date: Tuesday, 23 August 2022 10:57:00 AM
Attachments: image001.png
Project 2647 - 2206002093 - Photos.PPTX
Project 2647 - 2206002093 -Web Alert Photo.JPG
Project 2647 - RC-018899 - Ivervid-12 - 2206002093 - Laboratory Report.DOCX
Project 2647 - RC-018899 - 2206002093 - Certificate of Responsible Analyst.PDF

Good morning s22 [redacted]

Please find attached the laboratory report, Certificate of Responsible Analyst and photos relating to RC reference number RC-006302.

If you have any questions around our findings, please get in touch with me.

Regards,

s22 [redacted]
Senior Chemist - Chemistry Section
Laboratories Branch

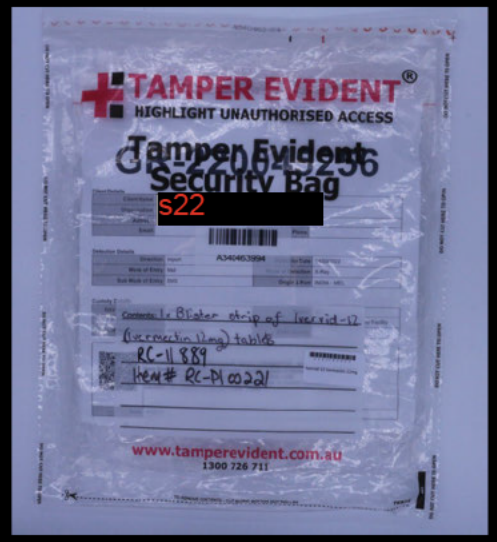
Medical Devices & Product Quality Division | Health Products Regulation Group
Australian Government Department of Health and Aged Care
s22 [redacted]
Location: Level 1, 1 Tindal Lane, Fairbairn, ACT
PO Box 100, Woden ACT 2606, Australia

Photo Album

Project 2647 - 2206002093

Project 2642, 2641, 2647 Outer Packaging Front

Project 2642, 2641, 2647 Outer Packaging Back



Project 2647 - 2206002093 - Sealed Tamper Evident Security Bag Front

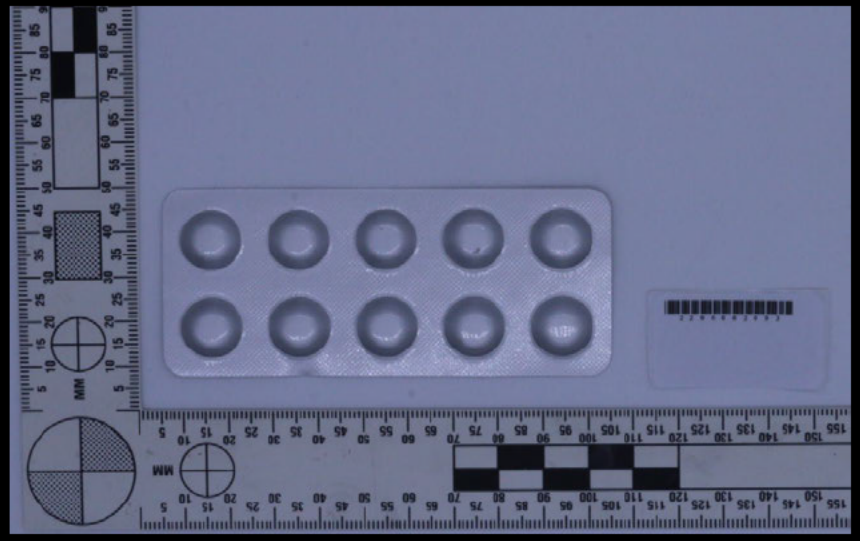
Project 2647 - 2206002093 - Sealed Tamper Evident Security Bag Back

Project 2647 - 2206002093 - ABF
Packaging Front

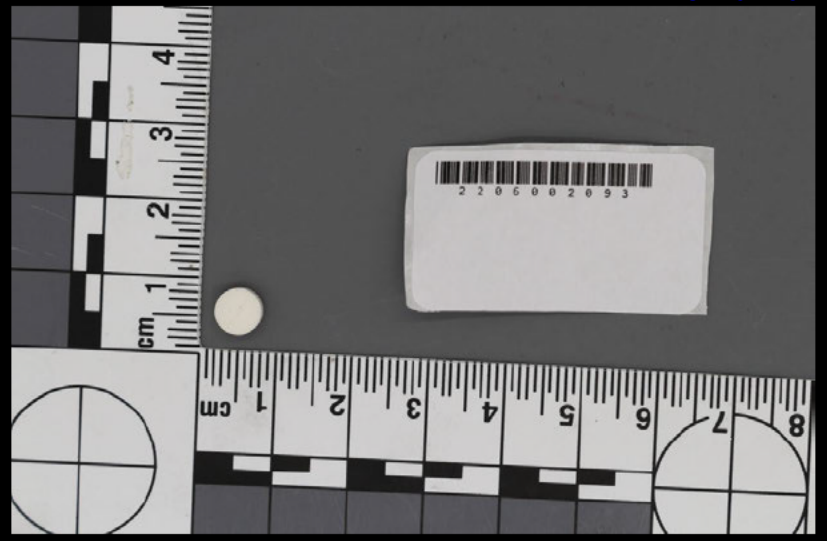
Project 2647 - 2206002093 - ABF
Packaging Back

Project 2647 - 2206002093 - Inner
Packaging Front

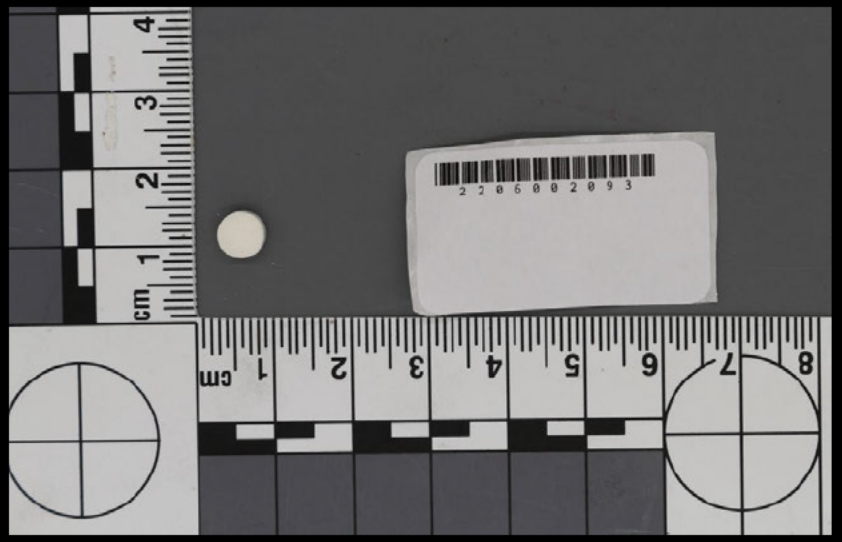
Project 2647 - 2206002093 -Blister Pack Front



Project 2647 - 2206002093 -Blister Pack Back



Project 2647 -2206002093 - Single Tablet Front



Project 2647 - 2206002093 - Single Tablet Back

Ivermectin Tablets USP 12 mg

IVERVID 12

इवेरविड-१२

Each uncoated tablet contains:
Ivermectin IP.....12 mg
Excipients.....q.s.
Dosage: As directed by the Physician.
Storage: Store at a temperature not exceeding 30°C, protect from moisture.
Keep out of reach of children.

Not to be used in children who weigh below 15kg, or during pregnancy or breast feeding and also in the elderly.

Manufactured by:
Fortune Health Care®
7 Satyanarayan Industrial Estate,
S/V. Ganwa Water Tank,
Vadodara - 390016
At: G/5 & G/6 Industrial Estate,
Ganwa, Vadodara - 390016

B.NO.TI-620004
MFD.01/2022
EXP.12/2024
MRP.RS.385.00
PER 10 TABS I.A.T.

Mfg.Lic.No. : G/25A/3167-A

[redacted]