Export Only Application General

Product Name:	DR. NATURE IMMUNITY & LUNG TABLET
Client Name:	GMP Pharmaceuticals Pty Limited
Sponsor Name:	GMP Pharmaceuticals Pty Limited
Contact Details:	s22 [redacted]@gmp.com.au s22 [redacted]

This application is to:	create a new listing
Submission Cost:	$983
Application Status:	Under Review
Application Type:	New
Validation Report:	1/04/2025 1:14:51 PM

Failure Messages

Information Messages

Australian Laboratory Services Pty Ltd - MI-2012-LI-05733-3 - has conditions -No further conditions are applicable.

Chem-Chrom Laboratories and Services - MI-2015-LI-13129-1 - has conditions -No further conditions are applicable

Chemika Pty Limited - MI-2012-LI-00095-3 - has conditions -No further conditions are applicable.

Eurofins ams Laboratories Pty Ltd - MI-2021-LI-08995-1 - has conditions -The authorisation for chemical testing is restricted to the testing of Ethylene oxide residues by gas-liquid chromatography. The authorisation for physical testing is restricted to the testing of sub-visible particles. This licence also authorises the potency testing of antibiotics using bioassay, and disinfectant testing.

GMP Pharmaceuticals Pty Limited - MI-21042005-LI-000516-1 - has conditions -This licence does not authorise the manufacture of preparations containing any drug to which any Schedule of the Poisons Standard applies. This licence does not authorise the manufacture of medicinal products in the dosage form 'spray, pressurised'. Chemical testing is restricted to the testing of water from the water system only.

GMP Pharmaceuticals Pty Limited - MI-2019-LI-01002-1 - has conditions -This licence does not authorise the manufacture of medicines listed for export that include substances at a level only permitted in medicines contained within schedules 2, 3, 4 & 8 of the Poisons Standard.

GMP Pharmaceuticals Pty Limited - MI-2016-LI-12063-1 - has conditions -This licence does not authorise the manufacture of preparations containing any drug to which any Schedule of the Poisons Standard applies. The licence excludes the manufacture of the dosage form ‘spray pressurised’ contained within the liquids group. Chemical testing is restricted to the testing of water from the water system only.

Intertek Testing Services Australia Pty Ltd - MI-25112004-LI-000218-1 - has conditions -No further conditions are applicable.

Scientest Analytical Services Pty Ltd - MI-2014-LI-08343-1 - has conditions -No further conditions are applicable.

Southern Cross Analytical Research Laboratory - MI-01122004-LI-000264-1 - has conditions -This licence authorises the physical and chemical testing of medicinal products at level 3, T-Block and metals analysis of medicinal products at N-Block.

COMPONENT DETAILS

Dosage Form:	Tablet - film coated
Route of Administration:	Oral

Container Type: unable to find the description of BULK
Visual Identification of Dosage Form: A grey coloured;oval shaped coated tablet
Sterile Component: N

FORMULATION DETAILS

ACTIVE INGREDIENTS:

STANDARD

Ingredient: Astragalus membranaceus 66.667 mg
Plant Part: root
Ratio: (22.5:1)
Equivalent Preparation: Dry 1.5 g
Animal Origin?: No
Preparation Steps:
Plant Preparation: Extract dry concentrate (22.5:1)
Plant Preparation Step: 1
Solvents: ethanol 20%
Water - purified 80%

Ingredient: Platycodon grandiflorus 150 mg
Plant Part: root
Ratio: (10:1)
Equivalent Preparation: Dry 1.5 g
Animal Origin?: No
Preparation Steps:
Plant Preparation: Extract dry concentrate (10:1)
Plant Preparation Step: 1
Solvents: ethanol 30%
Water - purified 70%

Ingredient: Echinacea purpurea 90 mg
Plant Part: herb
Ratio: (15:1)
Equivalent Preparation: Dry 1.35 g
Animal Origin?: No
Preparation Steps:

Plant Preparation: Extract dry concentrate (15:1)

Plant Preparation Step: 1

Solvents: ethanol 70%

Water - purified 30%

Ingredient: ascorbic acid 50 mg

Animal Origin?: No

Ingredient: zinc oxide 8.713 mg

Animal Origin?: No

Equivalents: zinc 7 mg

EXCIPIENT INGREDIENTS:

STANDARD

Ingredient: maltodextrin (Default unit as QS)

Animal Origin?: No

Ingredient: tartaric acid (Default unit as QS)

Animal Origin?: No

Ingredient: povidone 24 mg

Animal Origin?: No

Ingredient: crospovidone 24 mg

Animal Origin?: No

Ingredient: croscarmellose sodium 24 mg

Animal Origin?: No

Ingredient: microcrystalline cellulose 160 mg

Animal Origin?: No

Ingredient: calcium hydrogen phosphate dihydrate 173.162 mg

Animal Origin?: No

Ingredient: colloidal anhydrous silica 8 mg

Animal Origin?: No

Ingredient: magnesium stearate 4 mg

Animal Origin?: No

Ingredient: Carnauba Wax .2 mg

Animal Origin?: No

PROPRIETARY INGREDIENTS

Ingredient: OPADRY II Complete Film Coating System 85F675018-CN GREY 23.8 mg (PI number:139696)

Animal Origin?: No

MANUFACTURER DETAILS

Name: Australian Laboratory Services Pty Ltd
Manufacturer ID: 48761
Licence ID: MI-2012-LI-05733-3
Location: Unit 10 2-8 South Street RYDALMERE NSW 2116
Manufacturing Steps: Testing chemical and physical
Testing microbial

Name: Chem-Chrom Laboratories and Services
Manufacturer ID: 62982
Licence ID: MI-2015-LI-13129-1
Location: Unit 15 / 10-12 Montore Road Minto NSW 2566
Manufacturing Steps: Testing chemical and physical
Testing microbial

Name: Chemika Pty Limited
Manufacturer ID: 27664
Licence ID: MI-2012-LI-00095-3
Location: 119 Magowar Road GIRRAWEEN NSW 2145
Manufacturing Steps: Testing chemical and physical

Name: Eurofins ams Laboratories Pty Ltd
Manufacturer ID: 26145
Licence ID: MI-2021-LI-08995-1
Location: 179 Magowar Road GIRRAWEEN NSW 2145
Manufacturing Steps: Testing microbial

Name: GMP Pharmaceuticals Pty Limited
Manufacturer ID: 29989
Licence ID: MI-21042005-LI-000516-1
Location: 7-9 Amax Avenue GIRRAWEEN NSW 2145
Manufacturing Steps: Manufacture of dosage form
Packaging and labelling
Secondary packaging
Testing chemical and physical
Release for supply

Name: GMP Pharmaceuticals Pty Limited
Manufacturer ID: 29989
Licence ID: MI-2019-LI-01002-1
Location: 60 Huntingwood Drive HUNTINGWOOD NSW 2148
Manufacturing Steps: Manufacture of dosage form
Packaging and labelling

	Release for supply
	Secondary packaging
	Testing chemical and physical
	Testing microbial

Name:	GMP Pharmaceuticals Pty Limited
Manufacturer ID:	29989
Licence ID:	MI-2016-LI-12063-1
Location:	14 Amax Avenue Girraween NSW 2145
Manufacturing Steps:	Packaging and labelling
	Release for supply
	Secondary packaging

Name:	Intertek Testing Services Australia Pty Ltd
Manufacturer ID:	31163
Licence ID:	MI-25112004-LI-000218-1
Location:	Building 1 / 19-23 Paramount Road WEST FOOTSCRAY VIC 3012
Manufacturing Steps:	Testing chemical and physical

Name:	Scientest Analytical Services Pty Ltd
Manufacturer ID:	48126
Licence ID:	MI-2014-LI-08343-1
Location:	6/22 Mavis Court ORMEAU QLD 4208
Manufacturing Steps:	Testing chemical and physical

Name:	Southern Cross Analytical Research Laboratory
Manufacturer ID:	26183
Licence ID:	MI-01122004-LI-000264-1
Location:	Level 3 T Block and N Block Military Road Southern Cross University LISMORE NSW 2480
Manufacturing Steps:	Testing chemical and physical

PRODUCT DETAILS

Will the product comply with specific and general standards applicable to product under Chapter 3, Part3/1 Standards of the Therapeutic Goods Act 1989 during the entire shelf life of the product?

N/A

Has this product been cancelled, recalled or rejected for registration or listing on the Register for supply in Australia?

No

Has this product been granted marketing approval for supply in the importing country?

No

Have you launched an application for grant of marketing approval in the importing country?

No

To be exported as fully finished product?

Bulk Product

Basis for shelf file claim:

Stability studies

Proposed Therapeutic Indications:

Antioxidant/Reduce free radicals formed in the body Traditionally used in Chinese medicine to disseminate/diffuse lungs/lung-qi Maintain/support immune system health Traditionally used in Western herbal medicine to decrease/reduce/relieve common cold duration Traditionally used in Chinese medicine to clear/expel/dissolve/resolve Phlegm Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold Traditionally used in Chinese medicine to maintain/support lung health

ELECTRONIC SUPPORTING ATTACHMENT LIST

Attachments:	Label - Shipper Label - Dr. Nature Immunity and Lung bulk tablet.pdf
	Patent Certificate - Patent Certificate.pdf
	Product Specification - signed AUBG001446 spec.pdf

GMP PHARMACEUTICALS

Global Headquarters
60 Huntingwood Drive, Huntingwood NSW 2148
Tel +61 2 9631 9999

Compiled by:	s22 [redacted]	BULK PRODUCT SPECIFICATION FORMULATION	CODE: AUBG001446
Checked by:			Reference: BGSPEC001446
Authorised by:			Version: 001
Date of Issue:	29/09/20		Change Control: CP3744
Review Date:	September 2025		Page: 1 of 4

DR. NATURE IMMUNITY & LUNG TABLET (PHARM)

PRODUCT SPECIFICATION		
Analysis	**Specification**	**Std. Reference**
Physical Characteristics		
Core Tablet		
Appearance	A brown mottled beige coloured, oval shaped tablet	GMP
Identification	Positive by sensible characteristics	GMP
Dosage form	Tablet, Core	GMP
Average Tablet Weight (Core)	800.0 mg ± 5% w/w (760.0 to 840.0 mg)	TGO 101
Uniformity of Tablet Weight	± 5% w/w	TGO 101
Disintegration Time	15 minutes maximum @ 37 °C (water)	GMP
Tablet Length	19.40 mm ± 0.3 mm (19.10 to 19.70 mm)	GMP
Tablet Width	9.61 mm ± 0.3 mm (9.31 to 9.91 mm)	GMP
Tablet Thickness	5.16 mm ± 0.3 mm (4.86 to 5.46 mm)	GMP
Tablet Friability (Core)	<0.3% Maximum per 10 tablets (in process)	GMP
Tablet Hardness	20.0 kg ± 5.0 kg (15.0 kg to 25.0 kg)	GMP
Coated Tablet		
Appearance	A grey coloured, oval shaped coated tablet	GMP
Identification	Positive by sensible characteristics	GMP
Dosage form	Tablet, Coated	GMP
Average Tablet Weight (Coated)	824.0 mg ± 5% w/w (782.8 to 865.2 mg)	TGO 101
Uniformity of Tablet Weight	± 5% w/w	TGO 101
Disintegration Time	30 minutes maximum @ 37 °C (water)	TGO 101
Tablet Length	19.50 mm ± 0.3 mm (19.20 to 19.80 mm)	GMP
Tablet Width	9.70 mm ± 0.3 mm (9.40 to 10.00 mm)	GMP
Tablet Thickness	5.27 mm ± 0.3 mm (4.97 to 5.57 mm)	GMP
Tablet Hardness	25.0 kg ± 10.0 kg (15.0 kg to 35.0 kg)	GMP
Chemical Characteristics		
Assay	**Release Specifications**	**Expiry Specifications**
Equiv. Astragalus Membranaceus Root (Dry)	1500 mg (95% to 120% of the stated amount) Quantified by input	1500 mg (90% to 120% of the stated amount) Quantified by input

SPONSOR CERTIFICATION

The Sponsor of this product certifies that the above information is a true & accurate copy of the product that they have specified.

s22 [redacted]	s22 [redacted] 30/9/2020
Name (printed)	Signature & Date

GMP PHARMACEUTICALS
Global Headquarters
60 Huntingwood Drive, Huntingwood NSW 2148
Tel +61 2 9631 9999

Compiled by:	s22 [redacted]	**BULK PRODUCT SPECIFICATION FORMULATION**	CODE	AUBG001446
Checked by:			Reference	BGSPEC001446
Authorised by:			Version:	001
Date of Issue:	29/09/20		Change Control:	CP3744
Review Date:	September 2025		Page	2 of 4

DR. NATURE IMMUNITY & LUNG TABLET (PHARM)

Equiv. Platycodon Grandiflorus Root (Dry)	1500 mg (95% to 120% of the stated amount) Quantified by input	1500 mg (90% to 120% of the stated amount) Quantified by input
Equiv. Echinacea Purpurea Herb (Dry)	1350 mg (95% to 120% of the stated amount) Quantified by input	1350 mg (90% to 120% of the stated amount) Quantified by input
Equiv. Ascorbic Acid	50 mg (95% to 150% of the stated amount) Quantified by Chromatography	50 mg (90% to 150% of the stated amount) Quantified by Chromatography
Equiv. Zinc	7 mg (95% to 125% mg). Quantified by AA / ICP	7 mg (90% to 125% mg). Quantified by AA / ICP
Elemental Impurities		
Lead (Pb)	0.5 ppm maximum	TGO 101
Cadmium (Cd)	0.5 ppm maximum	TGO 101
Arsenic (As)	1.5 ppm maximum	TGO 101
Total Mercury (Hg)	1.5 ppm maximum	TGO 101
Methylmercury (as Hg)*	0.2 ppm maximum	TGO 101
Residual Solvents	Any individual solvent complies with the specification as per Ph. Eur 5.4	TGO 101
*If level of total Mercury is less than 0.2ppm, then Methylmercury is compliant to specification.		
Microbiological Characteristics		
Total aerobic microbial	10^4 cfu/g maximum.	TGO 101
Total Yeasts &Mould	10^2 cfu/g maximum.	TGO 101
Bile-tolerant gram neg	10^2 cfu/g maximum.	TGO 101
Salmonella	Not detected/10 grams.	TGO 101
Escherichia coli	Not detected/gram.	TGO 101
Staphylococcus aureus	Not detected/ gram.	TGO 101
Bulk Packaging	Polyethylene lined corrugated cardboard	
Expiry Period	As determined by Sponsor's stability	
Storage Condition	Store below 25°C	

SPONSOR CERTIFICATION

The Sponsor of this product certifies that the above information is a true & accurate copy of the product that they have specified.

s22 [redacted]	s22 [redacted] 30/9/2020
Name (printed)	Signature & Date

GMP PHARMACEUTICALS

Global Headquarters
60 Huntingwood Drive, Huntingwood NSW 2148
Tel +61 2 9631 9999

Compiled by:	s22 [redacted]	**BULK PRODUCT SPECIFICATION FORMULATION**	**CODE** AUBG001446
Checked by:			Reference: BGSPEC001446
Authorised by:			Version: 001
Date of Issue:	29/09/20		Change Control: CP3744
Review Date:	September 2025		Page: 3 of 4

DR. NATURE IMMUNITY & LUNG TABLET (PHARM)

PRODUCT FORMULATION					
Code	**Ingredients**	**Standard**	**Amount (Nominal)**	**Overage**	**Amount (Actual)**
	Active Ingredients	Reference	mg/tab	%	mg/tab
AURM002180	Astragalus membranaceus Root Ext (20E:80W) 20-25:1 Granular (1-10% Malto) (Pharm)	GMP	66.667	-	66.667
	equiv. Astragalus membranaceus root dry (1500 mg)				
	extraction solvent. 20% ethanol: 80% water				
	excipient. Maltodextrin				
AURM002148	Platycodon Grandiflorus Root Ext (30E:70W) 10:1 (1-10%Malto) (Pharm)	GMP	150.000	-	150.000
	equiv. Platycodon grandiflorus root dry (1500 mg)				
	extraction solvent. 30% ethanol: 70% water				
	excipient. Maltodextrin				
AURM002169	Echinacea Purpurea Herb Ext (70E:30W) 15:1 Powder (Pharm)	GMP	90.000	-	90.000
	equiv. Echinacea purpurea herb dry (1350 mg)				
	extraction solvent. 70% ethanol: 30% water				
AURM002182	Ascorbic Acid 97% DC Granule (HPMC, Tartaric Acid) (Pharm)	GMP	51.555	30	67.022[1]
	equiv. Ascorbic acid (50 mg)				
	excipient. Hypromellose				
	excipient. Tartaric acid				
AURM000431	Zinc Oxide (Pharm)	BP/USP	8.713	5	9.149[1]
	equiv. Zinc (7 mg)				
	Excipient Ingredients				
AURM000459	Povidone (Pharm)	BP/USP	24.000	-	24.000
AURM000416	Crospovidone (Pharm)	BP	24.000	-	24.000
AURM000199	Croscarmellose Sodium (Pharm)	BP	24.000	-	24.000
AURM000007	Microcrystalline Cellulose (Pharm)	BP	160.000	-	160.000
AURM000075	Calcium Hydrogen Phosphate Dihydrate DC(Pharm)	BP	173.162	-	173.162
AURM000013	Silica Colloidal Anhydrous (Pharm)	BP	8.000	-	8.000
AURM000008	Magnesium Stearate (Pharm)	BP	4.000	-	4.000
		Total Ingredient Weight:			**800.000**
	Other Materials				

SPONSOR CERTIFICATION

The Sponsor of this product certifies that the above information is a true & accurate copy of the product that they have specified.

s22 [redacted]	s22 [redacted] 30/9/2020
Name (printed)	Signature & Date

GMP PHARMACEUTICALS
Global Headquarters
60 Huntingwood Drive, Huntingwood NSW 2148
Tel +61 2 9631 9999

Compiled by:	s22 [redacted]	**BULK PRODUCT SPECIFICATION FORMULATION**	CODE	AUBG001446
Checked by:			Reference	BGSPEC001446
Authorised by:			Version:	001
Date of Issue:	29/09/20		Change Control:	CP3744
Review Date:	September 2025		Page	4 of 4

DR. NATURE IMMUNITY & LUNG TABLET (PHARM)

AURM002172	OPADRY II Complete Film Coating System 85F675018-CN GREY PI 139696 (Pharm)	GMP	23.800	-	23.800
AURM001980	Carnauba Wax (Pharm)	GMP	0.200	-	0.200
		Total Final Product Weight:			824.000

[1]Overage quantities not nominal weights are included in the manufacturing documents.

Statement:

1.The stability, efficacy & any claims related to this Formula are the sole responsibility of the Sponsor/Customer.
2.Supply of this Formula does not constitute or assure the approval or acceptance by the Regulatory Authorities.
3.Where analysis is performed by external laboratories, they will be TGA licensed.
4.This specification is the expiry specification except where the release limit is indicated in the specification.
5.GMP Pharmaceuticals reserves the right to amend our specification in the interest of continuous improvement. Customers should ensure that the current specification meets their needs.

SPONSOR CERTIFICATION

The Sponsor of this product certifies that the above information is a true & accurate copy of the product that they have specified.

s22 [redacted]	s22 [redacted] 30/9/2020
Name (printed)	Signature & Date

Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Notice that a certificate under subsection 26B(1) of the *Therapeutic Goods Act 1989* is not required

I, s22 [redacted] of GMP Pharmaceuticals

[Name and where applicable, relationship to applicant]

GMP Pharmaceuticals Pty Limited

[Applicant name]

60 Huntingwood Drive, Huntingwood, NSW, 2148

[Applicant address]

hereby notify the Secretary of the Department of Health that, in relation to the application under section 23B and 23C of the *Therapeutic Goods Act 1989* (the Act) for the registration under section 25AB (registered medicines), or listing under section 26 (export only medicines) or section 26AE (assessed listed medicines), of the following therapeutic goods (the goods):

Dr. Nature Immunity & Lung Tablets

[Product name*]

[Submission number]

a certificate under subsection 26B(1) of the Act is not required because either (1) or (2) below applies (strike out whichever of these is inapplicable):

(1) I, as the Applicant, am not required to submit evidence or information to establish the safety or efficacy of the goods as part of the process of applying for registration or listing.

OR

(2) I, as the Applicant, am required to submit evidence or information to establish the safety or efficacy of the goods as part of the process of applying for registration or listing but, in order to satisfy this requirement, I am not relying (in whole or in part) on evidence or information that another person submitted to the Secretary:

(a) to establish the safety or efficacy of other therapeutic goods that have already been registered or listed; and

(b) as part of the process of applying for the registration or listing of those other goods.

Signature s22 [redacted] Date 01/04/2025

* As it is to appear on the Registration or Listing Certificate – generally trade name, active ingredient name (if one only) and quantity, dosage form and container type, so as to distinguish the product from other products entered in the ARTG.

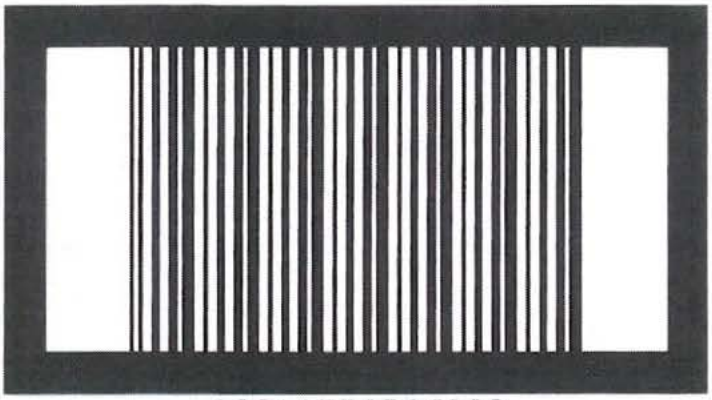
Document 4

Dr. Nature Immunity & Lung Bulk Tablet

Code: AUBG001446

Shipper No: 01

STORE BELOW 30C



19311770596203

Lot No: 1234567890

Expiry : MM/YYYY

G. Weight: 16.0 kg

80011854 V1 / 01XXXXXXXX GMP PHARMACEUTICALS PTY LIMITD, SYDNEY AUSTRALIA

CHECKED

14.03.14 s22 [redacted]

Lot No: XXXXXXXXXX

Expiry: MM/YYYY

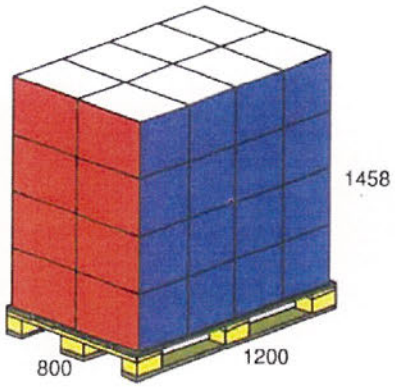
Quantity: 8 shippers per layer
4 layers high
8 x 4 = 32 shippers/boxes per pallet

CHECKED
18.03.14 s22

CHECKED
14.03.14

s22

60011854 V1 / 01XXXXXXXX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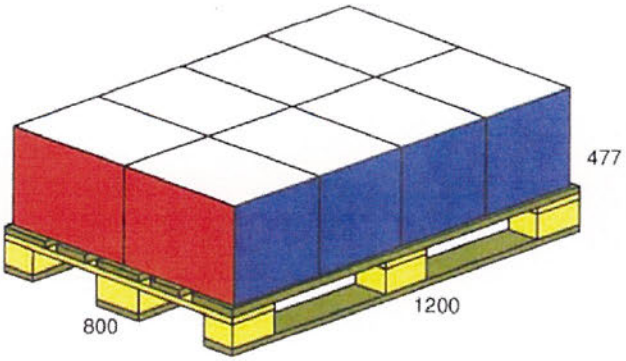
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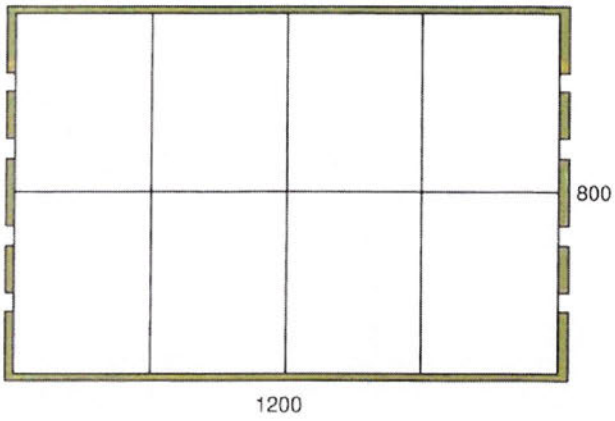
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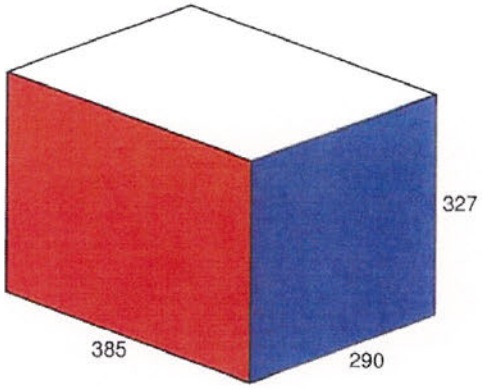
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