Ferngrove Pharmaceuticals Australia

Finished Product Specification

Product name	**5-MTHF Biologically Active Folate**		
Brand name	Vitopharm Biotech Pty.Ltd		
AUST L	445966	**Prepared by Technical Officer**	
Product code - Ferngrove	TB-LECA400	Name: Nicole Yang	NY 09/12/2024
Document No.	STP-02-4469-1		
Version No.	6	**Checked by Technical Manager**	
Issue date	09-Dec-24	Name: Yueting Lu	YL 9/12/2024
Review date	09-Dec-27		

1. General Specification

No.	Fields	Specification	Reference
1.1	Dosage form	Tablet, film coated	
1.2	Route of Administration	Oral	
1.3	Physical appearance	8 mm round white film coated tablet.	
1.4	Total weight (uncoated)	195 mg ± 7.5%	In house
1.5	Total weight (coated)	200 mg ± 7.5%	BP.
1.6	Uniformity of Mass	Complies to Current Therapeutic Goods Order	TGO101
1.7	Disintegration	Not more than 30 minutes.	BP.

2. Master Formulation

No.	Active Ingredient	RM Code	Label claim mg/tablet	Actual mg/tablet	Overage %	Release limit %	Test method
2.1	**Levomefolate calcium**	VT096	0.46	0.59	30	90 -150 *	USP.
	Equiv. Levomefolic acid		0.40	—			
	Ingredient weight			0.59			

* The first 3 batches of finished products will be assayed and then as part of a rotational testing program 1 batch in every 10th batch manufactured or annually, whichever comes first, will be tested thereafter.

No.	Excipient	RM Code	Quantity mg/tablet	Actual mg/tablet	Overage %	Release limit %	Test method
2.2	**Magnesium stearate**	EX004	q.s	q.s	–	–	–
2.3	**Microcrystalline cellulose**	EX019T	q.s	q.s	–	–	–
2.4	**Colloidal anhydrous silica**	EX005	q.s	q.s	–	–	–
2.5	**Croscarmellose sodium**	EX009	q.s	q.s	–	–	–
2.6	**Povidone**	EX031	q.s	q.s	–	–	–
	Excipients weight		194.41				

No.	Coating ingredient	RM Code	Quantity mg/tablet	Actual mg/tablet	Overage %	Release limit %	Test method
2.7	**Hypromellose**	CO001	q.s	–	–	–	–
2.8	**Macrogol 400**	EL012	q.s	–	–	–	–
2.9	**Carnauba wax**	CO005	q.s	–	–	–	
2.10	**Titanium dioxide**	DY006	q.s	–	–	–	–
	Excipients weight		5.00				

3. Fill Weight & Total Weight

No.	Item	Weight mg/tablet	Release limit (mg)	Reference standard
3.1	Active ingredients	0.59	–	–
3.2	Excipients	194.41	–	–
	Total weight (uncoated)	195.00	180 _ 210	In house
3.3	Coating ingredients	5.00	–	–
	Total weight (coated)	200.00	185 _ 215	BP.

4. Microbial Release Limits

No.	Item	Release limit	Reference standard
4.1	Total aerobic microbial count	NMT. 1 x 10^4cfu/g	TGO100
4.2	Total yeast and mould count	NMT. 1 x 10^2cfu/g	TGO100
4.3	Bile-tolerant Gram negative bacteria	NMT. 1 x 10^2cfu/g	TGO100
4.4	Salmonella	Not detected/10g	TGO100
4.5	Escherichia coli	Not detected/g	TGO100
4.6	Staphylococcus aureus	Not detected/g	TGO100

The first 3 batches of finished products will be microbiologically tested for compliance to TGO100 and then as part of a rotational testing program 1 batch in every 10th batch manufactured or annually, whichever comes first, will be tested thereafter.

5. Heavy Metals and Residual Solvent Release Limits for Finished Products

No.	Item	Release limit	Reference standard
5.1	Cadmium	NMT 5 ppm ^	TGO101
5.2	Lead	NMT 5 ppm ^	TGO101
5.3	Arsenic (Inorganic)	NMT 15 ppm ^	TGO101
5.4	Mercury	NMT 2 ppm ^	TGO101
5.5	Residual solvent	Not required #	TGO101

^ Heavy Metals Release Limits are calculated based on maximum daily dose of 1 tablet. Heavy metals concentration of finish product will be either quantified by input based on the heavy metal concentration in each raw material or tested as the below rotational testing program.
Rotational testing program: the first 3 batches of finished products will be tested and then as part of a rotational testing program 1 batch in every 10th batch manufactured or annually, whichever comes first, will be tested thereafter.

The starting materials of this formulation have been verified and assessed to be compliant to the requirement of Ph Eur 5.4 . Organic solvents are not involved on the manufacture of this product, therefore further test is not required.

6. Product Stability Information

No.	Item	Specification
6.1	Storage temperature	Store below 25°C
6.2	Storage condition	Store away from direct heat & sunlight

7. Revision History

No.	Amendment details	Section & Item	Revision date
7.1	New document	All	04-May-23
7.2	Version 2	Update Aust L No..	01-Jun-23
7.3	Version 3	Update tablet weight, total weight release limit and excipients` quantities.	24-Aug-23
7.4	Version 4	Update product name, Aust L No., section 2.1 &2.3: input quantities.	05-Apr-24
7.5	Version 5	Update product name and Aust L No.	24-Apr-24
7.6	Version 6	Update section 6.1: storage temperature	09-Dec-24

8. Sponsor/Customer Approval:

I hereby certify that the finished product specification complies with market authorisation, and stability data exists to support the shelf life based on scientific ground.

Product/Brand Name:	5-MTHF Biologically Active Folate
AUST L No:	445966
Sponsor/Customer Name:	Vitopharm Biotech Pty.Ltd
Expire date:	( ) years from the date of manufacture
Approved By:	
Position:	
Signature& date:	

"BP" = British Pharmacopoeia; "BHP" = British Herbal Pharmacopoeia; "USP" = United States Pharmacopoeia;
"EP" = European Pharmacopoeia; "BPC" = British Pharmacopoeia Codex; "Manuf." Manufacturer's specification;
"TGA" = Therapeutic Goods Administration; "MI" = Merck Index; "FCC" = Food Chemicals Codex; "CI" = Colour Index.
"QBI" = Quantified by Input, Refer to the Australian Department of Health and Ageing Therapeutic Goods Administration's document "Guidance on the Use of the term 'Quantified by Input' for Complementary Medicines".
Please note that all pharmacopeia referenced are current edition, unless otherwise stated.

Release limit test may be conducted by contract laboratories:

Ferngrove Pharma Aust Pty Ltd 5 Ferngrove Place, South Granville, NSW 2142 - Chemical & Physical testing (MI-19092007-LI-002109-11)
Naturalab Pty Ltd Level 2 / 111 Stephens Road, Botany, NSW 2019 - Chemical & Physical testing (MI-20062007-LI-001909-11)
Chem-Chrom laboratories and Services Unit 15/10-12 Montore Road, Minto, NSW 2566 -Chemical & Physical testing (MI-2015-LI-13129-1)
Australian Laboratory Services Pty Ltd Unit 10 2-8 South Street, Rydalmere, NSW 2116 - Chemical & Physical testing (MI-2012-LI-05733-3)
Silliker Australia Pty Ltd C2 / 391 Park Road, Regents Park, NSW 2143 - Microbial testing (MI-04072005-LI-00664-2)
Southern Cross Analytical Research Laboratory Level 3 T Block, Military Road, Lismore, NSW 2480 - Chemical Testing (MI-01122004-LI-000264-1)
Symbio Laboratories Pty Ltd 2 Sirius Road, Lane Cove West, NSW 2066 - Microbial testing (MI-2019-LI-13348-1)

Please note : It is the sponsors responsibility for checking contraventions of patents or patent pending.

End of documentation