

PRODUCT SPECIFICATION
5-MTHF Biologically Active Folate

AUST L: 445966
Specification no.: MTHF-spec
Version: 001
Issue date: March 28, 2024

A. PHYSICAL PARAMETERS		
Test	Specification	Reference
Manufacturer	Ferngrove Pharmaceuticals Australia Pty Ltd 5 Ferngrove Place SOUTH GRANVILLE NSW 2142	
Dosage form	Tablet, film coated	
Physical appearance	8 mm round white film coated tablet	
Total weight (uncoated)	195 mg \pm 7.5%	In house
Total weight (coated)	200 mg \pm 7.5%	BP
Uniformity of mass	Complies to Current Therapeutic Goods Order	TGO101
Disintegration	Not more than 30 minutes	
Shelf life	3 years from the date of manufacture	
Storage condition	Store below 25°C	
Packaging & Material	Box of 2 blisters x 15 tablets/blister Material: PVC blister with aluminium foil with carton box	

B. FORMULATION	
Each tablet contains:	
Ingredients: Levomefolate calcium 460 microgram Equivalent to levomefolic acid 400 microgram	
Excipients: carnauba wax, colloidal anhydrous silica, croscarmellose sodium, hypromellose, macrogol 400, magnesium stearate, microcrystalline cellulose, povidone, titanium dioxide.	

C. TESTING			
Active ingredient			
Actives	Unit	Limits	Method
Levomefolic acid	mcg/tablet	360 - 600	In house
Microbiological assay <i>(Micro testing will be conducted on a rotational basis after the first three batches. One in five batches or annually)</i>			
Test		Limits	Method
Total Aerobic Microbial Count		≤ 2 x 10 ³ CFU/g	In house
Total Yeast and Mould Count		≤ 2 x 10 ² CFU/g	In house
Bile-tolerant Gram negative bacteria		≤ 1 x 10 ² CFU/g	In house
Escherichia coli		Not detected/g	In house
Salmonella spp.		Not detected/10 g	In house
Staphylococcus aureus		Not detected/g	In house
Heavy metal <i>(Conducted annually)</i>			
Arsenic (As)		≤ 5.0 mg/kg	In house
Cadmium (Cd)		≤ 1.0 mg/kg	In house
Lead (Pb)		≤ 5.0 mg/kg	In house
Mercury (Hg)		≤ 0.5 mg/kg	In house
Arsenic (inorganic)* <i>*will be conducted if As total exceeds 1.5 ppm</i>		≤ 1.5 mg/kg	In house

BP: British Pharmacopoeia

Approved by

Name of representative: ALICE YANG
Title: CHIEF OPERATIONS OFFICER