National Vector Borne Disease Control Programme

Technical Specifications of Capsule Miltefosine 50 mg & 10 mg

Currently, Capsule Miltefosine monograph is not available in any Pharmacopoeia. Till the time, it is made available in any Pharmacopoeia, the following parameters should be applicable.

Test No	Test Particulars	Technical Specifications of Cap Miltefosine - 50 mg & 10 mg
1	**Identify**	
1.1	Miltefosine HPTLC (High Performance Thin Layer Chromatography)	Positive by HPTLC methods
2	**Properties**	
2.1	Filling of the individual capsule	Net content per capsule deviation not more than ± 5%
2.2	Average weight of filled capsule	+/- 5 % of average filing weight declared by the manufacturer
2.3	Disintegration time	not more than 30 minutes
3	**Assay (HPTLC)**	
3.1	Miltefosine content as per labelled claimed	95% – 105%
3.2	Content uniformity test	85%-115%
4	**Purity (HPTLC)**	
4.1	Unknown individual impurity	Limit not more than 0.5%
4.2	Sum of impurities	Limit not more than 2 %
4.3	Impurity 1-Hexadecanol	Limit not more than 0.2%

5	**Dissolution of the Active Ingredient** (Miltefosine after 30 minutes)	More than 75.00% of the declared content
6	**Microbial limit**	1. Total Aerobic Microbial Count (not more than 1000 CFU/gm 2. Total Yeast and Mould count (not more than 100 CFU/gm) 3. Test for following pathogens should be absent a) Escherichia coli b) Salmonella c) Staphylococcus aureus
7	Storage	Store in a cool dry place away from Sunlight.
8	Shelf life	Shelf life should be minimum 24 months from the date of manufacture.
9.	Packaging	• The drug is initially packed in a strip containing 07 capsules. • Individual capsules duly identified should be packed in an Alu / Alu blister strip. • 8 such blister strips would be further packed in Millboard/Grey board boxes and 10 such boxes will be finally packed in 5 Ply Shippers • Initial Packing: The aluminum strip should be of thickness of not less than 0.03mm. The packing material should have compatibility with the capsule. The supplier will submit a self-certificate with each consignment specifying thickness of Aluminum Foil. Blister / Aluminum strip pack of not more than 150 capsules should be packed in thick carboard box so that container should provide adequate protection to the drugs. • Final Packing: Final packing shall be done in corrugated fiber board boxes confirming to IS:2771 (part-1):1990 suitable cushioned /lined and strong enough to bear rail/road transport hazards. The supplier should furnish a self-certificate with each consignment to the effect that packing material is confirming to IS:2771(part-1):1990. • Each blister strip / Millboard/Grey board box / 5 Ply shipper should be marked "**NVBDCP, Dte.GHS SUPPLY – NOT FOR SALE**".

		• Marking: Printing / marking / labelling on blister / Millboard/ Greyboard box and 5 Ply shipper will be as per Drugs & Cosmetics 1940 Act and Rules made thereunder and as amended from time to time. All stores shall be securely packed in normal trade packing of corrugated boxes to avoid loss or damage during the transit by rail / road.

Approved as on 06/06/2022

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