

National Center for Vector Borne Diseases Control
Technical Specifications of Capsule Miltefosine 50 mg & 10 mg (Meeting date 06.05.2024)

14.06.2024

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	
	Miltefosine HPTLC	
1.1	(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 filling 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

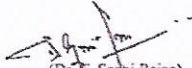

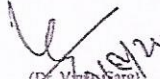

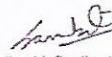




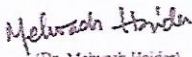
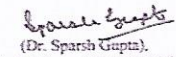
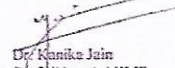

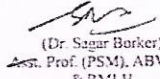
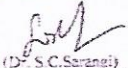
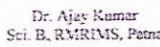

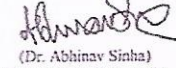
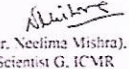

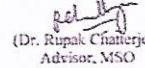
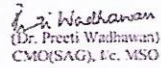
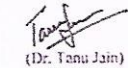

[Handwritten signatures and initials across the bottom of the page, including names like Ravindra, Anand, and others.]

National Center for Vector Borne Diseases Control

Technical Specifications of Capsule Miltfosine 50 mg & 10 mg (Meeting date 06.05.2024)

- 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

Above Technical Specification of Miltfosine Capsule 50 mg and 10 mg under NCVBDCP has been approved by Technical Specification Committee in the meeting held on 06.05.2024.

(Ms. Akansha Jain) AGM(QA), CMSS	 (Dr. T. Sonji Rajan) Asst. Director, CIB&RC	 (Dr. Shaliwar Kazmi) NPO-VL, WHO	 (Dr. Vinay Karg) Dir. Gen., ICDC	 (Dr. M.P.S. Chawla) Cons. Prof. & HoD(Med.) ABVIMS & RML H
 (Dr. Sambit Pradhan) Asst. Director, NCVBDC & Member Secretary	 (Dr. Rinku Sharma) Jt. Director, NCVBDC	 (Dr. Annam Visala) JDC(I), CDSO	 (Dr. Prashanta Saini) Scientist C, VCRC	 (Dr. Mala Chhabra) Cons. (Microb.) ABVIMS & RMLH
 (Dr. Mehvash Haider) Asst. Prof., VMMC-SJH	 (Dr. Sparsh Gupta) Prof. (Pharm.), VMMC-SJH	 (Dr. Kanika Jain) Asst. Prof. (Hosp.) AHIMS	 (Dr. Arvind Kumar) Addl. Prof. (Med.) AHIMS	 (Dr. Sagar Burker) Asst. Prof. (PSM), ABVIMS & RMLH
 (Dr. S.C. Sarangi) Addl. Prof. (Pharm.) AIIMS	 Dr. Ajay Kumar Sci. B, RMRIMS, Patna	 (Dr. Roshan K. Topno) Sci. E, RMRIMS, Patna	 (Dr. Abhinav Sinha) Scientist F, NIMR, Delhi	 (Dr. Neelima Mishra) Scientist G, ICMR
 (Sh. Rakesh Kumar) DDG(Stat.), Dte. GHS	 (Dr. Rupak Chatterjee) Advisor, MSO	 (Dr. Preeti Wadhawan) CMO(SAG), I.c. MSO	 (Dr. Tanu Jain) Director, NCVBDC	
		 Prof. (Dr.) Atul Goel Director General, Dte. GHS & Chairperson		