Directorate of National Vector Borne Disease Control Programme

Technical Specification of Capsule MILTE FOSINE 10 mg & 50 mg

Test No.	Test	Specification as per EU
1	**Identify**	
1.1	Miltefosine HPTLC	Positive by HPTLC methods
2	**Properties**	
2.1	Filling of the individual capsule	Contents of 20 capsules; 18 of the individual weights must not deviate by more than 10%, none deviate by more than 20% from the average weight.
2.2	Average filling weight	± 5 % of average filing weight declared by the manufacturer
2.3	Disintegration time	not more than 30 minutes
3	**Assay (HPTLC)**	
3.1	Miltefosine	95% – 105%
3.2	Content uniformity test	85%-115%
4	**Purity (HPTLC)**	
4 (i)	Unknown individual impurity	Limit not more than 0.5%
4 (ii)	Sum of impurities	Limit not more than 2 %
4 (iii)	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)The aerobic microbial total count (Not exceed 1000 CFU per gm) (2) Escherichia coli (Negative) (3) Yeasts and moulds; (Not exceed 100 CFU per gm)
7	Storage	Store at a temperature not exceeding 30°C
8	Shelf life	**Minimum 2 years**

Approved as on 10th Dec, 2015