



SUNRISE REMEDIES PVT LTD

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QUALITY CONTROL DEPARTMENT THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

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FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : MALEGRA FXT PLUS TABLET	A.R. No. : FPE220311
Packing : 10x10 TAB	Release Dt. : 02-02-2023
Generic Name : SILDENAFIL WITH FLUOXETINE TABLET	T.R. Slip No. : FGTEST0897
Product Code : MALE02	T.R. Slip Dt. : 02-02-2023
Batch No. : SE-0649	Mfg. Dt. : JAN/23
Actual Batch Size : 30,000.000 TAB	Exp. Dt. : DEC/24
Sample Size : 60.00 Tab	Test As per : IHS
Released Qty. : 29,920.000 TAB	Specification No. : SPC/FP/MALE02/06
	Specification Dt. : 10-02-2022
	STP No. : MOA/FP/MALE02/06
	Mfg. Lic. No. : GUJ/DRUG/25/1428
	Location : SANTEJ
	Company : SUNRISE

Sr. No.	Test	Result	Specification
1.00	DESCRIPTION	ORANGE COLORED DIAMOND SHAPED FILM COATED SLIGHTLY BICONVEX TABLET.	ORANGE COLORED DIAMOND SHAPED FILM COATED SLIGHTLY BICONVEX TABLET.
2.00	WEIGHT OF 20 TABLETS	10.1373 GM	9.9990 GM ± 5 %
3.00	AVERAGE WEIGHT (TABLET)	506.86 MG	499.950 MG ± 5 %
4.00	UNIFORMITY OF WEIGHT	COMPLIES	AV. WEIGHT OF TAB ± 5 % NOT MORE THAN 2 OF INDIVIDUAL TABLET WEIGHT DEVIATE FROM THE AVERAGE WEIGHT ± 5.0 % AND NONE DEVIATE FROM THE AVERAGE WEIGHT ± 10.0 %
5.00	THICKNESS	5.0 MM	5.2 ± 0.3 MM
6.00	DISINTEGRATION TIME	02 MIN 26 SEC	NMT 30 MINUTES
7.00	DISSOLUTION	MIN : 96.51 % MAX : 103.12 % AVG : 99.77 % MIN : 82.60 % MAX : 86.80 % AVG : 84.92 %	SILDENAFIL : NLT 70 % FLUOXETINE : NLT 70 %
8.00	ASSAY	102.09 MG 102.09 % 60.78 MG 101.30 %	EACH FILM COATED TABLET CONTAINS: SILDENAFIL CITRATE EQ. TO SILDENAFIL 100.0 MG [LIMIT : 90.0 MG TO 110.0 MG] [BET : 90.0 % TO 110.0 %] FLUOXETINE HCL 60.0 MG [LIMIT : 54.0 MG TO 66.0 MG] [BET : 90.0 % TO 110.0 %]

Conclusion : The above sample complies as per IHS

Analysis By	Checked By	Approved By
 AMEE Q.C.OFFICER 02/02/23	 MAYUR QC-EXECUTIVE 02/02/23	 JASMITA QA & QC MANAGER 02/02/23

