

QUALITY CONTROL DEPARTMENT

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

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : MALEGRA-100 TABLET	A.R. No. : FPE220039
Packing : 10x10 TAB	Release Dt. : 05-05-2022
Generic Name : SILDENAFIL TABLETS USP 100MG	T.R. Slip No. : FGTEST0091
	T.R. Slip Dt. : 05-05-2022
Product Code : MALE07	Specification No. : SPC/FP/MALE07/04
Batch No. : SE-0407	Specification Dt. : 20-05-2020
Actual Batch Size : 2,00,000.000 TAB	STP No. : MOA/FP/MALE07/04
Sample Size : 60.00 Tab	Mfg. Lic. No. : GUJ/DRUG/25/1428
Released Qty. : 1,98,680.000 TAB	Location : SANTEJ
	Company : SUNRISE

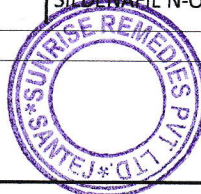
Sr. No.	Test	Result	Specification
1.00	DESCRIPTION	BLUE COLOURED DIAMOND SHAPED BICONVEX FILMCOATED TABLET WITH BOTH SIDE PLAIN	BLUE COLOURED DIAMOND SHAPED BICONVEX FILMCOATED TABLET WITH BOTH SIDE PLAIN
2.00	WEIGHT OF 20 TABLETS	10.0282 GM	10.0500 GM $\pm$ 5 %
3.00	AVERAGE WEIGHT (TABLET)	501.4 MG	502.5 MG $\pm$ 5 %
4.00	UNIFORMITY OF WEIGHT	COMPLIES	AV. WEIGHT OF TAB $\pm$ 5 % NOT MORE THAN 2 OF INDIVIDUAL TABLET WEIGHT DEVIATE FROM THE AVERAGE WEIGHT $\pm$ 5.0 % AND NONE DEVIATE FROM THE AVERAGE WEIGHT $\pm$ 10.0 %
5.00	IDENTIFICATION	A : THE IR SPECTRA OF THE SAMPLE IS CONCORDANT WITH THE REFERENCE SPECTRA OF SILDENAFIL. HENCE COMPLIES. B : THE RETENTION TIME OF THE SAMPLE SOLUTION CORRESPONDS TO THAT OF THE STANDARD SOLUTION, AS OBTAINED IN THE ASSAY. Lab : VAIBHAV ANALYTICAL SERVICES Report No. : 220422/01562/60 Dt. : 22/04/2022	A : THE IR SPECTRA OF THE TEST SOLUTION SHALL BE CONCORDANT WITH THE IR SPECTRA OF STANDARD SOLUTION B : THE RETENTION TIME OF THE SAMPLE SOLUTION SHALL CORRESPOND TO THAT OF THE STANDARD SOLUTION, AS OBTAINED IN THE ASSAY
6.00	THICKNESS	5.17 MM	5.1 $\pm$ 0.2 MM
7.00	DISINTEGRATION TIME	01 MIN 30 SEC	NMT 30 MINUTES
8.00	DISSOLUTION	MIN : 99 % MAX : 100 % AVG : 100 %	NLT 80 % (Q)
9.00	ORGANIC IMPURITIES	NOT DETECTED	SILDENAFIL N-OXIDE : NMT 0.20 %

Checked By

Approved BY


NIDHI
Q.C.OFFICER


BHUMIKA
QC MANAGER



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	Company : SUNRISE

Sr. No.	Test	Result	Specification
			ANY INDIVIDUAL DEGRADATION PRODUCT : NMT 0.20 %
			TOTAL DEGRADATION PRODUCT : NMT 0.5 %
10.00	ASSAY	RESULT LABEL CLAIM 100.0 MG 100.0 MG 100.0 %	EACH FILM COATED TABLET CONTAINS : SILDENAFIL CITRATE EQ. TO SILDENAFIL USP 100.0 MG [LIMIT : 90.0 MG TO 110.0 MG] [BET : 90.0 % TO 110.0 %]

Conclusion : The above sample complies as per USP

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