

SUNRISE REMEDIES PVT LTD

BLOCK NO.2244, OPP. SHAH ALLOYS LTD, AT-SANTEJ,
TAL.:KALOL- District : GANDHINAGAR State : GUJARAT -382721
Phone(O) :2764 286719 E-Mail:-accounts@sunriseremedies.in

REG.OFF.: 104, SAHJANAND COMPLEX,,NR. THALTEJ CROSS ROAD,,S.G.HIGHWAY,,AHMEDABAD-380059

QUALITY CONTROL DEPARTMENT

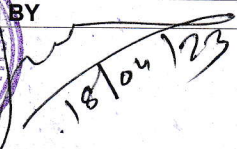
THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

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FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : MALEGRA PRO-100 TABLET	A.R. No. : FPE230014
Packing : 10x10 TAB	Release Dt. : 18-04-2023
Generic Name : SILDENAFIL TABLETS USP 100MG	T.R. Slip No. : FGTEST2300024
	T.R. Slip Dt. : 18-04-2023
Product Code : MALE06	Specification No. : SPC/FP/MALE06/06
Batch No. : SE-0741	Specification Dt. : 19-04-2022
Actual Batch Size : 25,000.000 TAB	STP No. : MOA/FP/MALE06/06
Sample Size : 10.00 Tab	Mfg. Lic. No. : GUJ/DRUG/25/1428
Released Qty. : 24,620.000 TAB	Location : SANTEJ
	Company : SUNRISE
Mfg. Dt. : 04/23	
Exp. Dt. : 03/26	
Test As per : USP	

Sr. No.	Test	Result	Specification
1.00	DESCRIPTION	PINK COLOURED DIAMOND SHAPED BICONVEX UNCOATED TABLET WITH BOTH SIDE PLAIN.	PINK COLOURED DIAMOND SHAPED BICONVEX UNCOATED TABLET WITH BOTH SIDE PLAIN.
2.00	WEIGHT OF 20 TABLETS	9.8984 GM	9.8000 GM $\pm$ 5 %
3.00	AVERAGE WEIGHT (TABLET)	494.92 MG	490.0 MG $\pm$ 5 %
4.00	UNIFORMITY OF WEIGHT	COMPLIES	AVG. 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 : COMPLIES B : THE RETENTION TIME OF THE SAMPLE SOLUTION CORRESPONDS TO THAT OF THE STANDARD SOLUTION, AS OBTAINED IN THE ASSAY Lab : HITECH LABORATORY Report No. : HTL/D/FP/230408008 Dt. : 08/04/2023	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	4.91 MM	4.8 $\pm$ 0.2 MM
7.00	HARDNESS	5.66 KG/CM ²	NLT 3.0 KG/CM ²
8.00	FRIABILITY	0.1 %	NMT 1.0 %
9.00	DISINTEGRATION TIME	01 MIN 50 SEC	NMT 15 MINUTES
10.00	ORGANIC IMPURITIES	NOT DETECTED	SILDENAFIL N-OXIDE : NMT 0.20 %

Analysis By	Checked By	Approved BY
 DHAVAL Q.C.OFFICER 18/04/23	 MAYUR QC-EXECUTIVE 18/04/23	  JASMITA QA & QC MANAGER 18/04/23

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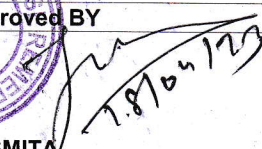
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Sr. No.	Test	Result	Specification
			ANY INDIVIDUAL DEGRADATION PRODUCT : NMT 0.20 %
			TOTAL DEGRADATION PRODUCT : NMT 0.5 %
11.00	DISSOLUTION	MIN : 89.18 % MAX : 92.57 % AVG : 90.64 %	NLT 80 % (Q)
12.00	ASSAY	98.35 MG 98.35 %	EACH FILM COATED TABLET 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

Analysis By	Checked By	Approved BY
 18/04/23 DHAVAL Q.C.OFFICER	 18/04/23 MAYUR QC-EXECUTIVE	 18/04/23 JASMITA QA & QC MANAGER

