

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))
FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Page 1 of 2

Product Name :	MALEGRA-25 TABLET	A.R. No. :	FPE220049
Packing :	10x10 TAB	Release Dt. :	13-05-2022
Generic Name :	SILDENAFIL TABLETS USP 25 MG	T.R. Slip No. :	FGTEST0109
Product Code :	MALE08	T.R. Slip Dt. :	13-05-2022
Batch No. :	SE-0434	Specification No. :	SPC/FP/MALE08/05
Actual Batch Size :	20,000.000 TAB	Specification Dt. :	26-07-2020
Sample Size :	60.00 Tab	STP No. :	MOA/FP/MALE08/05
Released Qty. :	19,680.000 TAB	Mfg. Lic. No. :	GUJ/DRUG/25/1428
		Location :	SANTEJ
		Company :	SUNRISE
		Mfg. Dt. :	MAY/22
		Exp. Dt. :	APR/25
		Test As per :	USP

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	10.3604 GM	10.0450 GM $\pm$ 5 %
3.00	AVERAGE WEIGHT (TABLET)	518.0 MG	502.25 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 : COMPLIES OUTSIDE LAB.: VAIBHAV ANALYTICAL SERVICES REPORT NO. 220510/02982/ 65 REPORT DATE:10/05/2022 B : THE RETENTION TIME OF THE SAMPLE SOLUTION SHALL CORRESPOND TO THAT OF THE STANDARD SOLUTION, AS OBTAINED IN THE ASSAY	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	4.12 MM	5.1 $\pm$ 0.3 MM
7.00	DISINTEGRATION TIME	03 MIN. 27 SEC.	NMT 30 MINUTES
8.00	DISSOLUTION	MIN: 92% MAX:96% AVG: 94%	NLT 80 % (Q)
9.00	ORGANIC IMPURITIES	ANY INDIVIDUAL DEGRADATION PRODUCT : NOT DETECTED TOTAL DEGRADATION PRODUCT : NOT	SILDENAFIL N-OXIDE : NMT 0.20 % ANY INDIVIDUAL DEGRADATION PRODUCT : NMT 0.20 %

Checked By

Approved BY

NIDHI
Q.C.OFFICER

BHUMIKA
QC MANAGER

DRBHUMIKA 04-06-2022 11:41 AM

FgAniCert04_REN07

SUNRISE REMEDIES PVT LTD