



# 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

Page 1 of 2

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

## FINISHED PRODUCT CERTIFICATE OF ANALYSIS

<b>Product Name</b> : FEMALEGRA-100 TABLET	<b>A.R. No.</b> : FPE220158
<b>Packing</b> : 10x4 TAB	<b>Release Dt.</b> : 06-09-2022
<b>Generic Name</b> : SILDENAFIL TABLETS USP 100MG	<b>T.R. Slip No.</b> : FGTEST0387
<b>Product Code</b> : FEMA01	<b>T.R. Slip Dt.</b> : 06-09-2022
<b>Batch No.</b> : SE-0529	<b>Specification No.</b> : SPC/FP/FEMA01/06
<b>Actual Batch Size</b> : 1,00,000.000 TAB	<b>Specification Dt.</b> : 10-02-2022
<b>Sample Size</b> : 60.00 Tab	<b>STP No.</b> : MOA/FP/FEMA01/06
<b>Released Qty.</b> : 99,120.000 TAB	<b>Mfg. Lic. No.</b> : GUJ/DRUG/25/1428
<b>Remarks</b> : Data transferred from AR NO- SBP220666	<b>Location</b> : SANTEJ
	<b>Company</b> : SUNRISE

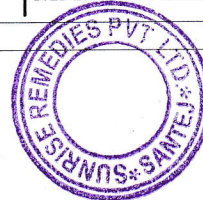
Sr. No.	Test	Result	Specification
1.00	DESCRIPTION	PINK COLOURED DIAMOND SHAPED BICONVEX FILM COATED TABLET WITH BOTH SIDE PLAIN.	PINK COLOURED DIAMOND SHAPED BICONVEX FILM COATED TABLET WITH BOTH SIDE PLAIN.
2.00	WEIGHT OF 20 TABLETS	10.0719 GM	10.0830 GM $\pm$ 5 %
3.00	AVERAGE WEIGHT (TABLET)	503.6 MG	504.15 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. : 220827/11374/ 71 Dt. : 27/08/2022	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	5.1 MM	5.2 $\pm$ 0.2 MM
7.00	DISINTEGRATION TIME	03 MIN 11 SEC	NMT 30 MINUTES
8.00	DISSOLUTION	MIN : 90 % MAX : 100 % AVG : 97 %	NLT 80 % (Q)
9.00	ORGANIC IMPURITIES	NOT DETECTED	SILDENAFIL N-OXIDE : NMT 0.20 %

Checked By

Approved BY

HIMANSHU  
Q.C.OFFICER

BHUMIKA  
QC MANAGER





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Sr. No.	Test	Result	Specification
			ANY INDIVIDUAL DEGRADATION PRODUCT : NMT 0.20 % TOTAL DEGRADATION PRODUCT : NMT 0.5 %
10.00	ASSAY	RESULT LABEL CLAIM 100.9 MG 100.0 MG 100.9 %	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

<b>Checked By</b>  HIMANSHU Q.C.OFFICER	<b>Approved BY</b>  BHUMIKA QC MANAGER
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