

# SUNRISE REMEDIES PVT. LTD.

Formerly named as : SUNRISE REMEDIES PRIVATE LIMITED

BLOCK NO. 2244,,OPP. SHAH ALLOYS LTD,,TAL.: KALOL,,SANTEJ-382721

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

C.I.No. : U24231GJ1996PTC028804

## 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> : SILDISOFT-100 TABLET	<b>A.R. No.</b> : FPE210215
<b>Packing</b> : 10x10 TAB	<b>Rel. Dt.</b> : 19-10-2021
<b>Generic Name</b> : SILDENAFIL CITRATE TABLET 100MG	<b>T.R. Slip No.</b> : PAQA210574
<b>Product Code</b> : SILD01	<b>T.R. Slip Dt.</b> : 19-10-2021
<b>Batch No.</b> : SE-0177	<b>Analysis Date</b> : 19-10-2021
<b>Actual Batch Size</b> : 50000 TAB (500 BOX)	<b>Specification No.</b> : SPC/FP/SILD01/04
<b>Packing Batch Size</b> : 50000 TAB	<b>Specification Dt.</b> : 24-10-2019
<b>Sample Size</b> : 10.000 TAB	<b>STP No.</b> : MOA/FP/SILD01/04
<b>Released Qty</b> : 50000.000 TAB (500 BOX)	<b>Location</b> : SANTEJ
<b>Remarks</b> :	<b>Make</b> : SUNRISE
<b>Mfg. Dt.</b> : 10/2021	
<b>Exp. Dt.</b> : 09/2024	
<b>Test Packing</b> : 10 TAB	
<b>Mfg. Lic No.</b> : G/25/1428	
<b>Test As Per</b> : IH	

Sr.	Test	Result	Specification
1	DESCRIPTION	WHITE COLOURED DIAMOND SHAPED BICONVEX UNCOATED TABLET WITH BOTH SIDE PLAIN.	WHITE COLOURED DIAMOND SHAPED BICONVEX UNCOATED TABLET WITH BOTH SIDE PLAIN.
2	WEIGHT OF 20 TABLETS	10.0712 GM	10.0000 GM $\pm$ 5 %
3	AVERAGE WEIGHT (TABLETS)	503.4 MG	500.0 MG $\pm$ 5 %
4	UNIFORMITY OF WEIGHT	COMPLIES	AV. WEIGHT OF TABLET $\pm$ 5 % NOT MORE THAN 2 OF INDIVIDUAL TABLETS WEIGHTS DEVIATE FROM THE AVERAGE WEIGHT $\pm$ 5.0 % AND NONE DEVIATE FROM THE AVERAGE WEIGHT $\pm$ 10.0 %
5	THICKNESS	5.1 MM	5.0 $\pm$ 0.2 MM
6	HARDNESS	10.45 KG/CM <sup>2</sup>	NOT LESS THAN 3.0 KG/CM <sup>2</sup>
7	FRIABILITY	0.16 %	NOT MORE THAN 1.0 %
8	DISINTEGRATION TIME	00 MIN 28 SEC	NOT MORE THAN 15 MINUTES
9	IDENTIFICATION	IDENTIFICATION A : THE IR ABSORPTION SPECTRUM OF THE SAMPLE PREPARATION IS CONCORDANT WITH THE IR SPECTRUM OBTAINED FROM WORKING STANDARD.  IDENTIFICATION B : THE RETENTION TIME OF THE SAMPLE SOLUTION CORRESPONDS TO THAT OF THE STANDARD SOLUTION, AS OBTAINED IN THE ASSAY.  <b>Lab</b> : PARISHIL LABORATORIES <b>Report No.</b> : PLPL/PH/211011060	IDENTIFICATION A : THE IR SPECTRA OF THE TEST SOLUTION SHALL BE CONCORDANT WITH THE IR SPECTRA OF STANDARD SOLUTION.  IDENTIFICATION B : THE RETENTION TIME OF THE SAMPLE SOLUTION SHALL CORRESPOND TO THAT OF THE STANDARD SOLUTION, AS OBTAINED IN THE ASSAY.

Conclusion : The above sample complies as per IH  
In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

ANALYSIS BY

APPROVED BY

HIMANSHU THAKOR  
LAB CHEMIST

BHUMIKA G RATHOD  
MANAGER Q.C.

FGANLCERTQA

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Sr.	Test	Result	Specification
		<b>Dt.</b> : 19-10-21	
10	ORGANIC IMPURITIES	NOT DETECTED NOT DETECTED NOT DETECTED	SILDENAFIL N-OXIDE : NOT MORE THAN 0.20 % ANY INDIVIDUAL DEGRADATION PRODUCT : NOT MORE THAN 0.20 % TOTAL DEGRADATION PRODUCT : NOT MORE THAN 0.5 %
11	DISSOLUTION	MIN : 95 % MAX : 99 % AVG : 97 %	NOT LESS THAN 80 % (Q)
12	ASSAY	RESULT LABEL CLAIM 100.0 MG 100.0 MG 100.0 %	EACH UNCOATED TABLET CONTAINS : SILDENAFIL CITRATE EQ. TO SILDENAFIL 100.0 MG [ LIMIT : 90.0 MG TO 110.0 MG ] [ BET : 90.0 % TO 110.0 % ]

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