

# 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

Product Name : SUPER TADARISE TABLET	A.R. No. : FPE200078
Packing : 10x10 TAB	Rel. Dt. : 21-06-2020
Generic Name : TADALAFIL WITH DAPOXETINE TABLET	T.R. Slip No. : PAQA200163
Product Code : SUPE05	T.R. Slip Dt. : 20-06-2020
Batch No. : ST3620	Analysis Date : 21-06-2020
Actual Batch Size : 200000 TAB (2000 BOX)	Specification No. : SPC/FP/SUPE05/04
Packing Batch Size : 200000 TAB	Specification Dt. : 01-04-2019
Sample Size : 40.000 TAB	STP No. : MOA/FP/SUPE05/04
Released Qty : 200000.000 TAB (2000 BOX)	Location : SANTEJ
Mfg. Dt. : 06/06/2020	Make : SUNRISE
Exp. Dt. : 31/05/2022	
Test Packing : 40 TAB	
Mfg. Lic No. : G/1428	
Test As Per : IH	

Sr.	Test	Result	Specification
1	DESCRIPTION	GOLDEN YELLOW COLOURED FILMCOATED BICONVEX TRIANGULAR SHAPED TABLET WITH ONE SIDE EMBOSSED SRPL AND OTHER SIDE PLAIN.	GOLDEN YELLOW COLOURED FILMCOATED BICONVEX TRIANGULAR SHAPED TABLET WITH ONE SIDE EMBOSSED SRPL AND OTHER SIDE PLAIN.
2	WEIGHT OF 20 TABLETS	10.4162 GM	10.2500 GM ± 5 %
3	AVERAGE WEIGHT (TABLETS)	520.8 MG	512.52 MG ± 5 %
4	UNIFORMITY OF WEIGHT	COMPLIES	AV. WEIGHT OF TAB ± 5%  NOT MORE THAN 2 OF INDIVIDUAL TABLET WEIGHT DEVIATE FROM THE AVERAGE WEIGHT ± 5.0 % AND NONE DEVIATE FROM THE AVERAGE WEIGHT ± 10.0 %.
5	DISINTEGRATION TIME	01 MIN 21 SEC	NOT MORE THAN 30 MINUTES.
6	THICKNESS	4.7 MM	4.7 ± 0.3 MM
7	ASSAY	RESULT      LABEL CLAIM 20.2 MG      20.0 MG 100.9 %	EACH FILMCOATED TABLET CONTAINS : TADALAFIL      20.0 MG [ LIMIT : 18.0 MG TO 22.0 MG ] [ BET : 90.0 % TO 110.0 % ]
		59.1 MG      60.0 MG 98.6 %	DAPOXETINE HCL EQ. TO DAPOXETINE      60.0 MG [ LIMIT : 54.0 MG TO 66.0 MG ] [ BET : 90.0% TO 110.0% ]
8	DISSOLUTION	MIN: 88 % MAX: 92 %	TADALAFIL : NLT 70.0%

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"

APPROVED BY



BHUMIKA G RATHOD  
MANAGER Q.C.

ANALYSIS BY



MAYUR P PATEL  
LAB CHEMIST



FGANLCERTQA

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

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<b>Product Name</b> : SUPER TADARISE TABLET	<b>A.R. No.</b> : FPE200078
<b>Packing</b> : 10x10 TAB	<b>Rel. Dt.</b> : 21-06-2020
<b>Generic Name</b> : TADALAFIL WITH DAPOXETINE TABLET	<b>T.R. Slip No.</b> : PAQA200163
<b>Product Code</b> : SUPE05	<b>T.R. Slip Dt.</b> : 20-06-2020
<b>Batch No.</b> : ST3620	<b>Analysis Date</b> : 21-06-2020
<b>Actual Batch Size</b> : 200000 TAB (2000 BOX)	<b>Specification No.</b> : SPC/FP/SUPE05/04
<b>Packing Batch Size</b> : 200000 TAB	<b>Specification Dt.</b> : 01-04-2019
<b>Sample Size</b> : 40.000 TAB	<b>STP No.</b> : MOA/FP/SUPE05/04
<b>Released Qty</b> : 200000.000 TAB (2000 BOX)	<b>Location</b> : SANTEJ
<b>Mfg. Dt.</b> : 06/06/2020	<b>Make</b> : SUNRISE
<b>Exp. Dt.</b> : 31/05/2022	
<b>Test Packing</b> : 40 TAB	
<b>Mfg. Lic No.</b> : G/1428	
<b>Test As Per</b> : IH	

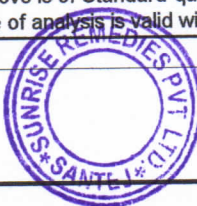
Sr.	Test	Result	Specification
		AVG: 91 % MIN: 82 % MAX: 89 % AVG: 87 %	DAPOXETINE : NLT 70.0%

Conclusion : The above sample complies as per IH  
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