



# 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

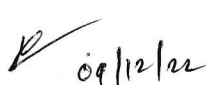
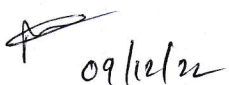
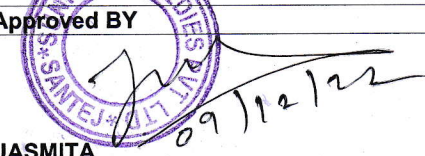
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THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

### FINISHED PRODUCT CERTIFICATE OF ANALYSIS

<b>Product Name</b> : TADASOFT 40 TABLET	<b>A.R. No.</b> : FPE220261
<b>Packing</b> : 10x10 TAB	<b>Release Dt.</b> : 09-12-2022
<b>Generic Name</b> : TADALAFIL TABLETS USP 40 MG	<b>T.R. Slip No.</b> : FGTEST0657
<b>Product Code</b> : TADA08	<b>T.R. Slip Dt.</b> : 09-12-2022
<b>Batch No.</b> : SE-0629	<b>Specification No.</b> : SPC/FP/TADA08/05
<b>Actual Batch Size</b> : 1,00,000.000 TAB	<b>Specification Dt.</b> : 07-05-2022
<b>Sample Size</b> : 60.00 TAB	<b>STP No.</b> : MOA/FP/TADA08/05
<b>Released Qty.</b> : 99,820.000 TAB	<b>Mfg. Lic. No.</b> : GUJ/DRUG/25/1428
<b>Mfg. Dt.</b> : NOV/22	<b>Location</b> : SANTEJ
<b>Exp. Dt.</b> : OCT/25	<b>Company</b> : SUNRISE
<b>Test As per</b> : USP	

Sr. No.	Test	Result	Specification
1.00	DESCRIPTION	LIGHT ORANGE COLOURED UNCOATED BICONVEX ALMOND SHAPED TABLET WITH BOTH SIDE PLAIN.	LIGHT ORANGE COLOURED UNCOATED BICONVEX ALMOND SHAPED TABLET WITH BOTH SIDE PLAIN.
2.00	WEIGHT OF 20 TABLETS	6.7008 GM	6.7000 GM ± 5 %
3.00	AVERAGE WEIGHT (TABLET)	335.04 MG	335.0 MG ± 5 %
4.00	UNIFORMITY OF WEIGHT	COMPLIES	AVG. WEIGHT OF TAB ± 5 % NOT MORE THAN 2 OF INDIVIDUAL TABLET WEIGHTS DEVIATE FROM THE AVERAGE WEIGHT ± 5.0 % AND NONE DEVIATE FROM THE AVERAGE WEIGHT ± 10.0 %
5.00	DISINTEGRATION TIME	08 MIN 47 SEC	NOT MORE THAN 15 MINUTES
6.00	THICKNESS	3.83 MM	4.0 ± 0.3 MM
7.00	HARDNESS	7.36 KG/CM <sup>2</sup>	NOT LESS THAN 3.0 KG/CM <sup>2</sup>
8.00	FRIABILITY	0.28 %	NOT MORE THAN 1.0 %
9.00	IDENTIFICATION	IDENTIFICATION A : THE IR SPECTRA OF THE SAMPLE IS CONCORDANT WITH THE REFERENCE SPECTRA OF TADALAFIL. HENCE COMPLIES.  IDENTIFICATION B : THE RETENTION TIME OF THE MAJOR PEAK OF THE SAMPLE SOLUTION CORRESPONDS TO THAT OF THE STANDARD SOLUTION, AS OBTAINED IN THE ASSAY.  Lab : VAIBHAV ANALYTICAL SERVICES Report No. : 221202/18415/ 94 Dt. : 02/12/2022	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 MAJOR PEAK OF THE SAMPLE SOLUTION SHALL CORRESPOND TO THAT OF THE STANDARD SOLUTION, AS OBTAINED IN THE ASSAY.
10.00	ORGANIC IMPURITIES	NOT DETECTED	INDIVIDUAL IMPURITIES : NMT 0.2 %

<b>Analysis By</b>  URVI Q.C.OFFICER	<b>Checked By</b>  MAYUR QC-EXECUTIVE	<b>Approved BY</b>  JASMITA QA & QC MANAGER
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## QUALITY CONTROL DEPARTMENT THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F)) FINISHED PRODUCT CERTIFICATE OF ANALYSIS

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<b>Released Qty.</b> : 99,820.000 TAB	<b>Location</b> : SANTEJ
	<b>Company</b> : SUNRISE

Sr. No.	Test	Result	Specification
			TOTAL IMPURITIES : NMT 0.3 %
11.00	DISSOLUTION	10 MIN : 44 % 30 MIN : 89 %	10 MIN : NLT 40% (Q) 30 MIN : NLT 80% (Q)
12.00	ASSAY	RESULT LABEL CLAIM 38.52 MG 40.0 MG 96.30 %	EACH UNCOATED TABLET CONTAINS: TADALAFIL USP 40.0 MG [ LIMIT : 36.0 MG TO 44.0 MG ] [ BET : 90.0 % TO 110.0 % ]

Conclusion : The above sample complies as per USP

<b>Analysis By</b>  09/12/22 URVI Q.C.OFFICER	<b>Checked By</b>  09/12/22 MAYUR QC-EXECUTIVE	<b>Approved BY</b>  09/12/22  JASMITA QA & QC MANAGER
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