



# 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

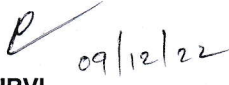
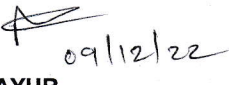

QUALITY CONTROL DEPARTMENT  
THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

Page 1 of 2

## FINISHED PRODUCT CERTIFICATE OF ANALYSIS

<b>Product Name</b> : TADASOFT-20 TABLET	<b>A.R. No.</b> : FPE220260
<b>Packing</b> : 10x10 TAB	<b>Release Dt.</b> : 09-12-2022
<b>Generic Name</b> : TADALAFIL TABLET USP 20 MG	<b>T.R. Slip No.</b> : FGTEST0656
	<b>T.R. Slip Dt.</b> : 09-12-2022
<b>Product Code</b> : TADA03	<b>Specification No.</b> : SPC/FP/TADA03/06
<b>Batch No.</b> : SE-0600	<b>Specification Dt.</b> : 09-02-2022
<b>Actual Batch Size</b> : 1,00,000.000 TAB	<b>STP No.</b> : MOA/FP/TADA03/06
<b>Sample Size</b> : 60.00 Tab	<b>Mfg. Lic. No.</b> : GUJ/DRUG/25/1428
<b>Released Qty.</b> : 99,820.000 TAB	<b>Location</b> : SANTEJ
	<b>Company</b> : SUNRISE
<b>Mfg. Dt.</b> : NOV/22	
<b>Exp. Dt.</b> : OCT/25	
<b>Test As per</b> : USP	

Sr. No.	Test	Result	Specification
1.00	DESCRIPTION	YELLOW COLORED UNCOATED BICONVEX ALMOND SHAPED TABLET WITH BOTH SIDE PLAIN	YELLOW COLORED UNCOATED BICONVEX ALMOND SHAPED TABLET WITH BOTH SIDE PLAIN
2.00	WEIGHT OF 20 TABLETS	6.6579 GM	6.7000 GM ± 5%
3.00	AVERAGE WEIGHT (TABLET)	332.90 MG	335.0 MG ± 5%
4.00	UNIFORMITY OF WEIGHT	COMPLIES	AVG. WT. OF TABLET ± 5.0% NOT MORE THAN 2 OF INDIVIDUAL TABLETS WEIGHT DEVIATE FROM AVG. WT. ± 5.0% AND NONE DEVIATES FROM AVG. WT. ± 10.0%
5.00	IDENTIFICATION	A : COMPLIES  B : THE RETENTION TIME OF THE MAJOR PEAK OF THE SAMPLE SOLUTION CORRESPONDS TO THAT OF STANDARD SOLUTION AS OBTAINED IN THE ASSAY  Lab : VAIBHAV ANALYTICAL SERVICES Report No. : 221116/17044/ 49 Dt. : 18/11/2022	A : THE IR SPECTRA OF TEST SOLUTION SHALL BE CONCORDANT WITH THE IR SPECTRA OF STANDARD SOLUTION  B : THE RETENTION TIME OF THE MAJOR PEAK OF THE SAMPLE SOLUTION SHALL CORRESPOND TO THAT OF STANDARD SOLUTION AS OBTAINED IN THE ASSAY
6.00	THICKNESS	4.0 MM	4.0 ± 0.3 MM
7.00	HARDNESS	4.22 KG/CM <sup>2</sup>	NLT 3.0 KG/CM <sup>2</sup>
8.00	FRIABILITY	0.2 %	NMT 1.0%
9.00	DISINTEGRATION TIME	02 MIN 48 SEC	NMT 15 MINUTES
10.00	ORGANIC IMPURITIES	NOT DETECTED	INDIVIDUAL IMPURITIES : NMT 0.2% TOTAL IMPURITIES : NMT 0.3%

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

MAYUR1

FgAnlCert04\_REN07



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

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<b>Test As per</b> : USP	

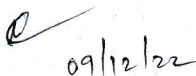
Sr. No.	Test	Result	Specification
11.00	DISSOLUTION	10 MIN : 75.80 % 30 MIN : 97.78 % Lab : VAIBHAV ANALYTICAL SERVICES Report No. : 221116/17044/ 49 Dt. : 18/11/2022	10 MIN : NLT 40% (Q) 30 MIN : NLT 80% (Q)
12.00	UNIFORMITY OF CONTENT	MIN : 98.7 % MAX : 102.5 % AVG : 101.4 %	85.0% TO 115.0%
13.00	ASSAY	RESULT LABEL CLAIM 20.97 MG 20.0 MG 104.85 % Lab : VAIBHAV ANALYTICAL SERVICES Report No. : 221116/17044/ 49 Dt. : 18/11/2022	EACH UNCOATED TABLET CONTAINS TADALAFIL USP 20.0 MG [LIMIT : 18.0 MG TO 22.0 MG] [BET. 90.0% TO 110.0%]

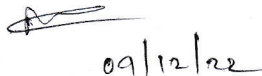
Conclusion : The above sample complies as per USP


Analysis By

Checked By

Approved BY

  
09/12/22  
URVI  
Q.C.OFFICER

  
09/12/22  
MAYUR  
QC-EXECUTIVE

  
09/12/22  
JASMITA  
QA & QC MANAGER