



# 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



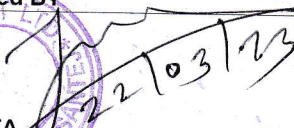
QUALITY CONTROL DEPARTMENT  
 THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

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## FINISHED PRODUCT CERTIFICATE OF ANALYSIS

<b>Product Name</b> : TADARISE-60 TABLET	<b>A.R. No.</b> : FPE220376
<b>Packing</b> : 10x10 TAB	<b>Release Dt.</b> : 22-03-2023
<b>Generic Name</b> : TADALAFIL TABLETS USP 60 MG	<b>T.R. Slip No.</b> : FGTEST1063
	<b>T.R. Slip Dt.</b> : 22-03-2023
<b>Product Code</b> : TADA13	<b>Specification No.</b> : SPC/FP/TADA13/05
<b>Batch No.</b> : SE-0719	<b>Specification Dt.</b> : 13-05-2021
<b>Actual Batch Size</b> : 1,00,000.000 TAB	<b>STP No.</b> : MOA/FP/TADA13/05
<b>Sample Size</b> : 30.00 Tab	<b>Mfg. Lic. No.</b> : GUJ/DRUG/25/1428
<b>Released Qty.</b> : 99,620.000 TAB	<b>Location</b> : SANTEJ
	<b>Company</b> : SUNRISE
<b>Mfg. Dt.</b> : 03/23	
<b>Exp. Dt.</b> : 02/26	
<b>Test As per</b> : USP	

Sr. No.	Test	Result	Specification
1.00	DESCRIPTION	GOLDEN COLORED ALMOND SHAPED BICONVEX FILM COATED TABLET WITH BOTH SIDE PLAIN	GOLDEN COLORED ALMOND SHAPED BICONVEX FILM COATED TABLET WITH BOTH SIDE PLAIN
2.00	WEIGHT OF 20 TABLETS	6.7367 GM	6.8600 GM ± 5 %
3.00	AVERAGE WEIGHT (TABLET)	336.84 MG	343.0 MG ± 5 %
4.00	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 %.
5.00	IDENTIFICATION	A : COMPLIES  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 : HITECH LABORATORY Report No. : HTL/D/FP/230321019 Dt. : 21/03/2023	A : THE IR SPECTRA OF THE 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 THE STANDARD SOLUTION, AS OBTAINED IN THE ASSAY
6.00	THICKNESS	3.91 MM	4.0 ± 0.3 MM
7.00	DISINTEGRATION TIME	06 MIN 02 SEC	NMT 30 MINUTES
8.00	ORGANIC IMPURITIES	NOT DETECTED	INDIVIDUAL IMPURITIES : NMT 0.2 %  TOTAL IMPURITIES : NMT 0.3 %
9.00	DISSOLUTION	AFTER 10 MIN : 67.42 %	AFTER 10 MIN : NLT 40 % (Q)

<b>Analysis By</b>	<b>Checked By</b>	<b>Approved BY</b>
 CHETAN QC-EXECUTIVE	 MAYUR QC-EXECUTIVE	 JASMITA QA & QC MANAGER

MAYUR1

FgAniCert04\_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
00	ASSAY	AFTER 30 MIN : 90.17 %  58.13 MG 96.89 %	AFTER 30 MIN : NLT 80 % (Q)  EACH FILM COATED TABLET CONTAINS : TADALAFIL 60.0 MG [ LIMIT : 54.0 MG TO 66.0 MG ] [ BET : 90.0 % TO 110.0 % ]

Conclusion : The above sample complies as per USP

<b>Analysis By</b>  CHETAN QC-EXECUTIVE 22/03/23	<b>Checked By</b>  MAYUR QC-EXECUTIVE 22/03/23	<b>Approved BY</b>  JASMITA QA & QC MANAGER 22/03/23
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