



# 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

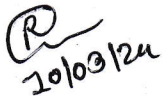
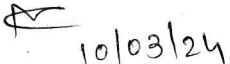
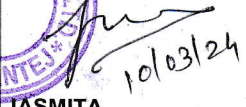
Page 1 of 2

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

### FINISHED PRODUCT CERTIFICATE OF ANALYSIS

<b>Product Name</b> : TADARISE-40 TABLET	<b>A.R. No.</b> : FPE230387
<b>Packing</b> : 10x10 TAB	<b>Release Dt.</b> : 10-03-2024
<b>Generic Name</b> : TADALAFIL TABLETS USP 40 MG	<b>T.R. Slip No.</b> : FGTEST2300687
	<b>T.R. Slip Dt.</b> : 10-03-2024
<b>Product Code</b> : TADA12	<b>Specification No.</b> : SPC/FP/TADA12/06
<b>Batch No.</b> : SE-1058	<b>Specification Dt.</b> : 15-06-2022
<b>Actual Batch Size</b> : 2,00,000.00 TAB	<b>STP No.</b> : MOA/FP/TADA12/06
<b>Sample Size</b> : 1.00 Strip	<b>Mfg. Lic. No.</b> : GUJ/DRUG/25/1428
<b>Released Qty.</b> : 1,99,000.00 TAB	<b>Location</b> : SANTEJ
	<b>Company</b> : SUNRISE

Sr. No.	Test	Result	Specification
1.00	DESCRIPTION	GOLDEN COLOURED ALMOND SHAPED FILM COATED BICONVEX TABLET WITH BOTH SIDE PLAIN	GOLDEN COLOURED ALMOND SHAPED FILM COATED BICONVEX TABLET WITH BOTH SIDE PLAIN
2.00	WEIGHT OF 20 TABLETS	6.8926 GM	6.8670 GM ± 5 %
3.00	AVERAGE WEIGHT (TABLET)	344.63 MG	343.37 MG ± 5 %
4.00	UNIFORMITY OF WEIGHT	COMPLIES	AVG. WEIGHT OF TAB ± 5 % NOT MORE THAN 2 OF INDIVIDUAL TABLETS WEIGHTS DEVIATE FROM THE AVERAGE WEIGHT ± 5.0 % AND NONE DEVIATE FROM THE AVERAGE WEIGHT ± 10.0 %
5.00	IDENTIFICATION	A : COMPLIES  LAB. : HITECH LABORATORY REPORT NO. : HTL/D/FP/240228008 DATE : 28/02/2024  B : THE RETENTION TIME OF THE MAJOR PEAK OF THE SAMPLE SOLUTION CORRESPONDS TO THAT OF THE STANDARD SOLUTION, AS OBTAINED IN THE ASSAY	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	3.90 MM	4.0 ± 0.3 MM
7.00	DISINTEGRATION TIME	04 MIN 17 SEC	NOT MORE THAN 30 MINUTES
8.00	ORGANIC IMPURITIES	NOT DETECTED  NOT DETECTED	INDIVIDUAL IMPURITIES : NMT 0.2 %  TOTAL IMPURITIES : NMT 0.3 %
9.00	DISSOLUTION	10 MIN : AVG: 48.13 %	10 MIN : NLT 40% (Q)

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





# 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

Page 2 of 2


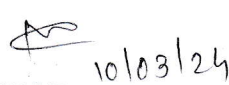
THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

### FINISHED PRODUCT CERTIFICATE OF ANALYSIS

<b>Product Name</b> : TADARISE-40 TABLET	<b>A.R. No.</b> : FPE230387
<b>Packing</b> : 10x10 TAB	<b>Release Dt.</b> : 10-03-2024
<b>Generic Name</b> : TADALAFIL TABLETS USP 40 MG	<b>T.R. Slip No.</b> : FGTEST2300687
<b>Product Code</b> : TADA12	<b>T.R. Slip Dt.</b> : 10-03-2024
<b>Batch No.</b> : SE-1058	<b>Specification No.</b> : SPC/FP/TADA12/06
<b>Actual Batch Size</b> : 2,00,000.00 TAB	<b>Specification Dt.</b> : 15-06-2022
<b>Sample Size</b> : 1.00 Strip	<b>STP No.</b> : MOA/FP/TADA12/06
<b>Released Qty.</b> : 1,99,000.00 TAB	<b>Mfg. Lic. No.</b> : GUJ/DRUG/25/1428
<b>Mfg. Dt.</b> : 02/24	<b>Location</b> : SANTEJ
<b>Exp. Dt.</b> : 01/27	<b>Company</b> : SUNRISE
<b>Test As per</b> : USP	

Sr. No.	Test	Result	Specification
		MIN: 47.65 % MAX: 48.65 %  30 MIN : AVG: 86.82 % MIN: 85.96 % MAX: 87.83 %	30 MIN : NLT 80% (Q)
10.00	UNIFORMITY OF DOSAGE UNITS	AVG : 98.60 % MIN : 95.87 % MAX : 100.69 %	BY CONTENT UNIFORMITY : ACCEPTANCE VALUE L1 < OR = TO 15, L2 < OR = TO 25
11.00	ASSAY	39.35 MG 98.37 %	EACH FILM COATED 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. "This computer generated certificate of analysis is valid without signature"

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