



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

Product Name : TADARISE-40 TABLET	A.R. No. : FPE240148
Packing : 10x10 TAB	Release Dt. : 24-07-2024
Generic Name : TADALAFIL TABLETS USP 40 MG	T.R. Slip No. : FGTEST2400275
Product Code : TADA12	T.R. Slip Dt. : 24-07-2024
Batch No. : SE-1177	Specification No. : SPC/FP/TADA12/07
Actual Batch Size : 2,00,000.00 TAB	Specification Dt. : 14-06-2024
Sample Size : 1.00 Strip	STP No. : MOA/FP/TADA12/07
Released Qty. : 1,99,000.00 TAB	Mfg. Lic. No. : GUJ/DRUG/25/1428
Mfg. Dt. : 06/24	Location : SANTEJ
Exp. Dt. : 05/27	Company : SUNRISE
Test As per : USP	

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	6.8561 GM	6.8670 GM ± 5 %
3.00	AVERAGE WEIGHT (TABLET)	342.81 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 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 : SHUKRA LABORATORY REPORT NO.: SL/CST/FP/240628/005 DATE : 28/06/2024	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 26 SEC	NOT MORE THAN 30 MINUTES
8.00	ORGANIC IMPURITIES	NOT DETECTED	INDIVIDUAL IMPURITIES : NMT 0.2 %

Analysis By JANAK PATIDAR SR.QC-OFFICER	Checked By CHETAN QC-EXECUTIVE	Approved BY MAYUR SR. QC-EXECUTIVE
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Mfg. Dt. : 06/24	Location : SANTEJ
Exp. Dt. : 05/27	Company : SUNRISE
Test As per : USP	

Sr. No.	Test	Result	Specification
		NOT DETECTED	TOTAL IMPURITIES : NMT 0.3 %
9.00	DISSOLUTION	10 MIN : AVG : 53.20 % 30 MIN : AVG : 90.64 %	10 MIN : NLT 40% (Q) 30 MIN : NLT 80% (Q)
10.00	UNIFORMITY OF DOSAGE UNITS	AVG : 97.02 % MIN : 89.28 % MAX : 102.77 %	BY CONTENT UNIFORMITY : ACCEPTANCE VALUE L1 < OR = TO 15, L2 < OR = TO 25
11.00	ASSAY	38.64 MG 96.60 %	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"

Analysis By JANAK PATIDAR SR.QC-OFFICER 24/07/24	Checked By CHETAN QC-EXECUTIVE 24/07/24	Approved BY MAYUR SR. QC-EXECUTIVE 24/07/24
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