



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

Product Name : TADARISE-5 TABLET	A.R. No. : FPE230083
Packing : 10x10 TAB	Release Dt. : 04-07-2023
Generic Name : TADALAFIL TABLETS USP 5 MG	T.R. Slip No. : FGTEST2300149
Product Code : TADA15	T.R. Slip Dt. : 04-07-2023
Batch No. : SE-0805	Mfg. Dt. : 06/23
Actual Batch Size : 2,00,000.000 TAB	Exp. Dt. : 05/26
Sample Size : 60.00 Tab	Test As per : USP
Released Qty. : 1,99,880.000 TAB	Specification No. : SPC/FP/TADA15/06
	Specification Dt. : 12-05-2023
	STP No. : MOA/FP/TADA15/06
	Mfg. Lic. No. : GUJ/DRUG/25/1428
	Location : SANTEJ
	Company : SUNRISE

Sr. No.	Test	Result	Specification
1.00	DESCRIPTION	GOLDEN COLOURED FILMCOATED BICONVEX ALMOND SHAPED TABLET WITH BOTH SIDE PLAIN	GOLDEN COLOURED FILMCOATED BICONVEX ALMOND SHAPED TABLET WITH BOTH SIDE PLAIN
2.00	WEIGHT OF 20 TABLETS	6.8220 GM	6.8680 GM ± 5 %
3.00	AVERAGE WEIGHT (TABLET)	341.10 MG	343.4 MG ± 5 %
4.00	UNIFORMITY OF WEIGHT	COMPLIES	AVG. 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 : COMPLIES Lab : HITECH LABORATORY Report No. : HTL/D/FP/230630015 Dt. : 30/06/2023	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	3.86 MM	4.0 ± 0.3 MM
7.00	DISINTEGRATION TIME	02 MIN 18 SEC	NMT 30 MINUTES
8.00	ORGANIC IMPURITIES	NOT DETECTED NOT DETECTED	INDIVIDUAL IMPURITIES : NMT 0.2 % TOTAL IMPURITIES: NMT 0.3 %
9.00	DISSOLUTION	AFTER 10 MIN : 69.03 % AFTER 30 MIN : 92.25 %	AFTER 10 MIN : NLT 40 % (Q) AFTER 30 MIN : NLT 80 % (Q)
10.00	UNIFORMITY OF CONTENT	MIN : 98.22 % MAX : 102.14 %	85.0 % TO 115.0 %

Analysis By CHETAN QC-EXECUTIVE	Checked By MAYUR QC-EXECUTIVE	Approved By QA & QC MANAGER
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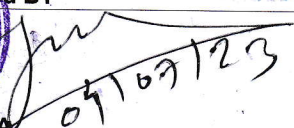
QUALITY CONTROL DEPARTMENT
THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

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	Company : SUNRISE
Mfg. Dt. : 06/23	
Exp. Dt. : 05/26	
Test As per : USP	

Sr. No.	Test	Result	Specification
		AVG : 100.12 %	
11.00	ASSAY	5.04 MG 100.81 %	EACH FILM COATED TABLET CONTAINS: TADALAFIL USP 5.0 MG [LIMIT : 4.5 MG TO 5.5 MG] [BET : 90.0% TO 110.0%]

Conclusion : The above sample complies as per USP

Analysis By	Checked By	Approved BY
 CHETAN QC-EXECUTIVE	 MAYUR QC-EXECUTIVE	 JASMITA QA & QC MANAGER

