



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-10 TABLET
Packing : 10x10 TAB
Generic Name : TADALAFIL TABLET USP 10 MG
Product Code : TADA10
Batch No. : SE-0482
Actual Batch Size : 1,00,000.000 TAB
Sample Size : 60.00 Tab
Released Qty. : 99,920.000 TAB
Remarks : Data transfered from AR NO- SBP220460
Mfg. Dt. : JUL/22
Exp. Dt. : JUN/25
Test As per : USP
A.R. No. : FPE220103
Release Dt. : 16-07-2022
T.R. Slip No. : FGTEST0276
T.R. Slip Dt. : 15-07-2022
Specification No. : SPC/FP/TADA10/06
Specification Dt. : 10-06-2022
STD No. : MQA/FP/TADA10/06
Mfg. Lic. No. : GUJ/DRUG/25/1428
Location : SANTEJ
Company : SUNRISE

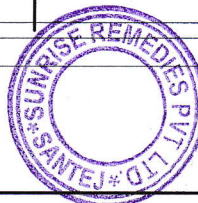
Sr. No.	Test	Result	Specification
1.00	DESCRIPTION	GOLDEN COLOURED ALMOND SHAPED FILM COATED BICONVEX TABLET WITH BOTH SIDE PLAIN	GOLDEN COLOURED ALMOND SHAPED FILM COATED BICONVEX TABLET WITH BOTH SIDE PLAIN
2.00	WEIGHT OF 20 TABLETS	6.7628 GM	6.8700 GM $\pm$ 5 %
3.00	AVERAGE WEIGHT (TABLET)	338.1 MG	343.5 MG $\pm$ 5 %
4.00	UNIFORMITY OF WEIGHT	COMPLIES	AV. WEIGHT OF TAB $\pm$ 5 % NOT MORE THAN 2 OF INDIVIDUAL TABLET WEIGHTS DEVIATE FROM THE AVERAGE WEIGHT $\pm$ 5.0 % AND NONE DEVIATE FROM THE AVERAGE WEIGHT $\pm$ 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 : VAIBHAV ANALYTICAL SERVICES Report No. : 220709/07669/ 90 Dt. : 09/07/2022	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	3.8 MM	4.0 $\pm$ 0.3 MM
7.00	DISINTEGRATION TIME	05 MIN 45 SEC	NMT 30 MINUTES
8.00	ORGANIC IMPURITIES	NOT DETECTED	INDIVIDUAL IMPURITIES : NMT 0.2 % TOTAL IMPURITIES : NMT 0.3 %
9.00	DISSOLUTION	10 MIN : 82 %	10 MIN : NLT 40% (Q)

Checked By

HIMANSHU
Q.C.OFFICER

Approved BY

BHUMIKA
QC MANAGER





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FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name	: TADARISE-10 TABLET	A.R. No.	: FPE220103
Packing	: 10x10 TAB	Release Dt.	: 16-07-2022
Generic Name	: TADALAFIL TABLET USP 10 MG	T.R. Slip No.	: PGTEST0270
		T.R. Slip Dt.	: 15-07-2022
Product Code	: TADA10	Specification No.	: SPC/FP/TADA10/06
Batch No.	: SE-0482	Specification Dt.	: 10-06-2022
Actual Batch Size	: 1,00,000.000 TAB	STD No.	: MOA/FP/TADA10/06
Sample Size	: 60.00 Tab	Mfg. Lic. No.	: GUJ/DRUG/25/1428
Released Qty.	: 99,920.000 TAB	Location	: SANTEJ
Remarks	: Data transfered from AR NO- SBP220460	Company	: SUNRISE

Sr. No.	Test	Result	Specification
		30 MIN : 99 %	30 MIN : NLT 80% (Q)
10.00	UNIFORMITY OF CONTENT	MIN : 96 % MAX : 101.0 % AVG : 98.6 %	85.0 % TO 115.0 %
11.00	ASSAY	RESULT 9.9 MG 99.0 %	EACH FILM COATED TABLET CONTAINS : TADALAFIL USP 10.0 MG [LIMIT : 9.0 MG TO 11.0 MG] [BET : 90.0 % TO 110.0 %]

Conclusion : The above sample complies as per USP

Checked By


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Q.C.OFFICER

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QC MANAGER

