



SUNRISE REMEDIES PVT LTD

BLOCK NO.2244, OPP. SHAH ALLOYS LTD, AT-SANTEJ,
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QUALITY CONTROL DEPARTMENT THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F)) FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Page 1 of 2

Product Name : TADARISE-20 TABLET	A.R. No. : FPST230214
Packing : 10x10 TAB	Release Dt. : 17-02-2024
Generic Name : TADALAFIL TABLETS IP 20 MG	T.R. Slip No. : FGTEST2300637
Product Code : TADA55	T.R. Slip Dt. : 17-02-2024
Batch No. : ST-4449	Specification No. : SPC/FP/TADA55/00
Actual Batch Size : 2,50,000.00 TAB	Specification Dt. : 15-10-2022
Sample Size : 1.00 Strip	STP No. : MOA/FP/TADA55/00
Released Qty. : 2,49,000.00 TAB	Mfg. Lic. No. : GUI/DRUG/25/1428
Mfg. Dt. : 01/24	Location : SANTEJ
Exp. Dt. : 12/26	Company : SUNRISE
Test As per : IP	

Sr. No.	Test	Result	Specification
1.00	DESCRIPTION	GOLDEN YELLOW COLORED FILM COATED BICONVEX ALMOND SHAPED TABLET WITH BOTH SIDE PLAIN.	GOLDEN YELLOW COLORED FILM COATED BICONVEX ALMOND SHAPED TABLET WITH BOTH SIDE PLAIN.
2.00	WEIGHT OF 20 TABLETS	6.8501 GM	6.8680 GM ± 5 %
3.00	AVERAGE WEIGHT (TABLET)	342.51 MG	343.4 MG ± 5 %
4.00	UNIFORMITY OF WEIGHT	COMPLIES	AVG. WEIGHT OF TAB ± 5% NOT MORE THAN 2 OF INDIVIDUAL TABLET WEIGHTS DEVIATE FROM THE AVERAGE WEIGHT ± 5.0 % AND NONE DEVIATE FROM THE AVERAGE WEIGHT ± 10.0 %
5.00	DISINTEGRATION TIME	04 MIN 17 SEC	NOT MORE THAN 30 MINUTES
6.00	THICKNESS	3.91 MM	4.2 ± 0.3 MM
7.00	IDENTIFICATION	IN THE ASSAY, THE PRINCIPAL PEAK IN THE CHROMATOGRAM OBTAINED WITH THE TEST SOLUTION CORRESPONDS TO THE PEAK IN THE CHROMATOGRAM OBTAINED WITH THE REFERENCE SOLUTION (A)	IN THE ASSAY, THE PRINCIPAL PEAK IN THE CHROMATOGRAM OBTAINED WITH THE TEST SOLUTION SHALL CORRESPOND TO THE PEAK IN THE CHROMATOGRAM OBTAINED WITH THE REFERENCE SOLUTION (A)
8.00	DISSOLUTION	10 MIN : 73.46 % 30 MIN : 101.04 %	10 MIN : NMT 40 % (D) 30 MIN : NMT 80 % (D)
9.00	UNIFORMITY OF CONTENT	AVG : 100.99 % MIN : 97.24 % MAX : 103.80 %	BY CONTENT UNIFORMITY : 85.0 % TO 115.0 %
10.00	RELATED SUBSTANCES	NOT DETECTED	OTHER IMPURITY : NMT 0.2 %

Analysis By

Checked By

Approved BY

CHETAN
QC-EXECUTIVE

17/02/24

MAYUR
SR. QC-EXECUTIVE

17/02/24

JASMITA
QA & QC MANAGER

17/02/24



