

SUNRISE REMEDIES PVT. LTD.

Formerly named as : SUNRISE REMEDIES PRIVATE LIMITED

BLOCK NO. 2244,,OPP. SHAH ALLOYS LTD,,TAL.: KALOL,,SANTEJ-382721

REG.OFF.: 104, SAHJANAND COMPLEX,,NR. THALTEJ CROSS ROAD,,S.G.HIGHWAY,,AHMEDABAD-380059

C.I.No. : U24231GJ1996PTC028804

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

Product Name : TADARISE PRO-20 TABLET	A.R. No. : FPE210453
Packing : 10x10 TAB	Rel. Dt. : 23-03-2022
Generic Name : TADALAFIL TABLET 20MG	T.R. Slip No. : PAQA211071
Product Code : TADA04	T.R. Slip Dt. : 23-03-2022
Batch No. : SE-0372	Analysis Date : 23-03-2022
Actual Batch Size : 100000 TAB (1000 BOX)	Specification No. : SPEC/FP/TADA04/05
Packing Batch Size : 100000 TAB	Specification Dt. : 15-06-2020
Sample Size : 60.000 TAB	STP No. : MOA/FP/TADA04/05
Released Qty : 100000.000 TAB (1000 BOX)	Location : SANTEJ
Remarks :	Make : SUNRISE
Mfg. Dt. : 03/2022	
Exp. Dt. : 02/2025	
Test Packing : 60 TAB	
Mfg. Lic No. : G/25/1428	
Test As Per : IH	


Sr.	Test	Result	Specification
1	DESCRIPTION	PINK COLOURED UNCOATED BICONVEX ALMOND SHAPED TABLET WITH BOTH SIDE PLAIN.	PINK COLOURED UNCOATED BICONVEX ALMOND SHAPED TABLET WITH BOTH SIDE PLAIN.
2	WEIGHT OF 20 TABLETS	6.7054 GM	6.7000 GM \pm 5 %
3	AVERAGE WEIGHT (TABLETS)	335.3 MG	335.0 MG \pm 5 %
4	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	DISINTEGRATION TIME	05 MIN 20 SEC	NOT MORE THAN 15 MINUTES
6	THICKNESS	3.9 MM	4.0 \pm 0.3 MM
7	HARDNESS	8.1 KG/CM ²	NOT LESS THAN 3.0 KG/CM ²
8	FRIABILITY	0.1 %	NOT MORE THAN 1.0 %
9	IDENTIFICATION	IDENTIFICATION A : THE IR SPECTRA OF THE SAMPLE IS CONCORDANT WITH THE REFERENCE SPECTRA OF TADALAFIL. HENCE COMPLIES. IDENTIFICATION B : THE RETENTION TIME OF THE SAMPLE SOLUTION CORRESPONDS TO THAT OF THE STANDARD SOLUTION, AS OBTAINED IN THE ASSAY. Lab : VAIBHAV ANALYTICAL SERVICES Report No. : 220314/24990/72	IDENTIFICATION A : THE IR SPECTRA OF THE TEST SOLUTION SHALL BE CONCORDANT WITH THE IR SPECTRA OF STANDARD SOLUTION. IDENTIFICATION 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.


Conclusion : The above sample complies as per IH.

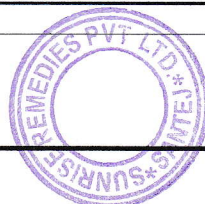
In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

ANALYSIS BY

APPROVED BY


HIMANSHU THAKOR
LAB CHEMIST


BHUMIKA G RATHOD
MANAGER Q.C.



FGANLCERTQA

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Sr.	Test	Result	Specification
		Dt. : 23-03-22	
10	ORGANIC IMPURITIES	NOT DETECTED	INDIVIDUAL IMPURITIES : NMT 0.2 % TOTAL IMPURITIES : NMT 0.3 %
11	DISSOLUTION	10 MIN : 62.84 % 30 MIN : 94.51 % Lab : VAIBHAV ANALYTICAL SERVICES Report No. : 220314/24990/72 Dt. : 23-03-22	10 MIN : NLT 40% (Q) 30 MIN : NLT 80% (Q)
12	UNIFORMITY OF CONTENT	MIN : 96.73 % MAX : 99.67 % AVG : 98.28 %	85.0 % TO 115.0 %
13	ASSAY	RESULT LABEL CLAIM 20.1 MG 20.0 MG 100.5 %	EACH UNCOATED TABLET CONTAINS: TADALAFIL 20.0 MG [LIMIT : 18.0 MG TO 22.0 MG] [BET : 90.0 % TO 110.0 %]

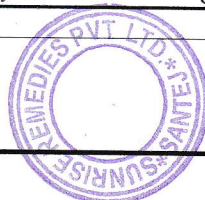
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