

BLOCK NO.2244, OPP. SHAH ALLOYS LTD, AT-SANTEJ,
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QUALITY CONTROL DEPARTMENT

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THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name	: SUPER TADARISE TABLET	A.R. No.	: FPE220055
Packing	: 10x10 TAB	Release Dt.	: 18-05-2022
Generic Name	: TADALAFIL WITH DAPOXETINE TABLET	T.R. Slip No.	: FGTEST0125
		T.R. Slip Dt.	: 18-05-2022
Product Code	: SUPE05	Mfg. Dt. :	MAY/22
Batch No.	: SE-0437	Exp. Dt. :	APR/24
Actual Batch Size	: 2,00,000.000 TAB	Test As per :	USP
Sample Size	: 60.00 Tab	Specification No. :	SPC/FP/SUPE05/05
Released Qty.	: 1,97,340.000 TAB	Specification Dt. :	02-04-2021
		STP No.	: MOA/FP/SUPE05/05
		Mfg. Lic. No.	: GUJ/DRUG/25/1428
		Location	: SANTEJ
		Company	: SUNRISE

Sr. No.	Test	Result	Specification
1.00	DESCRIPTION	GOLDEN YELLOW COLOURED FILMCOATED BICONVEX TRIANGULAR SHAPED TABLET WITH ONE SIDE EMBOSSED SRPL AND OTHER SIDE PLAIN	GOLDEN YELLOW COLOURED FILMCOATED BICONVEX TRIANGULAR SHAPED TABLET WITH ONE SIDE EMBOSSED SRPL AND OTHER SIDE PLAIN
2.00	WEIGHT OF 20 TABLETS	10.1067 GM	10.2500 GM $\pm$ 5 %
3.00	AVERAGE WEIGHT (TABLET)	505.34 MG	512.5 MG $\pm$ 5 %
4.00	UNIFORMITY OF WEIGHT	COMPLIES	AVG. 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	THICKNESS	4.7 MM	4.7 $\pm$ 0.3 MM
6.00	DISINTEGRATION TIME	00 MIN 52 SEC	NMT 30 MINUTES
7.00	DISSOLUTION	MIN : 98 % MAX : 100 % AVG : 99 % MIN : 94 % MAX : 100 % AVG : 97 %	TADALAFIL : NLT 70.0% DAPOXETINE : NLT 70.0%
8.00	ASSAY	RESULT LABEL CLAIM 20.14 MG 20.0 MG 100.7 % 59.74 MG 60.0 MG 99.57 %	EACH FILM COATED TABLET CONTAINS : TADALAFIL 20.0 MG [LIMIT : 18.0 MG TO 22.0 MG] [LIMIT : 90.0% TO 110.0%] DAPOXETINE HYDROCHLORIDE EQ. TO DAPOXETINE 60.0 MG

Checked By

Approved BY

NIDHI
Q.C.OFFICER

BHUMIKA
QC MANAGER

