



SUNRISE REMEDIES PVT LTD

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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 ZHEWITRA TABLET	A.R. No.	: FPE220381
Packing	: 1X4 TAB	Release Dt.	: 24-03-2023
Generic Name	: VARDENAFIL WITH DAPOXETINE HCI TABLETS	T.R. Slip No.	: FGTEST1071
		T.R. Slip Dt.	: 24-03-2023
Product Code	: SUPE04	Mfg. Dt.	: 03/23
Batch No.	: SE-0733	Exp. Dt.	: 02/25
Actual Batch Size	: 20,000.000 TAB	Test As per	: IHS
Sample Size	: 10.00 TAB	Specification No.	: SPC/FP/SUPE04/05
Released Qty.	: 19,620.000 TAB	Specification Dt.	: 27-09-2022
		STP No.	: MOA/FP/SUPE04/05
		Mfg. Lic. No.	: GUJ/DRUG/25/1428
		Location	: SANTEJ
		Company	: SUNRISE

Sr. No.	Test	Result	Specification
1.00	DESCRIPTION	GOLDEN COLORED TRIANGLE SHAPED FILM COATED BICONVEX TABLET WITH ONE SIDE EMBOSSED "SRPL" AND OTHER SIDE PLAIN.	GOLDEN COLORED TRIANGLE SHAPED FILM COATED BICONVEX TABLET WITH ONE SIDE EMBOSSED "SRPL" AND OTHER SIDE PLAIN.
2.00	WEIGHT OF 20 TABLETS	10.2626 GM	10.2500 GM $\pm$ 5 %
3.00	AVERAGE WEIGHT (TABLET)	513.13 MG	512.5 MG $\pm$ 5 %
4.00	UNIFORMITY OF WEIGHT	COMPLIES	AV. WEIGHT OF TAB $\pm$ 5% NOT MORE THAN 2 OF INDIVIDUAL TABLET WEIGHT DEVIATE FROM THE AVERAGE WEIGHT $\pm$ 5.0 % AND NONE DEVIATE FROM THE AVERAGE WEIGHT $\pm$ 10.0 %.
5.00	DISINTEGRATION TIME	01 MIN 27 SEC	NOT MORE THAN 30 MINUTES
6.00	THICKNESS	4.94 MM	5.0 $\pm$ 0.2 MM
7.00	DISSOLUTION	MIN : 95.63 % MAX : 99.07 % AVG : 97.97 % MIN : 97.77 % MAX : 99.77 % AVG : 98.57 %	VARDENAFIL : NLT 70 % DAPOXETINE : NLT 70 %
8.00	ASSAY	19.64 MG 98.20 % 57.28 MG 95.46 %	EACH FILM COATED TABLET CONTAINS : VARDENAFIL HYDROCHLORIDE EQ. TO VARDENAFIL 20.0 MG [LIMIT : 18.0 MG TO 22.0 MG] [BET : 90.0 % TO 110.0 %] DAPOXETINE HYDROCHLORIDE EQ. TO DAPOXETINE 60.0 MG

Analysis By

Checked By

Approved BY

DHAVAL
Q.C.OFFICER

MAYUR
QC-EXECUTIVE

JASMITA
QA & QC MANAGER

MAYUR1

FgAnlCert04_REN07

JASMITA
QA & QC MANAGER