

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

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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 : ZHEWITRA-20 TABLET Packing : 10x10 TAB Generic Name : VARDENAFIL TABLET 20MG Product Code : ZHEW01 Batch No. : SE-0308 Actual Batch Size : 100000 TAB (1000 BOX) Packing Batch Size : 100000 TAB Sample Size : 60.000 TAB Released Qty : 100000.000 TAB (1000 BOX) Remarks :	A.R. No. : FPE210372 Rel. Dt. : 31-01-2022 T.R. Slip No. : PAQA210881 T.R. Slip Dt. : 31-01-2022 Analysis Date : 31-01-2022 Specification No. : SPC/FP/ZHEW01/05 Specification Dt. : 03-04-2020 STP No. : MOA/FP/ZHEW01/05 Location : SANTEJ Make : SUNRISE
Mfg. Dt. : 01/2022 Exp. Dt. : 12/2023 Test Packing: 60 TAB Mfg. Lic No. : G/25/1428 Test As Per : IH	

Sr.	Test	Result	Specification
1	DESCRIPTION	YELLOW COLOURED ROUND SHAPED FILM COATED BICONVEX TABLET WITH BOTH SIDE PLAIN.	YELLOW COLOURED ROUND SHAPED FILM COATED BICONVEX TABLET WITH BOTH SIDE PLAIN.
2	WEIGHT OF 20 TABLETS	3.8404 GM	3.8000 GM \pm 7.5 %
3	AVERAGE WEIGHT (TABLETS)	192.0 MG	190.0 MG \pm 7.5 %
4	UNIFORMITY OF WEIGHT	COMPLIES	AV. WEIGHT OF TAB \pm 7.5 % NOT MORE THAN 2 OF INDIVIDUAL CAPSULES WEIGHTS DEVIATE FROM THE AVERAGE WEIGHT \pm 7.5 % AND NONE DEVIATE FROM THE AVERAGE WEIGHT \pm 10.0 %
5	DISINTEGRATION TIME	03 MIN 46 SEC	NOT MORE THAN 30 MINUTES
6	THICKNESS	4.0 MM	4.0 \pm 0.3 MM
7	DISSOLUTION	MIN : 97 % MAX : 99 % AVG : 98 %	NOT LESS THAN 70 %
8	UNIFORMITY OF CONTENT	MIN : 97.41 % MAX : 99.26 % AVG : 98.18 %	85.0 % TO 115.0 %
9	ASSAY	RESULT LABEL CLAIM 19.67 MG 20.0 MG 98.3 %	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 %]

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  JINAL B PATEL LAB CHEMIST	APPROVED BY  BHUMIKA G RATHOD MANAGER Q.C.
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