



SUNRISE REMEDIES PVT LTD

BLOCK NO.2244, OPP. SHAH ALLOYS LTD, AT-SANTEJ,
TAL.:KALOL- District : GANDHINAGAR State : GUJARAT -382721
Phone(O) :2764 286719 E-Mail:-accounts@sunriseremedies.in

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

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 : ZHEWITRA-20 TABLET	A.R. No. : FPE230340
Packing : 10x10 TAB	Release Dt. : 02-02-2024
Generic Name : VARDENAFIL TABLETS BP 20MG	T.R. Slip No. : FGTEST2300590
Product Code : ZHEW01	T.R. Slip Dt. : 02-02-2024
Batch No. : SE-1019	Specification No. : SPC/FP/ZHEW01/06
Actual Batch Size : 50,000.00 TAB	Specification Dt. : 02-04-2022
Sample Size : 1.00 Strip	STP No. : MOA/FP/ZHEW01/06
Released Qty. : 49,500.00 TAB	Mfg. Lic. No. : GUJ/DRUG/25/1428
Mfg. Dt. : 01/24	Location : SANTEJ
Exp. Dt. : 12/25	Company : SUNRISE
Test As per : BP	


Sr. No.	Test	Result	Specification
1.00	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.
2.00	WEIGHT OF 20 TABLETS	3.7754 GM	3.8000 GM ±7.5 %
3.00	AVERAGE WEIGHT (TABLET)	188.77 MG	190.0 MG ± 7.5 %
4.00	UNIFORMITY OF WEIGHT	COMPLIES	AVG. WT. OF TABLET ± 7.5 % NOT MORE THAN 2 OF INDIVIDUAL TABLETS WEIGHTS DEVIATE FROM THE AVERAGE WEIGHT ± 7.5 % AND NONE DEVIATE FROM THE AVERAGE WEIGHT ± 10.0 %
5.00	THICKNESS	3.86 MM	4.0 ± 0.3 MM
6.00	DISINTEGRATION TIME	01 MIN 15 SEC	NMT 30 MINUTES
7.00	IDENTIFICATION	A. THE PRINCIPAL SPOT IN THE CHROMATOGRAM OBTAINED WITH SOLUTION (1) IS CORRESPONDS IN POSITION AND SIZE TO THAT IN THE CHROMATOGRAM OBTAINED WITH SOLUTION (2). B. IN THE ASSAY, THE PRINCIPAL PEAK IN THE CHROMATOGRAM OBTAINED WITH SOLUTION (1) IS HAVE THE SAME RETENTION TIME AS THE PRINCIPAL PEAK IN THE CHROMATOGRAM OBTAINED WITH SOLUTION (2)	A. THE PRINCIPAL SPOT IN THE CHROMATOGRAM OBTAINED WITH SOLUTION (1) CORRESPOND IN POSITION AND SIZE TO THAT IN THE CHROMATOGRAM OBTAINED WITH SOLUTION (2). B. IN THE ASSAY, THE PRINCIPAL PEAK IN THE CHROMATOGRAM OBTAINED WITH SOLUTION (1) SHALL HAVE THE SAME RETENTION TIME AS THE PRINCIPAL PEAK IN THE CHROMATOGRAM OBTAINED WITH SOLUTION (2)
8.00	DISSOLUTION	AVG : 86.31 % MIN : 85.60 % MAX : 87.82 %	NLT 75 % (Q)

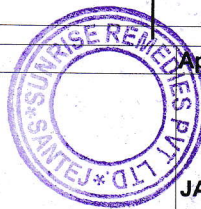
Analysis By

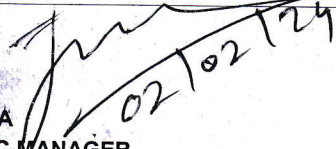
Checked By

Approved BY


02/02/24
AMEE
Q.C.OFFICER


02/02/24
MAYUR
SR. QC-EXECUTIVE




02/02/24
JASMITA
QA & QC MANAGER



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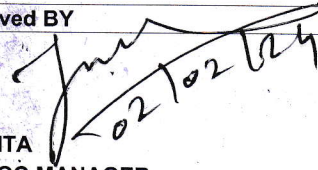
QUALITY CONTROL DEPARTMENT
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Exp. Dt. : 12/25	Company : SUNRISE
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Sr. No.	Test	Result	Specification
9.00	UNIFORMITY OF CONTENT	AVG : 94.21 % MIN : 91.91 % MAX : 95.25 %	85.0 % TO 115.0 %
10.00	RELATED SUBSTANCES	ANY PEAK DUE TO IMPURITY A : NOT DETECTED AREA OF ANY PEAK DUE TO IMPURITY 2 : NOT DETECTED AREA OF ANY OTHER SECONDARY : NOT DETECTED SUM OF THE AREAS OF ALL SECONDARY PEAKS : NOT DETECTED LAB : HITECH LABORATORY R.NO. : HTL/D/FP/240120008 DATE : 24/01/2024	ANY PEAK DUE TO IMPURITY A : NMT 0.5 % AREA OF ANY PEAK DUE TO IMPURITY 2 : NMT 0.3 % AREA OF ANY OTHER SECONDARY : NMT 0.2 % SUM OF THE AREAS OF ALL SECONDARY PEAKS : NMT 1.2 %
11.00	ASSAY	19.81 MG 99.05 %	EACH FILM COATED TABLET CONTAINS : VARDENAFIL HYDROCHLORIDE TRIHYDRATE BP 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 BP. "This computer generated certificate of analysis is valid without signature"

Analysis By  02/02/24 AMEE Q.C.OFFICER	Checked By  02/02/24 MAYUR SR. QC-EXECUTIVE	Approved BY  02/02/24 JASMITA QA & QC MANAGER
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