



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

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FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : ZHEWITRA -10 TABLET	A.R. No. : FPE230109
Packing : 10x10 Tab	Release Dt. : 22-07-2023
Generic Name : VARDENAFIL TABLETS BP 10MG	T.R. Slip No. : FGTEST2300188
	T.R. Slip Dt. : 21-07-2023
Product Code : ZHEW09	Specification No. : SPC/FP/ZHEW09/02
Batch No. : SE-0816	Specification Dt. : 29-04-2022
Actual Batch Size : 20,000.000 TAB	STP No. : MOA/FP/ZHEW09/02
Sample Size : 1.00 Strip	Mfg. Lic. No. : GUJ/DRUG/25/1428
Released Qty. : 19,680.000 TAB	Location : SANTEJ
	Company : SUNRISE
Mfg. Dt. : 07/23	
Exp. Dt. : 06/25	
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	3.9060 GM	3.8960 GM ± 7.5 %
3.00	AVERAGE WEIGHT (TABLET)	195.30 MG	194.8 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	3.90 MM	4.0 ± 0.3 MM
6.00	DISINTEGRATION TIME	00 MIN 59 SEC	NMT 30 MINUTES
7.00	DISSOLUTION	MIN : 100.42 % MAX : 103.65 % AVG : 102.29 %	NLT 75 % (Q)
8.00	UNIFORMITY OF CONTENT	MIN : 98.64 % MAX : 105.00 % AVG : 101.39 %	85.0% TO 115.0%
9.00	RELATED SUBSTANCES	NOT DETETED NOT DETETED NOT DETETED NOT DETETED	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 :

Analysis By	Checked By	Approved By
22/07/23 DHAVAL Q.C.OFFICER	22/07/23 MAYUR QC-EXECUTIVE	22/07/23 JASMITA QA & QC MANAGER

MAYUR1



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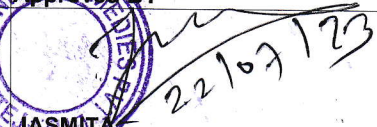
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Mfg. Dt. : 07/23	Location : SANTEJ
Exp. Dt. : 06/25	Company : SUNRISE
Test As per : BP	

Sr. No.	Test	Result	Specification
		Lab : HITECH LABORATORY Report No.: HTL/D/FP/230718024 Date : 20/07/2023	NMT 1.2 %
10.00	ASSAY	9.93 MG 99.31 %	EACH FILM COATED TABLET CONTAINS : VARDENAFIL HCL EQ.TO VARDENAFIL 10.0 MG [LIMIT : 9.5 MG TO 10.5 MG] [BET : 95.0 % TO 105.0 %]

Conclusion : The above sample complies as per BP

Analysis By  22/07/23 DHAVAL Q.C.OFFICER	Checked By  22/07/23 MAYUR QC-EXECUTIVE	Approved BY  22/07/23 JASMITA QA & QC MANAGER
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