



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

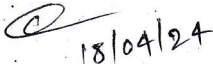
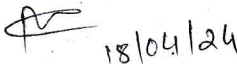
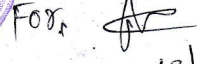
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THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name	: MALEGRA-200 TABLET	A.R. No.	: FPE240025
Packing	: 10x10 TAB	Release Dt.	: 18-04-2024
Generic-Name	: SILDENAFIL TABLETS USP 200 MG	T.R. Slip No.	: FGTEST2400048
		T.R. Slip Dt.	: 18-04-2024
Product Code	: MALE16	Specification No.	: SPC/FP/MALE16/05
Batch No.	: SE-1098	Specification Dt.	: 23-02-2023
Actual Batch Size	: 2,00,000.00 TAB	STP No.	: MOA/FP/MALE16/05
Sample Size	: 1.00 Strip	Mfg. Lic. No.	: GUJ/DRUG/25/1428
Released Qty.	: 1,99,000.00 TAB	Location	: SANTEJ
		Company	: SUNRISE
	Mfg. Dt. : 04/24		
	Exp. Dt. : 03/27		
	Test As per : USP		

Sr. No.	Test	Result	Specification
1.00	DESCRIPTION	BLUE COLOURED DIAMOND SHAPED BICONVEX FILMCOATED TABLET WITH BOTH SIDE PLAIN	BLUE COLOURED DIAMOND SHAPED BICONVEX FILMCOATED TABLET WITH BOTH SIDE PLAIN
2.00	WEIGHT OF 20 TABLETS	10.0526 GM	10.0500 GM $\pm$ 5 %
3.00	AVERAGE WEIGHT (TABLET)	502.63 MG	502.5 MG $\pm$ 5 %
4.00	UNIFORMITY OF WEIGHT	COMPLIES	AVG. 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	IDENTIFICATION	A : COMPLIES B : THE RETENTION TIME OF THE SAMPLE SOLUTION CORRESPONDS TO THAT OF THE STANDARD SOLUTION, AS OBTAINED IN THE ASSAY LAB : HITECH LABORATORY REPORT NO. : HTL/D/FP/240409012 DATE : 11/04/2024	A : THE IR-SPECTRA OF THE TEST SOLUTION SHALL BE CONCORDANT WITH THE IR SPECTRA OF STANDARD SOLUTION B : THE RETENTION TIME OF THE SAMPLE SOLUTION SHALL CORRESPOND TO THAT OF THE STANDARD SOLUTION, AS OBTAINED IN THE ASSAY
6.00	THICKNESS	5.02 MM	5.1 $\pm$ 0.3 MM
7.00	DISINTEGRATION TIME	01 MIN 11 SEC	NOT MORE THAN 30 MINUTES
8.00	DISSOLUTION	AVG : 99.79 % MIN : 97.50 % MAX : 102.68 %	NOT LESS THAN 80 % (Q)
9.00	ORGANIC IMPURITIES	NOT DETECTED	SILDENAFIL N-OXIDE : NMT 0.20 %

Analysis By	Checked By	Approved BY
 18/04/24 CHETAN QC-EXECUTIVE	 18/04/24 MAYUR SR. QC-EXECUTIVE	 18/04/24 JASMITA QA & QC MANAGER



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FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name	: MALEGRA-200 TABLET	A.R. No.	: FPE240025
Packing	: 10x10 TAB	Release Dt.	: 18-04-2024
Generic Name	: SILDENAFIL TABLETS USP 200 MG	T.R. Slip No.	: FGTEST2400048
		T.R. Slip Dt.	: 18-04-2024
Product Code	: MALE16	Specification No.	: SPC/FP/MALE16/05
Batch No.	: SE-1098	Specification Dt.	: 23-02-2023
Actual Batch Size	: 2,00,000.00 TAB	STP No.	: MOA/FP/MALE16/05
Sample Size	: 1.00 Strip	Mfg. Lic. No.	: GUJ/DRUG/25/1428
Released Qty.	: 1,99,000.00 TAB	Location	: SANTEJ
		Company	: SUNRISE

Sr. No.	Test	Result	Specification
		NOT DETECTED NOT DETECTED LAB : HITECH LABORATORY REPORT NO. : HTL/D/FP/240409012 DATE : 11/04/2024	ANY INDIVIDUAL DEGRADATION PRODUCT : NMT 0.20 % TOTAL DEGRADATION PRODUCT : NMT 0.5 %
10.00	UNIFORMITY OF DOSAGE UNITS	AVG : 100.95 % MIN : 99.32 % MAX : 102.80 %	BY WEIGHT VARIATION ACCEPTANCE VALUE L1 < OR = TO 15, L2 < OR = TO 25
11.00	ASSAY	201.91 MG 100.95 %	EACH FILM COATED TABLET CONTAINS : SILDENAFIL CITRATE USP EQ. TO SILDENAFIL 200.0 MG [LIMIT : 180.0 MG TO 220.0 MG] [BET : 90.0 % TO 110.0 %]

Conclusion : The above sample complies as per USP. "This computer generated certificate of analysis is valid without signature"

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 18/04/24 CHETAN QC-EXECUTIVE	 18/04/24 MAYUR SR. QC-EXECUTIVE	 18/04/24 JASMITA QA & QC MANAGER