

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 : CHOCOGRA-100 TABLET	A.R. No. : FPE220174
Packing : 1X5 TAB	Release Dt. : 24-09-2022
Generic Name : SILDENAFIL TABLETS BP 100MG	T.R. Slip No. : FGTEST0430
	T.R. Slip Dt. : 24-09-2022
Product Code : CHOC05	Specification No. : SPC/FP/CHOC05/00
Batch No. : SE-0544	Specification Dt. : 06-07-2021
Actual Batch Size : 10,000.000 TAB	STP No. : MOA/FP/CHOC05/00
Sample Size : 60.00 Tab	Mfg. Lic. No. : GUJ/DRUG/25/1428
Released Qty. : 9,680.000 TAB	Location : SANTEJ
Remarks : DATA TRANSFERED FROM A.R. NO. SBP220701	Company : SUNRISE

Sr. No.	Test	Result	Specification
1.00	DESCRIPTION	CHOCOLATE BROWN COLOURED UNCOATED TRIANGLE SHAPED TABLET WITH ONE SIDE EMBOSSED "SRPL" AND OTHER SIDE PLAIN.	CHOCOLATE BROWN COLOURED UNCOATED TRIANGLE SHAPED TABLET WITH ONE SIDE EMBOSSED "SRPL" AND OTHER SIDE PLAIN.
2.00	WEIGHT OF 20 TABLETS	10.4950 GM	10.5000 GM $\pm$ 5 %
3.00	AVERAGE WEIGHT (TABLET)	524.8 MG	525.0 MG $\pm$ 5 %
4.00	UNIFORMITY OF WEIGHT	COMPLIES	AV. WEIGHT OF TABLET $\pm$ 5 % NOT MORE THAN 2 OF INDIVIDUAL TABLETS WEIGHTS DEVIATE FROM THE AVERAGE WEIGHT $\pm$ 5.0 % AND NONE DEVIATE FROM THE AVERAGE WEIGHT $\pm$ 10.0 %
5.00	IDENTIFICATION	A : THE PRINCIPAL SPOT IN THE CHROMATOGRAM OBTAINED WITH SOLUTION (1) CORRESPONDS IN POSITION AND COLOUR TO THAT IN THE CHROMATOGRAM OBTAINED WITH SOLUTION (2). B : IN THE ASSAY, THE RETENTION TIME OF THE MAJOR PEAK OF THE SAMPLE SOLUTION CORRESPONDS TO THAT OF THE STANDARD SOLUTION, AS OBTAINED IN THE ASSAY.	A : THE PRINCIPAL SPOT IN THE CHROMATOGRAM OBTAINED WITH SOLUTION (1) CORRESPONDS IN POSITION AND COLOUR TO THAT IN THE CHROMATOGRAM OBTAINED WITH SOLUTION (2). B : IN THE ASSAY, THE RETENTION TIME OF THE MAJOR PEAK OF THE SAMPLE SOLUTION SHALL CORRESPOND TO THAT OF THE STANDARD SOLUTION, AS OBTAINED IN THE ASSAY.
6.00	THICKNESS	4.5 MM	4.5 $\pm$ 0.3 MM
7.00	HARDNESS	5.5 KG/CM ²	NLT 3.0 KG/CM ²
8.00	FRIABILITY	0.2 %	NMT 1.0%
9.00	DISINTEGRATION TIME	08 MIN 15 SEC	NMT 15 MINUTES
10.00	DISSOLUTION	MIN : 94% MAX : 96% AVG : 95%	NLT 75% (Q)

Checked By	Approved BY
 HIMANSHU Q.C.OFFICER	 BHUMIKA QC MANAGER



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Generic Name :	SILDENAFIL TABLETS BP 100MG	T.R. Slip No. :	FGTEST0430
		T.R. Slip Dt. :	24-09-2022
Product Code :	CHOC05	Specification No. :	SPC/FP/CHOC05/00
Batch No. :	SE-0544	Specification Dt. :	06-07-2021
Actual Batch Size :	10,000.000 TAB	STP No. :	MOA/FP/CHOC05/00
Sample Size :	60.00 Tab	Mfg. Lic. No. :	GUI/DRUG/25/1428
Released Qty. :	9,680.000 TAB	Location :	SANTEJ
Remarks :	DATA TRANSFERED FROM A.R. NO. SBP220701	Company :	SUNRISE

Sr. No.	Test	Result	Specification
11.00	ORGANIC IMPURITIES	NOT DETECTED	IMPURITY A : NMT 0.3 % OTHER IMPURITY : NMT 0.2 % TOTAL IMPURITY : NMT 0.5 %
12.00	ASSAY	RESULT LABEL CLAIM 99.8 MG 100.0 MG 99.8%	EACH UNCOATED TABLETS CONTAINS : SILDENAFIL CITRATE EQ. TO SILDENAFIL 100.0 MG [LIMIT : 95.0 MG TO 105.0 MG] [BET : 95.0 % TO 105.0 %]

Conclusion : The above sample complies as per BP

Checked By

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HIMANSHU
Q.C.OFFICER

BHUMIKA
QC MANAGER

