

BLOCK NO.2244, OPP. SHAH ALLOYS LTD, AT-SANTEJ,
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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	: AVANA-100 TABLET	A.R. No.	: FPE220116
Packing	: 4 TAB	Release Dt.	: 26-07-2022
Generic Name	: AVANAFIL TABLET 100MG	T.R. Slip No.	: FGTEST0299
		T.R. Slip Dt.	: 26-07-2022
Product Code	: AVAN02	Mfg. Dt.	: JUL/22
Batch No.	: SE-0491	Exp. Dt.	: JUN/24
Actual Batch Size	: 20,000.000 TAB	Test As per	: IHS
Sample Size	: 60.00 Tab	Specification No.	: SPC/FP/AVAN02/04
Released Qty.	: 19,460.000 TAB	Specification Dt.	: 15-08-2020
Remarks	: Data transferred from AR NO- SBP220514	STP No.	: MOA/FP/AVAN02/04
		Mfg. Lic. No.	: GUJ/DRUG/25/1428
		Location	: SANTEJ
		Company	: SUNRISE

Sr. No.	Test	Result	Specification
1.00	DESCRIPTION	MARRON COLORED TRIANGULAR SHAPED FILMCOATED BICONVEX TABLET WITH ONE SIDE PLAIN AND OTHER SIDE EMBOSSED "SRPL".	MARRON COLORED TRIANGULAR SHAPED FILMCOATED BICONVEX TABLET WITH ONE SIDE PLAIN AND OTHER SIDE EMBOSSED "SRPL".
2.00	WEIGHT OF 20 TABLETS	10.3556 GM	10.2000 GM $\pm$ 5 %
3.00	AVERAGE WEIGHT (TABLET)	517.8 MG	510.0 MG $\pm$ 5 %
4.00	UNIFORMITY OF WEIGHT	COMPLIES	AV. WEIGHT OF TAB $\pm$ 5% NOT MORE THAN 2 OF INDIVIDUAL TABLET WEIGHTS DEVIATE FROM THE AVERAGE WEIGHT $\pm$ 5.0 % AND NONE DEVIATE FROM THE AVERAGE WEIGHT $\pm$ 10.0 %
5.00	THICKNESS	5.2 MM	5.0 $\pm$ 0.3 MM
6.00	DISINTEGRATION TIME	00 MIN 50 SEC	NMT 30 MINUTES
7.00	DISSOLUTION	MIN : 98 % MAX : 101 % AVG : 99 %	NLT 70%
8.00	ASSAY	RESULT LABEL CLAIM 100.3 MG 100.0 MG 100.3 %	EACH FILM COATED TABLET CONTAINS : AVANAFIL 100.0 MG [LIMIT : 90.0 MG TO 110.0 MG] [BET : 90.0 % TO 110.0 %]

Conclusion : The above sample complies as per IHS

Checked By

Approved BY

ADITI
Q.C.OFFICER

BHUMIKA
QC MANAGER

