



CERTIFICATE OF ANALYSIS - FINISHED PRODUCT

NAME OF THE SAMPLE	VALIF 20 (Vardenafil Tablets 20 mg)		
PRODUCT CODE	5001312	INSPECTION LOT NO.	40000091551
BATCH NO.	CT03932	BATCH SIZE	90000 BL
MFG. DATE	04.2022	EXP. DATE	03.2025
SAMPLED BY	Abhijit Korde	SAMPLING DATE	10.05.2022
SAMPLED QTY.	18 BL	RELEASED DATE	08.06.2022
PROCESS ORDER NO.	10068833	PACK SIZE	1X10'S

SR.NO.	TEST	SPECIFICATION	RESULT
1.0	Description	Light yellowish brown to yellowish brown coloured, circular, biconvex, film coated tablets with '20' debossed on one side and 'V' debossed on other side.	Light yellowish brown coloured, circular, biconvex, film coated tablets with '20' debossed on one side and 'V' debossed on other side. Complies
2.0	Identification	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that of the peak due to Vardenafil in the chromatogram of the standard preparation, as obtained in the assay.	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that of the peak due to Vardenafil in the chromatogram of the standard preparation, as obtained in the assay. Complies
3.0	Average weight	195.0 mg \pm 5.0% (185.3 mg to 204.8 mg)	197.210 mg
4.0	Uniformity of weight	Not more than 2 of the individual weights deviate from the average weight by more than \pm 7.5% and none deviates by more than \pm 15%.	Min = 195.06 mg, Max = 200.44 mg Avg = 197.632 mg Complies
5.0	Diameter	8.0 mm to 8.3 mm	8.073 mm
6.0	Disintegration time	Not more than 30 minutes	01 min 42 sec Complies
7.0	Water	Not more than 7.0%	3.467 %
8.0	Dissolution	Not less than 70% of the labeled amount released in 30 minutes.	Individual Value 99.720 101.190 100.550 101.100 100.340 100.010 Average- 100.485 Minimum- 99.720

Remark: A - Release (Country: Bangladesh)

Comment: The sample submitted complies with the prescribed Finished product Specification FPS/W/19-20/0022 Ver.02

Analysed By	Vandana Ahire	Checked By	Vinod Umrikar	Approved By	Sudhir Deshpande	
Designation	Asst. Executive	Designation	Asst. Manager	Designation	Manager	
Date	07.06.2022	Date	07.06.2022	Date	07.06.2022	
Printed By :	Prashant Rajhans	Printed On :	08.06.2022 14:41:58	Page No.:	1 of 3	
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			Maximum- 101.190
9.0	Uniformity of content	Not less than 85.0% and not more than 115.0% of the labeled claim.	97.350 99.470 99.390 97.080 97.460 98.660 98.030 97.940 98.260 97.450 Average- 98.109 Minimum- 97.080 Maximum- 99.470
10.0	Assay		
10.1	Vardenafil HCL TH EQV to Vardenafil	Not less than 90.0% and not more than 110.0% of the labeled claim.	101.400 %
11.0	Microbiological purity		
11.1	Total Aerobic Microbial count	Not more than 10 ³ CFU/g	Less than 10 CFU/g Complies
11.2	Total combined yeasts and molds count	Not more than 10 ² CFU/g	Less than 10 CFU/g Complies
11.3	Pathogens		
11.3.1	Bile-Tolerant Gram-Negative Bacteria	Absent	Absent Complies
11.3.2	E.coli	Absent	Absent Complies
11.3.3	Salmonella	Absent	Absent

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SR.NO.	TEST	SPECIFICATION	RESULT
			Complies
11.3.4	S.aureus	Absent	Absent Complies
11.3.5	P.aeruginosa	Absent	Absent Complies
11.3.6	Candida albicans	Absent	Absent Complies

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