Gut No.11/12/14/15, Paithan Road, Chitegaon, F +9

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Maharashtra-INDIA W www.ajantapharma.com

## **CERTIFICATE OF ANALYSIS -FINISHED PRODUCT**

NAME OF THE SAMPLE	VALIF 20 (Vardenafil Tablets 20 mg)		
		T	
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,	Light yellowish brown coloured, circular,
		circular, biconvex, film coated tablets with '20'	biconvex, film coated tablets with '20' debossed
		debossed on one side and 'V' debossed on other side.	on one side and 'V' debossed on other side.
			Complies
2.0	Identification	The retention time of the major peak in the chromatogram	The retention time of the major peak in the
	~	of the sample preparation corresponds to that of the peak	chromatogram of the sample preparation
	7.3.	due to Vardenafil in the chromatogram of the standard	corresponds to that of the peak due to Vardenafil
	J. SP	preparation, as obtained in the assay.	in the chromatogram of the standard preparation,
	~0		as obtained in the assay.
			Complies
	Average weight	$195.0 \text{ mg} \pm 5.0\% \text{ (185.3 mg to 204.8 mg)}$	197.210 mg
4.0	Uniformity of weight	Not more than 2 of the individual weights deviate from	Min = 195.06 mg,Max = 200.44 mg
		the average weight by more than $\pm$ 7.5% and none deviates	Avg = 197.632 mg
		by more than± 15%.	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
	Water	Not more than 7.0%	3.467 %
8.0	Dissolution	Not less than 70% of the labeled amount released in 30	Individual Value
		minutes.	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	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	.0		
Printed By:	Printed By: Prashant Rajhans Printed On: 08.06.2022 14:41:58 Page No.: 1 of 3							
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## **CERTIFICATE OF ANALYSIS -FINISHED PRODUCT**

NAME OF THE SAMPLE	VALIF 20 (Vardenafil Tablets 20	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
			Maximum- 101.190
9.0	Uniformity of content	Not less than 85.0% and not more than 115.0% of the	97.350
		labeled claim.	99.470
			99.390
			97.080
			97.460
	SUDOU.IP	MGUDOU.JP	98.660 98.030 97.940 98.260 97.450 Average- 98.109 Minimum- 97.080 Maximum- 99.470
	, 5,	, 3,	98.030
	$\sim$ $\sim$ $\sim$	~).	97.940
	~0		98.260
			97.450
/			Average- 98.109
-1	9	S	Minimum- 97.080
17			Maximum- 99.470
10.0	Assay	~~	XV
10.1	Vardenafil HCL TH EQV	Not less than 90.0% and not more than 110.0% of the	101.400 %
	to Vardenafil	labeled claim.	
11.0	Microbiological purity		
11.1	Total Aerobic	Not more than 10 <sup>3</sup> CFU/g	Less than 10 CFU/g
	Microbial count		Complies
1	Total combined yeasts	Not more than 10 <sup>2</sup> CFU/g	Less than 10 CFU/g
	and molds count		Complies
	Pathogens		
	Bile-Tolerant	Absent	Absent
	Gram-Negative Bacteria		Complies
11.3.2	E.coli	Absent	Absent
			Complies
11.3.3	Salmonella	Absent	Absent

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	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	.0		
Printed By:	Printed By: Prashant Rajhans Printed On: 08.06.2022 14:41:58 Page No.: 2 of 3							
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## TENGUIDUE **CERTIFICATE OF ANALYSIS -FINISHED PRODUCT**

NAME OF THE SAMPLE	VALIF 20 (Vardenafil Tablets 20	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
			Complies
11.3.4	S.aureus	Absent	Absent
			Complies
11.3.5	P.aeruginosa	Absent	Absent
			Complies
11.3.6	Candida albicans	Absent	Absent
	Q		Complies
	1001.3	1001.	,
12		AGO.	AGO V

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	
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