

CERTIFICATE OF ANALYSIS -FINISHED PRODUCT

NAME OF THE SAMPLE	Valif Oral Jelly 20 mg (Vardenafil Oral Jelly 20 mg/5 g)		
PRODUCT CODE	5004117	INSPECTION LOT NO.	40000098366
BATCH NO.	CT08982	BATCH SIZE	100000 SAH
MFG. DATE	08.2022	EXP. DATE	07.2025
SAMPLED BY	Pravin Kocheta	SAMPLING DATE	04.09.2022
SAMPLED QTY.	84 SAH	RELEASED DATE	12.09.2022
PROCESS ORDER NO.	10078986	PACK SIZE	1X7'S

SR.NO.	TEST	SPECIFICATION	RESULT
1.0	Description	Yellow coloured, homogenized jelly with sweet taste and pleasant odour, with or without particles.	Yellow coloured, homogenized jelly with sweet taste and pleasant odour, without particles. 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 of filled sachet	7.20 g $\pm$ 7.5% (6.66 g to 7.74 g)	7.170 g
4.0	Average net filled weight per sachet	Not less than 5.0 g	5.08 g
5.0	Uniformity of weight (Mass)	Not more than 2 of the individual weight of the contents deviate from the average net filled weight by more than 7.5% and none deviates by more than 15.0%.	Min = 5.0058 g, Max = 5.1410 g Avg = 5.0814 g Complies
6.0	pH	3.0 to 5.0	4.11
7.0	Assay		
7.1	Vardenafil HCL TH BP EQV to Vardenafil	Not less than 90.0% and not more than 110.0% of the labeled claim.	97.400 %
8.0	Microbiological purity		
8.1	Total Aerobic Microbial count	Not more than 10 ² CFU/g	Less than 10 cfu /g Complies
8.2	Total combined yeasts and molds count	Not more than 10 ¹ CFU/g	Less than 10 cfu /g Complies
8.3	Pathogens		

Remark: A - Release (Domestic- Deemed Export)					
Comment: The sample submitted complies with the prescribed Finished product Specification FPS/W/20-21/0038 Ver.00					
Analysed By	Vandana Ahire	Checked By	Sachin Suryawanshi	Approved By	Chandrakant Patil
Designation	Asst. Executive	Designation	Sr. Executive	Designation	Manager
Date	12.09.2022	Date	12.09.2022	Date	12.09.2022
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SR.NO.	TEST	SPECIFICATION	RESULT
8.3.1	Escherichia coli	Absent	Absent Complies

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