

CERTIFICATE OF ANALYSIS - FINISHED PRODUCT

NAME OF THE SAMPLE	TADALIS SX 20 (Tadalafil Tablets IP 20 mg)		
PRODUCT CODE	5002430	INSPECTION LOT NO.	40000091224
BATCH NO.	CT03612	BATCH SIZE	100000 BL
MFG. DATE	04.2022	EXP. DATE	03.2025
SAMPLED BY	Abhijit Korde	SAMPLING DATE	04.05.2022
SAMPLED QTY.	19 BL	RELEASED DATE	18.05.2022
PROCESS ORDER NO.	10071115	PACK SIZE	1X4'S

Note : [a] for Abbreviations. Detail provided in Abbreviation section.

SR.NO.	TEST	SPECIFICATION	RESULT
1.0	Description	Pale yellow coloured, elliptical shaped, film coated tablets, plain on both sides.	Pale yellow coloured, elliptical shaped, film coated tablets, plain on both sides. Complies
2.0	Identification		
2.1	By HPLC [a]	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution (a).	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution (a). Complies
3.0	Average weight	258.0 mg \pm 5.0% (245.1 mg to 270.9 mg)	249.36 mg
4.0	Uniformity of weight	Not more than 2 of the individual weights deviate from the average weight by more than \pm 5% and none deviates by more than \pm 10%.	Min. = 245.00 mg Max. = 254.60 mg Avg. = 249.41 mg Complies
5.0	Disintegration time	Not more than 30 minutes.	05 min. 34 sec. Complies
6.0	Related substances		
6.1	Single maximum impurity	Not more than 0.2%	0.06 %
6.2	Total impurities [a]	Not more than 0.3%	0.06 %
7.0	Dissolution		
7.1	10 minutes	Not less than 40% *(D) of the labeled claim released in 10 minutes	Individual Value 82.00 87.40 82.80 77.20 80.60 84.20 Average- 82.37

Remark: A - Release (Domestic)

Comment: The sample submitted Complies with the prescribed Finished product specification FPS/17-18/0582 Ver.00

Analysed By	Vandana Ahire	Checked By	Sachin Suryawanshi	Approved By	Vinod Umrikar
Designation	Asst. Executive	Designation	Sr. Executive	Designation	Asst. Manager
Date	18.05.2022	Date	18.05.2022	Date	18.05.2022
Printed By :	Prashant Rajhans	Printed On :	18.05.2022 15:24:36	Page No.:	1 of 2

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SR.NO.	TEST	SPECIFICATION	RESULT
			Minimum- 77.20 Maximum- 87.40
7.2	30 minutes	Not less than 80% *(D) of the labeled claim released in 30 minutes.	91.00 90.90 91.40 90.70 89.50 90.10 Average- 90.60 Minimum- 89.50 Maximum- 91.40
8.0	Assay		
8.1	Tadalafil IP	Not less than 90.0% and not more than 110.0% of the labeled claim.	97.40 %

Section : [a] Abbreviation

By HPLC [a]: By High performance liquid chromatography.

Total impurities [a]: Total impurities (Sum of all specified and unspecified impurities).

Remark: A - Release (Domestic)					
Comment: The sample submitted Complies with the prescribed Finished product specification FPS/17-18/0582 Ver.00					
Analysed By	Vandana Ahire	Checked By	Sachin Suryawanshi	Approved By	Vinod Umrikar
Designation	Asst. Executive	Designation	Sr. Executive	Designation	Asst. Manager
Date	18.05.2022	Date	18.05.2022	Date	18.05.2022
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