

Gut N0:11,12,14,15,
Chitegaon, Paithan road,
Aurangabad-431 105
Maharashtra - INDIA

**CERTIFICATE OF ANALYSIS
(Finished Product)**

NAME OF THE PRODUCT: TADALIS SX 20 (Tadalafil Tablets IP 20 mg)			
MFG. DATE	Jan-2023	EXP. DATE	Dec-2025
BATCH SIZE	100000.000 BL	BATCH No.	CT00383
SAP LOT QTY.	96755.000 BL	SAMPLED QTY.	37 BL
SAMPLED BY	AAK	SAMPLED ON	Jan 16, 2023
A.R. NUMBER	CTGN/FP/2023/000013	INSPECTION LOT No.	040000106953
SPECIFICATION No.	FPS/17-18/0582/00	PRODUCT CODE	5002430
PACK SIZE	01 x 04	STP No.	FPT/17-18/0582/00

S. No.	TEST	RESULT	SPECIFICATION
1	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.
2	Identification By High performance liquid chromatography	Refer Assay	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).
3	Average weight	256.6 mg	258.0 mg \pm 5.0% (245.1 mg to 270.9 mg)
4	Uniformity of Weight	Minimum: -3.09 % Maximum: 2.40 %	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%.
5	Disintegration time	03 min 20 sec	Not more than 30 minutes.
6	Related substances		
6.1	(i) Individual impurity	Not Detected	Not more than 0.2%
6.2	(ii) Total impurities	Not Detected	Not more than 0.3%
7	Dissolution		
7.1	Dissolution	Tablet 1:89.3 % Tablet 2:89.0 % Tablet 3:87.1 % Tablet 4:82.0 % Tablet 5:88.7 % Tablet 6:88.8 % Minimum:82.0 % Maximum:89.3 % Mean:87.5%	Not less than 40.0% *(D) of the labeled claim released in 10 minutes.
7.2	Dissolution	Tablet 1:90.5 % Tablet 2:93.7 % Tablet 3:92.2 %	Not less than 80.0% *(D) of the labeled claim released in 30 minutes

Remarks: APPROVED (Sample Conforms to above Specification)

Comment(s): Domestic

ANALYSED BY	Aishwarya.Surale(A pprentice)	CHECKED BY	Vandana.Ahire (Assistant Executive)	APPROVED BY	Chandrakant..Patil (Manager)
DATE	Mar 18, 2023 15:33	DATE	Mar 18, 2023 17:22	DATE	Mar 18, 2023 17:33

Printed by: Vandana.Ahire

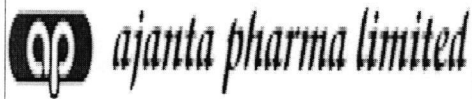
Printed on: Mar 18, 2023 17:41

Copy No.: 1

Page No.: 1 of 2

Note : This document has been generated electronically and is valid without signature.

Format No.CQA/F/198, Version: 02



Gut N0:11,12,14,15,
Chitegaon, Paithan road,
Aurangabad-431 105
Maharashtra - INDIA

**CERTIFICATE OF ANALYSIS
(Finished Product)**

NAME OF THE PRODUCT: TADALIS SX 20 (Tadalafil Tablets IP 20 mg)

MFG. DATE	Jan-2023	EXP. DATE	Dec-2025
BATCH SIZE	100000.000 BL	BATCH No.	CT00383
SAP LOT QTY.	96755.000 BL	SAMPLED QTY.	37 BL
SAMPLED BY	AAK	SAMPLED ON	Jan 16, 2023
A.R. NUMBER	CTGN/FP/2023/000013	INSPECTION LOT No.	040000106953
SPECIFICATION No.	FPS/17-18/0582/00	PRODUCT CODE	5002430
PACK SIZE	01 x 04	STP No.	FPT/17-18/0582/00

		Tablet 4:92.2 % Tablet 5:92.2 % Tablet 6:92.4 % Minimum:90.5 % Maximum:93.7 % Mean:92.2%	
8	Assay Tadalafil IP	100.4%	Not less than 90.0% and not more than 110.0% of the labeled claim.

Remarks: APPROVED (Sample Conforms to above Specification)

Comment(s): Domestic

ANALYSED BY	Aishwarya.Surale(A pprentice)	CHECKED BY	Vandana.Ahire (Assistant Executive)	APPROVED BY	Chandrakant..Patil (Manager)
DATE	Mar 18, 2023 15:33	DATE	Mar 18, 2023 17:22	DATE	Mar 18, 2023 17:33

Printed by: Vandana.Ahire

Printed on: Mar 18, 2023 17:41

Copy No.: 1

Page No.: 2 of 2

Note : This document has been generated electronically and is valid without signature.

Format No.CQA/F/198, Version: 02