

**CIPLA LTD.**  
**C/o SHIVALIK REMEDIES PVT. LTD.**  
Vill- Nanhera Anantpur, Puhana-Iqbalpur Road,  
Roorkee, Distt.-Haridwar (Uttarakhand) 247667

**FINISH PRODUCT**




Certificate of Analysis

The Drugs & Cosmetics Act 1940 & The rules thereunder

Product Name	<b>TADACIP 20 TABLET</b>			A.R.No.	CLLF-22-426
Generic Name	<b>Tadalafil Tablet IP 20 mg</b>			Specification No.	1035-32021903 Version 1.0 & 1035-32021903-01 Version 1.0
Batch No.	P120826	Batch Size	12.0 Lac	Sample Taken on	02/05/2022
Mfg. Date	04/2022	Exp. Date	03/2024	Date of release	09/05/2022
Mfg. Lic. No.	61/UA/LL/2018				

Sr. No.	Tests	Specification	Result
1.	Description	Yellow coloured, pear shaped, biconvex film coated tablet with "20" debossed on one side and plain on other side.	Yellow coloured, pear shaped, biconvex film coated tablet with "20" debossed on one side and plain on other side.
2.	Identification (By HPLC)	The principal peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with Reference solution (a) as obtained in the test for Assay.	Complies
3.	Average weight	0.3500 g $\pm$ 3 % (NLT: 0.3395g & NMT: 0.3605g)	0.34765 g
4.	Uniformity of weight	Not more than two of the individual weights deviate from the average weight by more than $\pm$ 5.0% & none deviates by more than $\pm$ 10.0%	-1.80% to + 1.65%
5.	Dissolution (By HPLC)	Each unit should not be less than 40% (D) + 5% which is equivalent to 45% of the labeled claim released in 10 minutes.	S1 Stage- 62.30% to 73.96% S2 Stage- 70.74% to 96.75% Avg. (S1+S2) = 73.98%
		Each unit should not be less than 80% (D) + 5% which is equivalent to 85% of the labeled claim released in 30 minutes. <b>S2 Stage Criteria:-</b> Average of 12 unites is equal to or greater than 80% (D). No unit is less than 65%.	S1 Stage- 75.84% to 91.90% S2 Stage- 83.55% to 104.76% Avg. (S1+S2) = 89.70%
6.	Related Substance (By HPLC)	Single maximum impurity (Not more than 0.2%)	0.024%
		Total unknown impurity ( Not more than 0.3%)	0.045%

**Remarks :** The above collected sample is complies / ~~does not complies~~ as per specification no. 1035-32021903 Version 1.0 & 1035-32021903-01 Version 1.0 .

	Prepared by	Checked by	Approved By (QC/QA)
Signature			
Date	09/05/2022	09/05/2022	09/05/2022

**CIPLA LTD.**  
**C/o SHIVALIK REMEDIES PVT. LTD.**  
 Vill- Nanhera Anantpur, Puhana-Iqbalpur Road,  
 Roorkee, Distt.-Haridwar (Uttarakhand) 247667

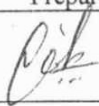


**FINISH PRODUCT**

Certificate of Analysis

The Drugs & Cosmetics Act 1940 & The rules thereunder

Product Name	<b>TADACIP 20 TABLET</b>			A.R.No.	CLLF-22-426
Generic Name	<b>Tadalafil Tablet IP 20 mg</b>			Specification No.	1035-32021903 Version 1.0 & 1035-32021903-01 Version 1.0
Batch No.	P120826	Batch Size	12.0 Lac	Sample Taken on	02/05/2022
Mfg. Date	04/2022	Exp. Date	03/2024	Date of release	09/05/2022
Mfg. Lic. No.	61/UA/LL/2018				

7.	Assay (By HPLC)	Content of Tadalafil in mg per tablet Not less than 18.00 mg and Not more than 22.00 mg per tablet. Not less than 90.0% & Not more than 110.0% of the labeled claim).	19.34 mg (96.70%)
8.	Microbial enumeration tests:	Total Aerobic Microbial Count (NMT 10 <sup>3</sup> cfu per g)	30 cfu/g
		Total combined yeast & mould count (NMT 10 <sup>2</sup> cfu per g)	Less than 10 cfu/g
	Test for specified microorganism	Escherichia coli (should be absent per g)	Absent/g

<b>Remarks :</b> The above collected sample is <b>complies / does not complies</b> as per specification no. 1035-32021903 Version 1.0 & 1035-32021903-01 Version 1.0 .			
	Prepared by	Checked by	Approved By (QC/QA)
Signature			
Date	09/05/2022	09/05/2022	09/05/2022