



FLOURISH PHARMA

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A/C: HEALING PHARMA INDIA PVT LTD.

CERTIFICATE OF ANALYSIS OF FINISHED PRODUCT

Product Name : Tastyia 5	Quality Control Department
Generic Name : Tadalafil Tablets IP 5 mg	Page 1 of 1

Batch No. : FH-23024	A.R. No. : FP/027/23-24.
Batch Size : 2,00,000Tablets	Sample quantity : 5 x 10 Tablets
Mfg. date : 04/23.	Exp. date : 03/26.
Date of sampling : 29.04.2023.	Date of release : 01.05.2023.

Packing presentation: 10 tablets in printed aluminium foil and transparent PVC blister packed.

Sr. No.	Test	Specification	Result
1.	Description	Yellow colored round shape biconvex film coated tablet on both side plain of each tablet.	Yellow colored round shape biconvex film coated tablet on both side plain of each tablet.
2.	Identification	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution (a).	Complies
3.	Average Weight	185.0 mg \pm 7.5% (171.125mg to 198.875mg).	187.82mg
4.	Uniformity of weight	\pm 7.5% of Average weight.	Complies
5.	Diameter	8.20mm \pm 0.20mm	Mini.:8.17mm Maxi.:8.21mm
6.	Thickness	3.30mm \pm 0.20mm	Mini.:3.32mm Maxi.:3.43mm
7.	Hardness	Not less than 4.0 kg/cm ²	Mini.:4.0 kg/cm ² Maxi.:5.0 kg/cm ²
8.	Disintegration time	Not more than 30.0 Minutes	02Min.08Sec.
9.	Dissolution	Not less than 40 per cent of the stated amount.	Mini.:70.48% Maxi.:71.96% Mean:71.43%
		not less than 80 per cent of the stated amount.	Mini.:92.28% Maxi.:94.89% Mean:93.38%
10.	Related substances	Any Secondary impurity: NMT 0.2% Total Impurity : NMT 0.3%	0.005% 0.010%
11.	Uniformity of dosage unites	85.0% to 115.0% of the stated amount Tadalafil	Mini.:99.11% Maxi.:100.62% Mean:99.78%

12. Assay : Each film coated tablet contains :

Ingredient	Label claim	Limit	Result
Tadalafil IP	5mg	4.50mg to 5.50mg	5.161mg
		90.0% to 110.0% of the labeled amount.	99.46%

Conclusion: The above sample **Complies / does not comply** as per IP' Specification.

	Analyst by :	Checked by :	Approved by :
Signature	<i>P. Patel</i>	<i>P. Patel</i>	<i>A. Patel</i>
Date	01/05/2023	01/05/2023	01/05/2023
Name	P. Patel	P. Patel	A. Patel
Designation	Q.C. Officer	Q.C. Manager	Q.A./Q.C. Head