



HETERO LABS LIMITED (UNIT-I)

(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: CELLTINIB 400 (Imatinib Tablets IP 400mg)			
Product Code	4034462	A.R. No.	H5FP25004741
Specification ID	FPS/B-3006182-1-03	Batch No.	AIC250802
Mfg. Date	08/2025	Batch Size	30000 Tablets
Exp. Date	07/2027	Date Of Release	30-08-2025

S. No.	TEST	RESULT	SPECIFICATION
1	Description	Light brick red coloured, capsule shaped, film coated tablets with break line on one side and plain on another side.	Light brick red coloured, capsule shaped, film coated tablets with break line on one side and plain on another side.
2	Identification (By HPLC)	The Retention time of the major peak in the chromatogram of the sample solution corresponds to that of the standard peak in the chromatogram of the standard solution, as obtained in the assay.	The Retention time of the major peak in the chromatogram of the sample solution should correspond to that of the standard peak in the chromatogram of the standard solution, as obtained in the assay.
3	Average weight	982.25 mg	979.20mg \pm 3% (949.82mg to 1008.58mg)
4	Uniformity of weight	Highest : 0.77 % Lowest:-1.01 %	\pm 5.0% of Average Weight
5	Water content (By KF)	4.36 % w/w	Not more than 7.0% w/w.
6	Dissolution (By HPLC)	Tablet 1- : 96.1 % Tablet 2- : 101.5 % Tablet 3- : 100.0 % Tablet 4- : 95.7 % Tablet 5- : 100.0 % Tablet 6- : 94.7 % Average::98.0 %	Not less than 75% (D) of labeled amount of Imatinib (C29H31N7O) should dissolve in 60 minutes.
7	Related Substances (By HPLC)		
7.1	Maximum single impurity	0.04 %	Not more than 1.0%
7.2	Total Impurities	0.05 %	Not more than 2.0%
8	Assay (By HPLC)		
8.1	Each film coated tablet contains Imatinib mesylate IP equivalent to Imatinib	98.1 %	Not less than 95.0% and Not more than 105.0%

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Geddapu.Krishna	Approved By	Naveen Kumar.Pundir
Date	30-08-2025 19:15	Date	30-08-2025 19:22
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Name: Naveen Kumar
Designation: Manager
Qualification: M.Sc.
Registration Number: M-0013423
University: Chaudhary Charan Singh University, Meerut