HETERO LABS LIMITED (UNIT-I)
(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: CELLTINIB 400 (Imatinib Tablets IP 400mg)			
Product Code	4034462	**A.R. No.**	H5FP26004225
Specification ID	FPS/B-3006182-1-04	**Batch No.**	AIC260805
Mfg. Date	08/2026	**Batch Size**	30000 Tablets
Exp. Date	07/2028	**Date Of Release**	27-08-2026

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 corresponds to that of the standard peak in the chromatogram of the standard solution, as obtained in the assay.
3	**Average weight**	982.35 mg	979.20mg ± 3% (949.82mg to 1008.58mg)
4	**Uniformity of weight**	Highest : 1.40 % Lowest::-2.11 %	± 5.0% of Average Weight
5	**Uniformity of dosage units (By Weight variation) Acceptance Value (L1)**	1.2	Not More than 15.0
6	**Water content (By KF)**	4.52 % w/w	Not more than 7.0% w/w.
7	**Dissolution (By HPLC)**	Tablet 1- : 97.9 % Tablet 2- : 98.4 % Tablet 3- : 99.6 % Tablet 4- : 102.7 % Tablet 5- : 98.4 % Tablet 6- : 102.1 % Average::99.9 %	Not less than 75% (D) of labeled amount of Imatinib ($C_{29}H_{31}N_7O$) should dissolve in 60 minutes.
8	**Related Substances (By HPLC)**		
8.1	**Maximum single Impurity**	0.09 %	Not more than 1.0%
8.2	**Total Impurities**	0.10 %	Not more than 2.0%
9	**Assay (By HPLC)**		

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	MANVVAR.HASAN	Approved By	Naveen Kumar.Pundir
Date	18-09-2026 12:10	Date	18-09-2026 12:11
Printed by: Naveen Kumar.Pundir		**Printed on: 18-09-2026 12:12**	
Copy No.: 1		**Page No.: 1 of 2**	

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CNo: C170005041

Approved By
Name: Naveen Kumar
Designation: Sr. Manager
Qualification: M. Sc.
Registration Number: M-0013423
University: Chaudhary Charan Singh University, Meerut

Office : 7-2-A/2, Hetero Corporate, Industrial Estate, Sanath Nagar, Hyderabad-18, INDIA. Tel : 040-23704923/24/25, Fax : 040-23704926
Factory : Village : Kalyanpur, Chakkan Road, BADDI, Tehsil : Baddi, Distt. Solan, H.P. - 173 205 INDIA.

HETERO LABS LIMITED (UNIT-I)

(Formulations Division)

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9.1	**Each film coated tablet contains Imatinib mesylate IP equivalent to Imatinib ($C_{29}H_{31}N_7O$) (% Labeled amount)**	100.6 %	Not less than 95.0% and Not more than 105.0%

Remarks: APPROVED (Sample Conforms to above Specification)

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