



# HETERO LABS LIMITED (UNIT-I)

## (Formulations Division)

### CERTIFICATE OF ANALYSIS

<b>Product Name: CELLTINIB 400 (Imatinib Tablets IP 400mg)</b>			
<b>Product Code</b>	4034462	<b>A.R. No.</b>	H5FP24003785
<b>Specification ID</b>	FPS/B-3006182-1-02	<b>Batch No.</b>	AIC240801
<b>Mfg. Date</b>	08/2024	<b>Batch Size</b>	25000 Tablets
<b>Exp. Date</b>	07/2026	<b>Date Of Release</b>	23-09-2024

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	976.83 mg	979.20mg $\pm$ 3% (949.82mg to 1008.58mg)
4	Uniformity of weight	Highest : 2.30 % Lowest:-1.16 %	$\pm$ 5.0% of Average Weight
5	Water content (By KF)	4.25 % w/w	Not more than 7.0% w/w.
6	Dissolution (By HPLC)	Tablet 1- : 100.7 % Tablet 2- : 98.4 % Tablet 3- : 101.0 % Tablet 4- : 100.8 % Tablet 5- : 98.4 % Tablet 6- : 101.0 % Average::100.1 %	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	0.03 %	Not more than 1.0%
7.2	Total Impurities	0.04 %	Not more than 2.0%
8	Assay (By HPLC)		
8.1	Each film coated tablet contains Imatinib mesylate IP equivalent to Imatinib	97.6 %	Not less than 95.0% and Not more than 105.0%

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Ajit Kumar.Singh	Approved By	TS.Rao
Date	01-10-2024 17:41	Date	01-10-2024 17:46
Printed by: TS.Rao		Printed on: 01-10-2024 17:47	
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	(C29H31N7O) (% Labeled amount)		
9	<b>Residual solvents (By GC)</b>		
9.1	<b>Isopropyl Alcohol</b>	536 ppm	Not more than 5000 ppm
9.2	<b>Methylene chloride</b>	Not Detected	Not more than 600 ppm.

Remarks: APPROVED (Sample Conforms to above Specification)

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