



# HETERO LABS LIMITED (UNIT-I)

(Formulations Division)

## CERTIFICATE OF ANALYSIS

Product Name: RECTAFOX 500 (Capecitabine Tablets IP 500mg)			
Product Code	4033377	A.R. No.	H5FP24003717
Specification ID	FPS/B-3006190-1-01	Batch No.	ACR240802
Mfg. Date	08/2024	Batch Size	20000 Tablets
Exp. Date	07/2026	Date Of Release	20-09-2024

S. No.	TEST	RESULT	SPECIFICATION
1	Description	Pink coloured, biconvex, capsule shaped, film coated tablets with break line on one side.	Pink coloured, biconvex, capsule shaped, film coated tablets with break line on one 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	1004.66 mg	993.89mg $\pm$ 3% (964.07mg to 1023.71mg)
4	Uniformity of weight	Highest : 1.39 % Lowest:-1.56 %	$\pm$ 5.0% of Average Weight
5	Water content (By KF)	2.32 %w/w	Not more than 6.0% w/w.
6	Uniformity of dosage units (By Weight variation) Acceptance value (L1)	1.3	Not more than 15.0
7	Dissolution (By HPLC)	Tablet 1- : 96.2 % Tablet 2- : 97.6 % Tablet 3- : 100.9 % Tablet 4- : 99.8 % Tablet 5- : 98.9 % Tablet 6- : 99.5 % Average::98.8 %	Not less than 80% (Q) of labeled amount of Capecitabine (C <sub>15</sub> H <sub>22</sub> FN <sub>3</sub> O <sub>6</sub> ) should dissolve in 60 minutes.
8	Related Substances (By HPLC)		
8.1	Maximum Single Impurity	0.13 %	Not more than 1.0%
8.2	Total Impurities	0.18 %	Not more than 2.0%
9	Assay (By HPLC) Each film	101.1 %	Not less than 90.0% and Not

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	MAHENDRA SINGH.BHATI	Approved By	Naveen Kumar.Pundir
Date	20-09-2024 17:26	Date	20-09-2024 17:29
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	coated tablet contains Capecitabine (C <sub>15</sub> H <sub>22</sub> FN <sub>3</sub> O <sub>6</sub> ) (% Labeled amount)		more than 110.0%
10	Residual solvents (By GC)		
10.1	Isopropyl Alcohol	562 ppm	Not more than 5000 ppm
10.2	Methylene chloride	Not Detected	Not more than 600 ppm

Remarks: APPROVED (Sample Conforms to above Specification)

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