



HETERO LABS LIMITED (UNIT-I)

(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: RECTAFOX 500 (Capecitabine Tablets IP 500mg)			
Product Code	4033377	A.R. No.	H5FP24002636
Specification ID	FPS/B-3006190-1-01	Batch No.	ACR240601
Mfg. Date	06/2024	Batch Size	20000 Tablets
Exp. Date	05/2026	Date Of Release	06-07-2024

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	999.25 mg	993.89mg \pm 3% (964.07mg to 1023.71mg)
4	Uniformity of weight	Highest : 0.88 % Lowest:-1.44 %	\pm 5.0% of Average Weight
5	Water content (By KF)	2.26 %w/w	Not more than 6.0% w/w.
6	Uniformity of dosage units (By Weight variation) Acceptance value (L1)	5.3	Not more than 15.0
7	Dissolution (By HPLC)	Tablet 1- : 101.5 % Tablet 2- : 107.4 % Tablet 3- : 95.1 % Tablet 4- : 99.4 % Tablet 5- : 100.7 % Tablet 6- : 100.6 % Average::100.8 %	Not less than 80% (Q) of labeled amount of Capecitabine (C15H22FN3O6) should dissolve in 60 minutes.
8	Related Substances (By HPLC)		
8.1	Maximum Single Impurity	0.04 %	Not more than 1.0%
8.2	Total Impurities	0.09 %	Not more than 2.0%
9	Assay (By HPLC) Each film coated tablet contains	103.3 %	Not less than 90.0% and Not more than 110.0%

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Dharmendra.Kumar	Approved By	Naveen Kumar.Pundir
Date	06-07-2024 17:20	Date	06-07-2024 17:22
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	Capecitabine (C15H22FN3O6) (% Labeled amount)		
10	Residual solvents (By GC)		
10.1	Isopropyl Alcohol	520 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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