



HETERO LABS LIMITED (UNIT-I)

(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: RECTAFOX 500 (Capecitabine Tablets IP 500mg)			
Product Code	4033377	A.R. No.	H5FP25000822
Specification ID	FPS/B-3006190-1-01	Batch No.	ACR250201
Mfg. Date	02/2025	Batch Size	20000 Tablets
Exp. Date	01/2027	Date Of Release	07-03-2025

S. No.	TEST	RESULT	SPECIFICATION
1	Description	Pink coloured, biconvex, capsules shaped, film coated 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	999.48 mg	993.89mg \pm 3% (964.07mg to 1023.71mg)
4	Uniformity of weight	Highest : 1.91 % Lowest:-1.55 %	\pm 5.0% of Average Weight
5	Water content (By KF)	1.62 %w/w	Not more than 6.0% w/w.
6	Uniformity of dosage units (By Weight variation) Acceptance value (L1)	2.1	Not more than 15.0
7	Dissolution (By HPLC)	Tablet 1- : 98.4 % Tablet 2- : 98.3 % Tablet 3- : 99.8 % Tablet 4- : 99.0 % Tablet 5- : 97.8 % Tablet 6- : 97.9 % Average::98.5 %	Not less than 80% (Q) of labeled amount of Capecitabine (C ₁₅ H ₂₂ FN ₃ O ₆) 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	0.05 %	Not more than 2.0%
9	Assay (By HPLC) Each film coated tablet contains	99.6 %	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	07-03-2025 14:55	Date	07-03-2025 14:57
Printed by: Naveen Kumar.Pundir		Printed on: 07-03-2025 14:59	
Copy No.: 1		Page No.: 1 of 2	
Note : This document has been generated electronically and is valid without signature.			
CNo: C160001227			

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



HETERO LABS LIMITED (UNIT-I)

(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: RECTAFOX 500 (Capecitabine Tablets IP 500mg)			
Product Code	4033377	A.R. No.	H5FP25000822
Specification ID	FPS/B-3006190-1-01	Batch No.	ACR250201
Mfg. Date	02/2025	Batch Size	20000 Tablets
Exp. Date	01/2027	Date Of Release	07-03-2025

	Capecitabine (C₁₅H₂₂FN₃O₆) (% Labeled amount)		
10	Residual solvents (By GC)		
10.1	Isopropyl Alcohol	1189 ppm	Not more than 5000 ppm
10.2	Methylene chloride	Not Detected	Not more than 600 ppm

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Dharmendra.Kumar	Approved By	Naveen Kumar.Pundir
Date	07-03-2025 14:55	Date	07-03-2025 14:57
Printed by: Naveen Kumar.Pundir		Printed on: 07-03-2025 14:59	
Copy No.: 1		Page No.: 2 of 2	
Note : This document has been generated electronically and is valid without signature.			
CNo: C160001227			

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