

CERTIFICATE OF ANALYSIS

Generic Name	Capecitabine Tablets IP (500 mg)	Brand Name	CAPEKAST
Generic Batch No.	BT23118	Brand Batch No.	BT23118C
Generic Batch size:	48500 Tablets	Brand Batch size:	25500 Tablets
Mfg. Date:	06/2023	Exp. Date:	05/2025
Specification No.:	FSP/066/001-00	STP No.:	FTP/066/001-00
Date of Sampling:	19/06/2023	Date of Release:	30/06/2023
A.R. Number	FP/06/23-0654		

S.No.	TEST	SPECIFICATION	RESULT
1.	Description	Brick red, elongated, biconvex, film coated tablet, plain on both side.	Brick red, elongated, biconvex, film coated tablet, plain on both side.
2.	Identification	In the Assay, the principle peak in chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	In the Assay, the principle peak in chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.
3.	Average Weight	665.0 mg \pm 5% (631.75 mg – 698.25 mg)	659.21 mg
4.	Uniformity of dosage Units (By Weight Variation)	Not more than two of the individual weights deviate from the average weight by more than the 5 percent and none should deviate by more than 10 percent of the average weight.	-Ve variation-1.56% +Ve variation-1.20%
5.	Thickness	5.30 mm – 5.70 mm	5.40 mm - 5.49 mm
6.	Length	16.80 mm – 17.20 mm	16.90 mm -17.05 mm

Remarks: In the opinion of the undersigned the sample complies / ~~does not comply~~ with the IP/BP/USP/In-House Specifications.

	Prepared By	Checked By	Reviewed By	Approved By
Department	Executive QC/ designee	Asst. Manager QC/ designee	Manager QC/ designee	Manager QA/ designee
Name	Ajay Bhatia	Vikas Kuma	Ganesh Chawla	Harman Singh
Date	03/07/2023	03/07/2023	03/07/2023	03/07/2023
Signature				

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7.	Width	7.80 mm - 8.20 mm	7.85 mm - 8.06 mm
8.	Dissolution	Not Less than 80 % (Q) Stated amount of Capecitabine dissolved in 60 minutes.	Minimum-98.92% Maximum-102.23% Average-100.18%
9.	Related Substances	Single unknown Impurity -NMT-1.0% Total Impurities - NMT 2.0%	0.076% 0.19%
10.	Assay- Each film coated Tablet contains- Capecitabine IP 500 mg	475.0 mg to 525.0 mg (95.0 % to 105.0 %)	505.32 mg (101.1%)

*-ADDITIONAL TEST

Remarks: In the opinion of the undersigned the sample complies / ~~does not comply~~ with the IP/BP/USP/In-House Specifications.

	Prepared By	Checked By	Reviewed By	Approved By
Department	Executive QC/ designee	Asst. Manager QC/ designee	Manager QC/ designee	Manager QA/ designee
Name	Ajay Bhatia	Vikesh Kumar	Ganesh Chawla	Arvind Singh
Date	03/07/2023	03/07/2023	03/07/2023	03/07/2023
Signature				

Page 2 of 2