

BETA DRUGS LIMITED

Kharuni - Lodhimajra Road, Vil. Nandpur,
Baddi, Distt. Solan, Himachal Pradesh



CERTIFICATE OF ANALYSIS FINISHED PRODUCT

Generic Name	CABOZANTINIB TABLETS 60 MG	Brand Name	CABOZER 60
Generic Batch No.	BT23239	Brand Batch No.	BT23239C
Generic Batch size:	13000 Tablets	Brand Batch size:	4000 Tablets
Mfg. Date:	09/2023	Exp. Date:	08/2025
Specification No.:	FSP/171/001-00	STP No.:	FTP/171/001-00
Date of Sampling:	04/10/2023	Date of Release:	20/10/2023
A.R. Number	FP/10/23-1139		

S.No.	TEST	SPECIFICATION	RESULT
1.	Description	Brick red colour round shaped convex film coated tablet plain on other sides.	Brick red colour round shaped convex film coated tablet plain on other sides.
2.	Identification	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution
3.	Average weight	308 mg \pm 5% (292.6 mg to 323.4 mg)	309.1 mg
4.	Dissolution	NLT 80%	Minimum: 90.1% Maximum: 90.9% Average: 90.4%
5.	Related Substances	Single highest impurity - NMT 0.5% Total impurity - NMT 1.0 %	0.05% 0.08%

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	Aisha Anand	Sanjeev Sharma	Gurpreet Grewal	Nirmal Singh
Date	20/10/2023	20/10/2023	20/10/2023	20/10/2023
Signature	Aisha	[Signature]	[Signature]	[Signature]

Beta Drugs Limited (Unit of Adley Group)

SCO 184, Sector-5, Panchkula-134114, Haryana (INDIA)

Phone No.: +91-172-2585481-82-83 Website: www.betadrugslimited.com e-mail: betabaddi@gmail.com

Format No.BQC006/F01-06

Page 1 of 2

BETA DRUGS LIMITED

Kharuni - Lodhimajra Road, Vil. Nandpur,
Baddi, Distt. Solan, Himachal Pradesh



CERTIFICATE OF ANALYSIS FINISHED PRODUCT

Generic Name	CABOZANTINIB TABLETS 60 MG	Brand Name	CABOZER 60
Generic Batch No.	BT23239	Brand Batch No.	BT23239C
Generic Batch size:	13000 Tablets	Brand Batch size:	4000 Tablets
Mfg. Date:	09/2023	Exp. Date:	08/2025
Specification No.:	FSP/171/001-00	STP No.:	FTP/171/001-00
Date of Sampling:	04/10/2023	Date of Release:	20/10/2023
A.R. Number	FP/10/23-1139		

6.	Assay: Each film coated Tablet contains: Cabozantinib S Malate equivalent to Cabozantinib 60 mg	57.0 mg to 63.0 mg (95.0% to 105.0%)	59.17 mg (98.6%)
7.	Residual Solvent	Iso propyl Alcohol-NMT- 5000 ppm Methylene dichloride-NMT - 600 ppm	Not Detected Not Detected
8.	Water Content	NMT 6.0 %	2.9%
9.	Disintegration	NMT 30 minutes	09 min; 02 sec
10.	Microbial Enumeration Test		
	Total Aerobic Microbial Count	NMT 1000 cfu/gm	15 cfu/gm
	Total Yeast and mold count	NMT 100 cfu/gm	< 10 cfu/gm
	Escherichia Coli	Should be absent	Absent

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	Alka Arora	Sanjeev Sharma	Gaurav Kumar	Niraj Singh
Date	20/10/2023	20/10/2023	20/10/2023	20/10/2023
Signature	Alka	Sanjeev	Gaurav	Niraj

Beta Drugs Limited (Unit of Adley Group)

SCO 184, Sector-5, Panchkula-134114, Haryana (INDIA)

Phone No.: +91-172-2585481-82-83 Website: www.betadrugslimited.com e-mail: betabaddi@gmail.com

Format No.BQC006/F01-06

Page 2 of 2