

## CERTIFICATE OF ANALYSIS FINISHED PRODUCT

<b>Brand Name</b>	<b>PALBOCIB 125 MG</b>	<b>Generic Name</b>	<b>Palbociclib capsules 125 mg</b>
<b>Brand Batch no.</b>	BC25225A	<b>Generic Batch No.</b>	BC25225
<b>Brand Batch size:</b>	17000 Capsules	<b>Generic Batch size:</b>	17000 Capsules
<b>Mfg. Date:</b>	07/2025	<b>Specification No.:</b>	FSP/174/001-01
<b>Exp. Date:</b>	06/2027	<b>STP No.:</b>	FTP/174/001-01
<b>Market</b>	NA	<b>Date of Sampling:</b>	01/08/2025
<b>A. R. Number:</b>	FP/08/25-1001	<b>Date of Release:</b>	20/08/2025

S. No.	TEST	SPECIFICATION	RESULT
1.	<b>Description*</b>	Red/Yellow colour Size 0 hard gelatin capsule contains a light-yellow granular powder.	Red/Yellow colour Size 0 hard gelatin capsule contains a light-yellow granular powder.
2.	<b>Identification (By HPLC)</b>	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the assay.	Complies
3.	<b>Average weight of filled contents</b>	350.0 mg ± 7.5 % (323.75 mg – 376.25 mg)	349.49 MG
4.	<b>Disintegration time</b>	NMT 30 minutes	05 Minutes 10 second
5.	<b>Dissolution (By HPLC) *</b>	NLT 75% (Q) of the labeled amount that dissolves in 45 minutes.	Minimum: 99% Maximum: 104% Average: 101%
6.	<b>Related Substance (By HPLC) *</b>	Single Highest impurity- NMT 0.2% Total Impurity – NMT 1.5%	0.12% 0.36%
7.	<b>Assay (By HPLC) *</b>	<b>Shelf-Life Limit</b>	121.63 mg 97.3%
		112.50 mg to 137.50 mg (90.0% to 110.0%)	
<b>Microbial Limit Test*</b>			
8.	<b>Total Aerobic microbial Counts</b>	NMT 1000 cfu/gm	40 CFU/gm
	<b>Total Yeast and Mold counts</b>	NMT 100 cfu/gm	Less than 10 CFU/gm
	<b>E. Coli</b>	Absent/g	Absent
9.	<b>Water Content*</b>	NMT 6.0 %	Complies
10.	<b>Residual solvent (By GC)</b>	Isopropyl alcohol- 5000 ppm	Not detected

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

Department	Prepared By (QC)	Checked By (QC/Micro)	Reviewed By (Head QC/Designee)	Approved By (Head QA/designee)
Name	Meholi	Sangeer Sharma	Parvina Soodant	Arunach Vana
Signature				
Date	20/08/2025	20/08/2025	20/08/2025	20/08/2025

