APRAZER

Aprazer Healthcare Pvt. Ltd.
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KVQA ISO 9001:2015

CERTIFICATE OF ANALYSIS
FINISHED PRODUCT

Brand Name of the Product:	**OLABIR-150**		
Generic Name of the Product:	**Olaparib Tablet 150mg**		
Product Code:	OL	A.R. Number:	FPACT2420OLA
Batch No.:	ACT2420OLA	Date of Sampling:	05/02/2025
Mfg. Date:	01/2025	Date of release:	01/03/2025
Exp. Date:	12/2026	Batch Size:	15500 Tablets
Specification No.:	FG/SPA/OLT/02-00	Reference:	IHS

S.NO	TEST	SPECIFICATION	RESULT
1.	Description	Creamish coloured, oval shaped biconvex, film Coated tablets, plain on both sides.	Creamish coloured, oval shaped biconvex, film Coated tablets, plain on both sides.
2.	Identification (By HPLC)	The retention time of the major peak in the chromatogram of the assay preparation should correspond to that in the chromatogram of the standard preparation, as obtained in the assay.	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.
3.	Average weight	800.0 mg ± 5.0 % (760.0 mg to 840.0 mg)	793.35 mg
4.	Uniformity of weight	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.	Minimum = - 1.23% Maximum = + 0.79%
5.	Thickness	6.5 mm ±0.3 mm (6.20 mm to 6.80 mm)	6.22 mm – 6.33 mm
6.	Disintegration time	Not more than 30 minutes	05 Minutes and 40 Seconds

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

Prepared By	A kumar	Checked By		Approved By	
Name	Amit Kumar	Name	Shanila	Name	[illegible]
Date	03/03/2025	Date	03/03/2025	Date	03/03/2025

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7.	Dissolution (By HPLC)	Not less than 70.0% (Q)	Minimum- 93.78 % Maximum- 100.47% Mean- 96.96%
8.	Related substance (By HPLC)	Any unknown impurity NMT 0.5% Total impurities NMT 1.5%	Not detected Not detected
9.	Assay-(By HPLC) Each film coated tablet contains: Olaparib 150 mg	135.0 mg to 165.0 mg (90.0% to 110.0%)	150.797 mg (100.53%)
10.	Microbial Enumeration Test		
	Total Aerobic Microbial Count	Not more than 1000 cfu/gm	20 cfu/gm
	Total yeast and mold count	Not more than 100 cfu/gm	Less than 10 cfu/gm
	E.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	A Kumar	Checked By		Approved By	
Name	Amit Kumar	Name	Sharila	Name	
Date	03/03/2025	Date	03/03/2025	Date	03/03/2025