CERTIFICATE OF ANALYSIS
FINISHED PRODUCT

Brand Name	**INDENZA 160**	**Generic Name**	**Enzalutamide Tablets 160 MG**
Brand Batch no.	BT26169A	**Generic Batch No.**	BT26169
Brand Batch size:	16000 Tablets	**Generic Batch size:**	16500 Tablets
Mfg. Date:	03/2026	**Specification No.:**	FSP/181/001-05
Exp. Date:	02/2028	**STP No.:**	FTP/181/001-05
Market	NA	**Date of Sampling:**	30/03/2026
A. R. Number:	FP/03/26-0477	**Date of Release:**	09/04/2026

S. NO.	TEST	SPECIFICATION	RESULT
1.	Description	Light brown, elongated capsules shaped, film-coated tablet having break line and embossing EZ/EZ and plain on other side.	Light brown, elongated capsules shaped, film-coated tablet having break line and embossing EZ/EZ and plain on other side.
2.	Identification	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.	Average Weight	1230 ± 5% (1168.5 mg – 1291.5 mg)	1219.93 mg
4.	Uniformity of dosage unit (By Weight Variation)	AV value: L1= NMT 15 (for 10 units) L2= NMT 25 (for 30 units)	L1= 1.8
5.	Dissolution	NLT 70% (Q) at 60 min	Minimum:77% Maximum:94% Average:85%

RELEASED BY
Name : Gaurav Chawla
Designation : Manager - QC
Qualification : M.Sc.
Enrollment No. : 10806[illegible]53
Name of Institution : LPU- Phagwara (Punjab)

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

Department	Prepared By (QC)	Checked By (QC/Micro)	Reviewed By (Head QC/Designee)	Approved By (Head QA/Designee)
Name	Ajay Bhatia	Sanjeev Sharma	Gaurav Chawla	T. Srinivasa Rao
Signature				
Date	09/04/2026	09/04/2026	09/04/2026	10/04/2026

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6.	Related Substance	Single highest impurity – NMT 0.2 % Total impurity - NMT 1.0 %	0.013% 0.04%
7.	Residual Solvent	Acetone- NMT 5000 ppm Isopropyl Alcohol- NMT 5000 ppm Methylene dichloride- NMT 600 ppm	354 ppm 1744 ppm Not detected
8.	Assay	95.0% to 105.0% (152.0 mg - 168.0 mg)	99.1% (158.51 mg)
Additional test			
9.	Microbial Enumeration Test		
	Total Aerobic microbial Counts	NMT 1000 cfu/gm	25 CFU/gm
	Total Yeast and Mold Counts	NMT 100 cfu/gm	Less than 10 CFU/gm
	E. Coli	Should be Absent	Absent
Additional test			
10.	Water Content	NMT 7.0 %	3.52%
11.	Disintegration	NMT 30 minutes	05 min 20 seconds

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

Department	**Prepared By (QC)**	**Checked By (QC/Micro)**	**Reviewed By (Head QC/Designee)**	**Approved By (Head QA/Designee)**
Name	Ajay Bhatia	Sanjeev Sharma	Sanjay Uppal	T. Srinivasa Rao
Signature				
Date	09/04/2026	09/04/2026	09/04/2026	10/04/2026