

**CERTIFICATE OF ANALYSIS
FINISHED PRODUCT**

Brand Name of the Product:	INDENZA-40 MG		
Generic Name of the Product:	Enzalutamide capsules (40 mg)		
Product Code:	EZ	A.R. Number:	FPACC2502EZB
Batch No.:	ACC2502EZB	Date of Sampling:	28/06/2025
Mfg. Date:	06/2025	Date of release:	14/07/2025
Exp. Date:	05/2027	Batch Size:	56304 CAPSULE
Specification No.:	FG/SPA/EZC-01-00	Reference:	IHS

S.NO	TEST	SPECIFICATION	RESULT
1.	Description	Yellow/Yellow "0" coloured hard gelatin capsules filled with white colored powder.	Yellow/Yellow "0" coloured hard gelatin capsules filled with white colored powder.
2.	Identification (By HPLC)	In the assay the principal peak obtained in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies
3.	Average Weight	750mg \pm 5.0% (712.5 mg to 787.5 mg)	753.36 mg
4.	Average fill Weight	625mg \pm 5.0% (593.75mg to 656.25 mg)	628.49 mg

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

Analysed By		Checked By		Approved By	
Name	N. Mag	Name	S. Singh	Name	P. Singh
Date	14/07/2025	Date	14/07/2025	Date	14/07/2025

**Manufacturing Plant: Aprazer Healthcare Pvt. Ltd. Village Kotla, PO - Barotiwala,
Distt.: Solan, Himachal Pradesh – INDIA**

**CERTIFICATE OF ANALYSIS
FINISHED PRODUCT**

Brand Name of the Product:	INDENZA-40 MG		
Generic Name of the Product:	Enzalutamide capsules (40 mg)		
Product Code:	EZ	A.R. Number:	FPACC2502EZB
Batch No.:	ACC2502EZB	Date of Sampling:	28/06/2025
Mfg. Date:	06/2025	Date of release:	14/07/2025
Exp. Date:	05/2027	Batch Size:	56304 CAPSULE
Specification No.:	FG/SPA/EZC-01-00	Reference:	IHS

5.	Uniformity of Weight	Not more than 2 of the individual weights deviate from the average weight by more than 5% and none deviate by more than 10%.	-2.15% +1.44%
6.	Disintegration time	NMT 30 minutes	07 minutes 40 seconds
7.	Dissolution	Not less than – 70%(D)	MIN-99.28% MAX-102.15% MEAN-100.25%
8.	Assay: Each hard gelatin capsule shell contain: Enzalutamide 40mg	38.0mg to 42.0mg (95.0% to 105.0%)	40.21 mg (100.53%)
9.	Microbial limit test		

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

Analysed By		Checked By		Approved By	
Name	Nmag	Name	Sunil	Name	Bhanu
Date	14/07/2025	Date	14/07/2025	Date	14/07/2025

**Manufacturing Plant: Aprazer Healthcare Pvt. Ltd. Village Kotla, PO - Barotiwala,
Distt.: Solan, Himachal Pradesh – INDIA**

**CERTIFICATE OF ANALYSIS
FINISHED PRODUCT**

Brand Name of the Product:	INDENZA-40 MG		
Generic Name of the Product:	Enzalutamide capsules (40 mg)		
Product Code:	EZ	A.R. Number:	FPACC2502EZB
Batch No.:	ACC2502EZB	Date of Sampling:	28/06/2025
Mfg. Date:	06/2025	Date of release:	14/07/2025
Exp. Date:	05/2027	Batch Size:	56304 CAPSULE
Specification No.:	FG/SPA/EZC-01-00	Reference:	IHS

i)	Total aerobic microbial count	Not more than 1000 cfu/gm	20 cfu/gm
ii)	Yeast & molds count	Not more than 100 cfu/gm	Less than 10 cfu/gm
iii)	E.coli	Should be absent	absent
iv)	Salmonella Sp.	Should be absent	absent
v)	S. aureus	Should be absent	absent
vi)	P. aeruginosa	Should be absent	absent
vii)	S. Bodyii	Should be absent	absent
viii)	Candida albicans	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.

Analysed By		Checked By		Approved By	
Name	Nima	Name	Sumit	Name	Bhuvan
Date	14/07/2025	Date	14/07/2025	Date	14/07/2025

**Manufacturing Plant: Aprazer Healthcare Pvt. Ltd. Village Kotla, PO - Barotiwala,
Distt.: Solan, Himachal Pradesh - INDIA**