

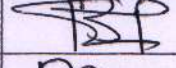


CERTIFICATE OF ANALYSIS

Brand Name of Product:	FULVEKAST-250 MG		
Generic Name of the Product:	Fulvestrant Injection (250 mg /5.0 ml)		
Product Code:	FV	A.R. Number:	FPADC2309FVC
Batch No.:	ADC2309FVC	Date of Sampling:	28/12/2023
Mfg. Date:	12/2023	Date of release:	12/01/2024
Exp. Date:	11/2025	Batch Size:	305 PFS
Specification No.:	FG/SPA/FVI/01-02	Reference:	IHS

S.NO	TEST	SPECIFICATION	RESULT
1.	Description	A pale yellow color oily viscous solution free from visible extraneous particulate matter filled in PFS	A pale yellow color oily viscous solution free from visible extraneous particulate matter filled in PFS
2.	Identification (By HPLC)	The retention time of major peak in the chromatogram of assay preparation corresponds to that in the chromatogram of the standard preparation. As obtained in the Assay.	Complies.
3.	Particulate Matter Visible particulate matter Sub Visible particulate matter	Free from visible particles Not more than 6000 average number of particles should be greater than or equal to 10µm Not more than 600 average number of particles should be greater than or equal to 25 µm	Free from visible particles 358 24
4.	Volume in container	NLT 5.0 ml	5.08 ml

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	Rm/GA	Name	ASIM	Name	Brown
Date	12/01/2024	Date	12/01/2024	Date	12/01/2024



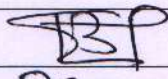
Manufacturing Plant: Aprazer Healthcare Pvt. Ltd. Village Kotla, PO - Barotiwala, Distt.: Solan, Himachal Pradesh – INDIA

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5.	Clarity of solution	A pale yellow color, Oily, viscous solution.	A pale yellow color, oily, viscous solution.
6.	Related Substances Any individual unspecified impurity	Not more than 1.5%	0.769%
	Total impurities	Not more than 3.0%	0.769%
7.	Assay : Each ml contains- Fulvestrant IP 50 mg	45.0 mg to 55.0 mg (90% to 110%)	49.22 mg (98.44%)
8.	Ethanol Content	85% to 115%	95.60%
9.	Sterility	Should be sterile	Sterile.
10.	Bacterial Endotoxins	Not more than 0.87 EU / mg of Fulvestrant	Less than 0.87 EU / mg of Fulvestrant

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	Anil Gita	Name	Asim	Name	Bhanu
Date	12/01/2024	Date	12/01/2024	Date	12/01/2024

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