SANZYME PRIVATE LIMITED

Plot No.8, SY.NO.542 Kolthur (Village), Shamirpet (Mandal)
Medchal-Malkajgiri(District) Hyderabad - 500101,Telangana,India.

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Brand Name	HUMEGO 150				
Brand Batch No.	ARM22601			**Released Qty**	5,000 VL
Generic Name	MENOTROPIN FOR INJECTION IP, 150 IU				
Generic Batch No.	DM022610			**Generic Batch Approved Qty**	57,561 VL
Mfg. Date	09/26	**STP No.**	STP/FP-011.07	**A.R.No.**	26IFP0176
Exp.Date	08/29	**Spec No.**	SPC/FP-035.07	**Market/ Customer**	Domestic/AMERICAN REMEDIES

S.No.	Test	Specification	Result
1	Description	Injection vial (clear glass) 2mL with grey bromo butyl rubber stopper (13mm). Flip off cap: Rim beaded with aluminum cap, Orange color plastic cap. A white or almost white lyophilized cake.	Complies
2	Identification	It causes enlargement of ovaries of immature female rats and increases in the weight of the seminal vesicles and prostate glands of immature male rats when administered as directed in the assay.	Complies
3	pH	6.0 to 8.0	6.95
4	Water content	NMT 5.0% w/w	0.46% w/w
5	Bacterial Endotoxins	NMT 0.78 IU per IU of FSH	Less than 0.39 IU/IU of FSH
6	Assay	The estimated potency is not less than 80% and not more than 125% of 150 IU/vial. The fiducial limits of error are not less than 64% and not more than 156% of 150 IU/vial.	FSH :154.04 IU/Vial 102.69%,LH : 158.36 IU/Vial 105.57% fiducial limits: FSH :147.10 - 161.33 IU/Vial 98.06% - 107.55% LH : 143.02 - 175.50 IU/Vial 95.35% - 117.00%
7	Test for viruses		
	Hepatitis B Surface Antigen (HBs Ag)	Should be absent	Complies
	Hepatitis C virus antibodies (HCV)	Should be absent.	Complies
	HIV antibodies (HIV-I)	Should be absent.	Complies
	HIV antibodies (HIV-II)	Should be absent.	Complies
	Additional tests		
8	Reconstitution time	Less than or equal to 30 seconds.	11.4 Seconds
9	Constituted solution	The constitution solution should not be significantly less clear than an equal volume of the diluent in a similar container and examined similarly	Complies
10	Particulate matter		
	Visible particulates:	Free from visible particulates.	Complies
	Sub-visible particulates:	>=10µm - Not exceed 6000 particles/container. >=25µm - Not exceed 600 particles/container.	10µm-38 and 25µm-22
11	Uniformity of dosage units by weight variation	The acceptance value of the first 10 dosage units less than or equal to 15	FSH: 3.1 and LH: 6.1
12	Sterility	No evidence of microbial growth.	Complies

Note: NA

Remarks: The above product was complies with the specification No. SPC/FP-035.07

Prepared By	D. Sreelekha	**Checked By**	Y DHANARAJU	**Approved By**	NALINI KUMARI
Sign & Date	24/09/2026	**Sign & Date**	24/09/2026	**Sign & Date**	24/09/2026

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