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	HCGCAN 5000 IU				
Brand Batch No.	ARC42607			**Released Qty**	5,200 No
Generic Name	CHORIONIC GONADOTROPHIN FOR INJECTION IP 5000 IU				
Generic Batch No.	DC042612			**Generic Batch Approved Qty**	58,008 VL
Mfg. Date	07/26	**STP No.**	STP/FP-001.11	**A.R.No.**	26HFP0157
Exp.Date	06/29	**Spec No.**	SPC/FP-013.04	**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, leafy green color plastic cap A white or almost white lyophilized cake	Complies
2	Identification	It causes an increase in the weight of the seminal vesicles or the prostate glands of immature male rats when administered as directed in the assay	Complies
3	pH	6.0 to 8.0	6.92
4	Assay	The estimated potency is not less than 80% and not more than 125% of 5000 IU/vial. The fiducial limits of error are not less than 64% and not more than 156% of 5000 IU/vial.	4988.51 IU/Vial 99.77%,fiducial limits: 4679.46 - 5317.73 IU/Vial 93.59% - 106.35%
5	Bacterial Endotoxin	NMT 15 EU per mL	Less than 7.5 EU/mL
6	Abnormal toxicity	No animals die or show signs of ill-health in 48 hours following the injection	Complies
	Additional tests		
7	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
8	Reconstitution time	Less than or equal to 30 seconds	14.2 Seconds
9	Water content	NMT 5.0% w/w	0.54% w/w
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-28 and 25µm-14
11	Uniformity of dosage units by weight variation	The acceptance value of the first 10 dosage units less than or equal to 15	0.9 (n = 10)
12	Sterility	No evidence of microbial growth	Complies
13	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

Note: NA

Remarks: The above product was complies with the specification No. SPC/FP-013.04

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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