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	HCG CAN 5000 IU				
Brand Batch No.	ARC42606			**Released Qty**	4,800 No
Generic Name	Chorionic Gonadotrophin for injection IP 5000 IU				
Generic Batch No.	DC042609			**Generic Batch Approved Qty**	57,214 VL
Mfg. Date	06/26	**STP No.**	STP/FP-001.10	**A.R.No.**	26FFP0110
Exp.Date	05/29	**Spec No.**	SPC/FP-013.04	**Market/ Customer**	Domestic/AMERICAN REMEDIES Health Care Pvt.Ltd

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.	101.18%
5	Bacterial Endotoxin	NMT 15 EU per mL	Less than 7.5 EU per 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	Complies
9	Water content	NMT 5.0% w/w	0.72% 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 -27 and 25µm - 16
11	Uniformity of dosage units by weight variation	The acceptance value of the first 10 dosage units less than or equal to 15	Complies
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	Ranjith	**Checked By**	Y DHANARAJU	**Approved By**	NALINI KUMARI
Sign & Date	29/07/2026	**Sign & Date**	29/07/2026	**Sign & Date**	30/07/2026

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