

サンザイム

Sanzyme®

SANZYME (P) LIMITED

Plot no. 08, Sy.No.542,

Koltur (Village), Shamirpet (Mandal),

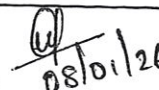
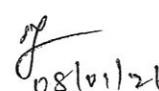
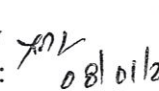
Medchal-Malkajgiri (District), Pin Code:500 101,Telangana State,India.

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT BRAND NAME

Brand Name of the Product:	HCGCAN 5000 IU				
Brand Batch No.	ARC42601	Approved Batch Qty:	5000 Vials		
Generic Name of the Product:	CHORIONIC GONADOTROPHIN INJECTION IP&IH 5000 IU				
Generic Batch No:	DC042521	Generic Batch Size	25.0L		
Mfg.Date:	12/25	STP No. :	STP/FP- 001.09	A.R.No.:	25LFP0244
Exp.Date:	11/28	Spec No.:	SPC/FP- 013.03	Market / Customer	Domestic/AMERICAN REMEDIES

S.No.	Test	Specification	Result
1	Description	A white or almost white powder in a freeze dried cake form duly sealed in 2 ml USP type I glass Vial .	Almost white powder in a freeze dried cake form duly sealed in 2 mL USP type I glass Vial.
2	Clarity of Solution	a) The solid dissolves completely, leaving no visible residue as undissolved matter. b) The constituted injection is not significantly less clear than an equal volume of the diluent or of water for injections contained in a similar container and examined in the same manner .	a)Solid dissolved completely leaving no visible residue as undissolved matter. b) Constituted injection and water for injection are equally clear when examined in the same manner contained in a similar container.
3	pH at 25°C (Determined in 1% w/v solution)	Between 6.0 to 8.0.	6.96
4	Particle matter (By visual inspection)	The constituted solution is essentially free from particles of foreign matter.	Constituted solution is free from particles of foreign matter.

Prepared By Sign & Date :  08/01/26	Checked By Sign & Date :  08/01/26	Approved By Sign & Date :  08/01/26
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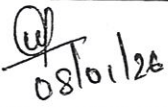
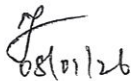
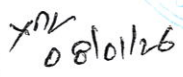
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S.No.	Test	Specification	Result
5	Uniformity of Weight	Not more than two of the individual weights deviate from the average weight by more than 10% and none deviate by more than 20%. RSD : NMT 3.0%	% of deviation Min: - 2.5424 % Max: 3.1073 % RSD: 1.49 %
6	Identification	Should causes an increase in the weight of seminal vesicles or of the Prostate glands of immature male rats when administered as directed in the Assay.	Enlargement of the weight of the seminal vesicles and prostate gland of immature male rats are observed.
7	Assay	The estimated potency is not less than 80% (4000 IU) and not more than 125% (6250 IU) of Chorionic Gonadotrophin 5000IU. The Fiducial limits of error are not less than 64% and not more than 156 % of Chorionic Gonadotrophin 5000 IU.	4987.13 IU/Vial 99.74 % 4281.47 – 5808.72 IU/Vial 85.63 % - 116.18 %

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S.No.	Test	Specification	Result
8	Abnormal Toxicity	Shall complies with the test for abnormal toxicity.	Complies
9	Bacterial Endotoxins	Not more than 15 EU/ 500 IU per mL.	Less than 15 EU/ 500 IU per mL.
10	Sterility	Shall comply with the test for sterility.	Sterile.
11	Water content	Not more than 5.0% w/w.	3.06 % w/w.
12	Hepatitis 'B' surface Antigens (HbsAG)	Hepatitis 'B' surface antigens should not be detected.	Not detected.
13	HIV I & II	HIV I & II should not be detected.	Not detected.
14	Anti HCV Antibodies	Anti HCV Antibodies should not be detected.	Not detected.

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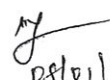

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S.No.	Test	Specification	Result
15	Particle matter (Light Obscuration particle count test)	Particles $\geq 10 \mu\text{m}$ – Not exceed 6000 per container. Particles $\geq 25 \mu\text{m}$ – Not exceed 600 per container.	$\geq 10 \mu\text{m}$ – 93 $\geq 25 \mu\text{m}$ – 57

NOTE : The above product is released based upon Generic Batch.

Remarks: The above Product complies/ does not comply with the specification No. SPC/FP-013.03as per IP&IH Specification.



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