

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:	<b>HCG CAN 5000 IU</b>				
Brand Batch No.	ARC42605	Approved Batch Qty:	15000 Vials		
Generic Name of the Product:	<b>CHORIONIC GONADOTROPHIN INJECTION IP 5000 IU</b>				
Generic Batch No:	EC042603	Generic Batch Size	25.0L		
Mfg.Date:	01/26	STP No. :	STP/FP- 001.10	A.R.No.:	26BFP0061
Exp.Date:	12/28	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	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. almost white lyophilized cake
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	Enlargement of the weight of the seminal vesicles and prostate gland of immature male rats are observed.
3	pH	6.0 to 8.0	6.98
4	Assay	<ul style="list-style-type: none"> <li>The estimated potency is not less than 80% and not more than 125% of 5000 IU/vial</li> <li>The fiducial limits of error are not less than 64% and not more than 156% of 5000 IU/vial</li> </ul>	4936.54 IU/Vial 98.74 % 4476.00 – 5442.56 IU/Vial 89.52% - 108.85 %

Prepared By Sign & Date : <i>J</i> 20/03/26	Checked By Sign & Date : <i>[Signature]</i> 20/03/26	Approved By Sign & Date : <i>[Signature]</i> 20/03/26
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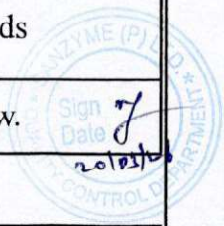
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S.No.	Test	Specification	Result
5	BacterialEndotoxins	NMT 15 EU per mL	Less than 15 EU per mL
6	Abnormal toxicity	No animals die or show signs of ill-health in 48 hours following the injection	Complies
7	Constituted solution	<ul style="list-style-type: none"> <li>• Solid should dissolve completely leaving no visible residue as undissolved matter</li> <li>• The constitution solution should not be significantly less clear than an equal volume of the diluent in a similar container and examined similarly</li> </ul>	<ul style="list-style-type: none"> <li>• Solid is dissolved completely leaving no visible residue as undissolved matter</li> <li>• Constituted injection and 0.9% Sodium Chloride Injection are equally clear when examined in the same manner contained in a similar container.</li> </ul>
8	Reconstitution time	Less than or equal to 30 seconds	13.8 seconds
9	Water content	NMT 5.0% w/w	0.99 % w/w.



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S.No.	Test	Specification	Result
10	Particulate matter	Visible particulates: Free from visible particulates	Free from visible particulates
		Sub-visible particulates: ≥10µm Not exceed 6000 particles/container ≥25µm Not exceed 600 particles/container	≥10µm – 20 ≥25µm - 08
11	Uniformity of dosage units by weight variation	The acceptance value of the first 10 dosage units less than or equal to 15. If the acceptance value is greater than 15 test the next 20 units and the acceptance value of the 30 dosage units less than or equal to 25	1.36
12	Sterility	No evidence of microbial growth	No evidence of microbial growth is found
13	Test for viruses		
	Hepatitis B surface antigen(HBs Ag)	Should be absent	Absent

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