

Sanzyme®

SANZYME (P) LIMITED
 Plot no. 08, Sy.No.542,
 Koltar (Village), Shamirpet (Mandal),
 Medchal-Malkajiri (District), Pin Code:500 101,Telangana State,India.

QUALITY CONTROL DEPARTMENT**CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT**

Brand Name of the Product :	PROFICIENT 5000 IU HP				
Brand Batch No.	ETC41901	Approved Qty. for Dispatch	6000 Vials		
Generic Name of the Product:	CHORIONIC GONADOTROPHIN INJECTION IP 5000 IU				
Generic Batch No:	1VC0418149	Generic Batch Size	25.0L		
Mfg. Date:	12/18	STP No.	STP/FP-001.05	A.R. No.:	18LFP0313
Exp. Date:	11/21	Spec No.:	SPC/FP-013.02	Market / Customer	Domestic / Exeltis.

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 : -0.75 % Max : 0.68/ % RSD: 0.49%
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.	Complies
7	Assay	The estimated potency is not less than 80%(4000 IU) and not more than 125%(6250 IU) of Chorionic Gonadotrophin 5000 IU. The Fiducial limits of error are not less than 64% and not more than 156 % of Chorionic Gonadotrophin 5000 IU.	5081.75 IU/Vial 101.64% 4788.78 – 5214.40 IU/Vial 95.78% - 104.29%
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.	Complies

Prepared By
Sign & Date :

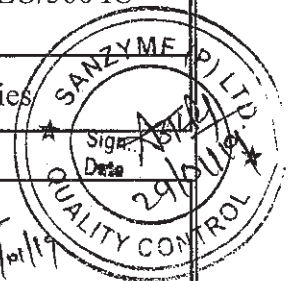
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29/01/19

Checked By
Sign & Date :

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29/01/19

Approved By
Sign & Date :

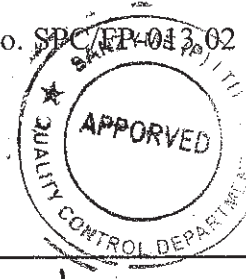



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S.No.	Test	Specification	Result
11	Water content	Not more than 5.0% w/w	3.11% w/w
12	Hepatitis 'B' surface Antigen (HbsAG)	Hepatitis 'B' surface antigens should not be detected.	Not Detected.
13	HIV I & II	HIV I & II should not be detected.	Not Detected.
14	Anti HCV Antibodies	Anti HCV Antibodies should not be detected.	Not Detected.
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.	$\geq 10 \mu\text{m}$ - 32 $\geq 25 \mu\text{m}$ - 01

Note : The above product is Released based upon Generic batch.**Remarks:** The above Material complies/ ~~does not comply~~ with the specification No. SPC/FP-013.02 as per IP & IH Specifications.Prepared By
Sign & Date : 
29/01/19Checked By 
Sign & Date : 29/01/19Approved By 
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