

Certificate of Analysis

产品/ Product: Jintropin 报告日期/ Report Date: 2017.03
 批号/ Batch No: 20170301 有效期至/ Expiry Date: 2019.10
 规格/Specifications: 3.7mg/10 IU/Vial 相对分子量/ Relative molecular: 22125D

Characterisation of a secreted form of recombinant derived human growth hormone, expressed in Escherichia coli cell

结果/results

项目/ITEMS	标准/STANDARD	检测结果/TEST RESULTS
性状/CHARACTERS	A white freeze-dried powder 白色冻干粉末	CONFORMED 一致
鉴别/IDENTIFICATION		
A (IEF)	Corresponding to the reference	CONFORMED 一致
B (HPLC/RP)	Corresponding to the reference	CONFORMED 一致
C (Peptide mapping)	Corresponding to the reference	CONFORMED 一致
D (HPLC/SEC)	Corresponding to the reference	CONFORMED 一致
检查/ tests		
Related proteins(HPLC/RP): 相关蛋白质 (HPLC/RP)	No greater than 13.0% 不大于 13.0%	4.022%
Dimer and related substances of higher molecular mass (HPLC/SEC):	No greater than 6.0% 不大于 6.0%	0.295%
Isoform distribution: 异构体分布	No greater than 6.25% 不大于 6.25%	CONFORMED 一致
Water: 水分	No more than 3.0% 不高于 3.0%	1.8%
Bacterial endotoxins: 细菌内毒素	No more than 5EU/mg hGH 不高于 5EU/mg hGH	<2.5EU/mg hGH
Host-cell-derived proteins: 宿主蛋白质	No more than 20 ng/mg hGH 不高于 20 ng/mg hGH	5ng/mg hGH
Host-cell-and vector-derived DNA: 宿主 DNA	No more than 20pg/mg hGH 不高于 20pg/mg hGH	<20pg/mg hGH
ASSAY (HPLC/SEC) 含量测定 (HPLC/SEC)	89.0%~105.0% the amount of somatropin stated on the label	99.8%
Storage: In a sterile and airtight condition at the temperature of 2°C to 8°C 储存条件: 2°C-8°C 无菌环境密封储存。		

