



R-SOP-QC-C07 (1) /00

Test Report of Recombinant Growth Hormone for Injection

No: C07-2015013

Item Name: Recombinant Growth Hormone for Injection	Specification: 10IU/3.33/mg/vial
Batch No: 20151213	Mdg Date: 2015.12.15
Expire Date: 2017.12.14	Storage: Away from light, Sealed, 2~8°C
Quantity: 26170 vials	Sample Date: 2015.12.15
Test standard: 《rhGH》	

Test Results

Test Items	Standard regulation	Test result
[[Category]]	White lyophilized Powder	White lyophilized powder
[[Identify]]		
IFE	Main belt position of test sample solution should be consistent with the main belt position reference substance solution	meet the standard
Retention time upon the method of Related Protein check	The main peak of retention time of test sample solution should be consistent with the main peak retention time of the reference substance solution	meet the standard
[[Check]]		
PH Value	pH Value will be 6.5~8.5	7.1
Solution clarity & Color	Solution should be clear colorless; Such as turbidity, compared with No.2 turbidity standard solution, shall not be thicker	Clear and colorless
Related protein	Total related protein Shall be not more than 10.0%	0.8%
High-molecular protein	shall be not more than 6.0%	0.1%
Water	No more than 3.0%	1.5%
Visible Particles	Can not check out the scrap metal, glass, or maximum particle size more than 2 mm in length and lumps obvious foreign visible particles	meet the standard
Undue toxicity	Should comply with the rule	meet the standard
Bacterial endotoxin	Every 1 mg content of bacterial endotoxin in recombinant human growth hormone should be less than 5.0EU	less than 5.0EU
Sterile	Should comply with the rule	meet the standard
Content uniformity	Should comply with the rule	meet the standard
Insoluble particle	Should comply with the rule	meet the standard
Air tightness	Should comply with the rule	meet the standard
Biological activity	Every 1mg protein contains growth hormone shall not be less than 3.0 units (Test should perform at least once a year)	3.0IU/mg
Solubility	Within 1 minute	meet the standard
[[Content test]]	Recombinant Growth Hormone should be 90.0%~110.0% of that labelled amount	101.3%
Content determination:	According to "rhGH quality standard" [QS-C07], The test results meet the standards	
Comment:		

Test: Dandan Sun

Date: 2015.12.31

Check: Qian Bo

Date: 2015.12.31