



R-SOP-QC-C06 (1) /00

Certificate of Analysis

No: C06-20180602

Product Name: Recombinant Human Growth Hormone		Quantity: 1146.6g
Batch No: 20180602		Mfg. Date: 2018.06.21
Expire Date: 2020.06.20		Storage: Sealed, 2~8℃
Sample Date: 2018.06.23		
Test standard: 《Quality Standards of Recombinant Human Growth Hormone》		
Test Results		
Test Items	Standard regulation	Test result
《Appearance》	White lyophilized Powder	Conforms
《Identify》		
HPLC	The retention time of test sample major peak complies to reference standard (Retention time upon the method of Related Protein test)	Conforms
Peptide map	The peptide map of test sample solution should be consistent with that of reference standard	Conforms
Retention time upon the method of content test	Test sample solution should be consistent with main peak retention time of reference	Conforms
IEF	Main belt position of test sample solution should be consistent with the main belt position reference substance solution	Conforms
《Check》		
Total protein	-----	0.1383mg/mg
Related protein	Total related protein should not be more than 6.0%	4.74%
High-molecular protein	Shall be not more than 4.0%	0.12%
Water	Shall be not more than 10.0%	4.13%
Bacterial endotoxin	No more than 5.0EU/mg	Less than 5.0EU/mg
Electrophoresis purity	No abnormal substance	Conforms
Mycoprotein residues	No more than 10ng/mg	Conforms
Exogenous DNA residues	No more than 10ng/dose	Conforms
《Assay》	Recombinant Growth Hormone should be not less than 0.91mg for every 1mg protein	1.0482mg/mg
Conclusion:	According to “rhGH quality standard”, the test results meet the standard	
Comment:	-----	

Reported by: LILI QIAO

Date: 2018.06.29

Checked by: WENJI YANG

Date: 2018.06.29