

Test Report

Sample			
Name	Recombinant human insulin	Number	W20200407-004
Weight	/	Formulation	/
Receipt Time	2020/04/07	Test Time	2020/04/09-04/10
Description	\		
Test			
Test Item	Content determination		
Standards			
Reference	Provided by customer	Standard Sample	Yes
Instrument			
Type	HPLC	Version	Agilent 1260

● **Chromatographic Condition:**

Column	Welch Xtimate® SEC-120 (7.8×300mm, 5 μm)
Mobile Phase	Water
Wavelength	214nm
Temperature	20°C
Flow Rate	1 mL/min
Injection Volume	20 μl
Notes	/

● **Preparation of Mobile Phase:**

Unless otherwise stated, the results shown in this test report refer only to this sample tested.

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Mobile phase: mix 100mL acetonitrile with 900mL pure water, and continue to add 0.5ml trifluoroacetic acid into the mixture. Degas to obtain.

● **Preparation of Sample Solution:**

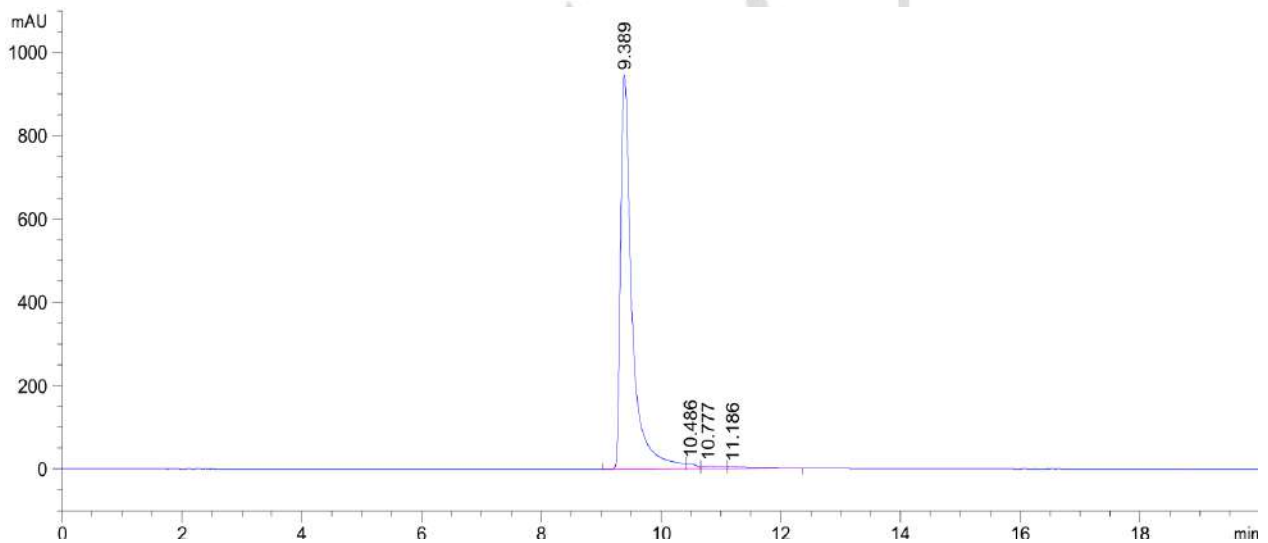
Test solution: take the original solution.

Insulin contrast solution: take appropriate amount of insulin contrast solution, then add mobile phase to dissolve it. Dilute it to the solution containing 1mg/1mL.

● **Chromatogram and Data:**

1. Verification of old column (60180300944 SEC05012.08)

The peak was normal when making the contrast, and the effect is consistent with the normal column used by the customer.



Rt [min]	k'	Area [nRIU*s]	Height [nRIU]	Symmetrical factor	Width [min]	Plates	Resolution	Selectivity
9.389	-	1.27080e4	945.49445	0.43	0.1759	15780	-	-
10.486	-	138.39590	12.58125	0.51	0.1870	17421	3.55	1.12
10.777	-	155.04192	6.77017	0.33	-	-	-	1.03
11.186	-	170.17300	5.13556	0.16	0.5730	2111	-	1.04

● **Conclusion:**

Conclusion: Using Xtimate® Sugar-Ca (7.8×300mm, 5 μm) under this chromatographic condition can meet the test requirements.

Welch

Signature

Test: Xui Lin

Date: 2020/04/10

Revise: Xiaomei Wu

Date: 2020/04/10

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