



合肥宏美双圣医药科技有限公司

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### Certificate of Analysis

Product	Empagliflozin		CAS NO.	864070-44-0
Analysis Standard	In-house Standard		Batch No.	20200412
Date of Analysis	2020-04-20		Quantity	28.0kg
Manufacturing Date	2020-04-12		Retest Date	2023-04-11
<b>Testing Items</b>	<b>Specifications</b>		<b>Results</b>	
Appearance	White to Off-white powder or crystallization		White crystalline powder	
Melting point	148°C~155°C		151.1°C~152.3°C	
Optical rotation	+15-+21°		+17.8°	
Identity test of HPLC	The retention time of the major peak in the chromatogram obtained with the test solution should match with that of the major peak in chromatogram obtained with standard solution in the test for assay by HPLC		Conform	
Related substances	Any single impurity	≤0.10%	0.05%	
	Total impurity	≤1.0%	0.31%	
R-Isomer	≤0.15%		0.06%	
Water	≤0.5%		0.15%	
Residue on ignition	≤0.1%		0.04%	
Heavy metals	≤20ppm		Conform	
Residual solvents	Methanol	≤0.3%	Not detected	
	Ethanol	≤0.5%	Not detected	
	Acetonitrile	≤0.041%	Not detected	
	Dichloromethane	≤0.06%	Not detected	
	Ethyl acetate	≤0.5%	0.17%	
	n-Hexane	≤0.029%	Not detected	
	THF	≤0.072%	0.04%	
Toluene	≤0.089%	Not detected		
Assay	Contains 98.0%~102.0% of C <sub>23</sub> H <sub>27</sub> ClO <sub>7</sub> ,calculated On anhydrous substance.		99.5%	
<b>Conclusion:</b> It conforms to the enterprise specifications.				

Q.C.: LIMEI

Q.C. Manager: WANGDONG