

Beijing Yibai Biotechnology Co., Ltd

北京屹柏生物科技有限公司

Add: Xuhui Plaza, Nanfaxin Fuqian street, Shunyi district, Beijing, China.

Phone: 0086-010-60404860

Email: sales@yibaibiotech.com**CERTIFICATE OF ANALYSIS**

Empagliflozin CAS No.: 864070-44-0		
Batch No.: QYB20181116		Quantity:120kg
Date of Production : Nov., 16, 2018		Date of Testing: Nov.,17 2018
Retest Date : Nov., 2020		Test according to: In-house
ITEMS	STANDARDS	RESULTS
Appearance	White to off-White Powder	Complies
Identification	HPLC	Complies
Melt Point	150 ~ 155 °C	152.0 ~ 154.0 °C
Loss on dry	≤0.5%	0.3%
Residue on ignition	≤0.1%	Complies
Heavy metals	≤10ppm	Complies
Water content	≤0.5%	0.32%
Optical rotation	+15 ~ +21	+19.5
Solubility in water	8-12mg/ 100ml	9mg/ 100ml
Solubility	soluble in methanol and DCM	Conformed
Related Substances	Total impurities ≤0.5%	0.23%
	Single impurity (max) ≤0.1%	0.04%
Isomer	≤0.15%	0.09%
Particle size	D90<20μ m	Complies
Assay(HPLC)	≥99.5%	99.86%
Residual solvents	Ethyl acetate≤0.5% Dichloromethane≤0.6% Ethyl alcohol≤0.5% Methanol≤0.3% ACN≤0.041% Tetrahydrofurans≤0.072% Methylbenzene≤0.089%	0.20% ND 0.03% ND ND 0.04% 0.06%
Conclusion	Complies with specification.	