



Hangzhou Huarong Pharmaceutical Co., Ltd.

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CERTIFICATE OF ANALYSIS

Product Name	Empagliflozin		
CAS NO.	864070-44-0	Mfg Date	Sep.08,2018
Batch NO.	3M042180902Z	Inspection Date	Sep.14,2018
Production Lot Size	10kg	Report Date	Sep.15,2018
Packing Specification	10Kg/drum	Report NO.	3M042160902Z001
Actual Quantity Delivered		Expiry Date	Sep.07,2020
Inspection Criteria	Corporate Inner Quality Standards & Volume IV of C.P (2015 version)		

Inspection Items	Standard	Inspection Result	Conclusion
Description	Off-white to slightly yellow powder	Off-white powder	Conforms
Identification	HPLC&IR	Conforms	Conforms
Solubility	Practically insoluble in water, soluble in methanol, slightly soluble in ethanol	Conforms	Conforms
Residue on ignition	$\leq 0.1\%$	$< 0.1\%$	Qualified
Heavy Metal	$\leq 20\text{ppm}$	Conforms	Qualified
Water	$\leq 0.5\%$	0.1%	Qualified
Chiral purity (HPLC)	Corresponding isomer $\leq 0.10\%$ Impurity D	0.03%	Qualified
	Intermediate isomer $\leq 0.10\%$ Impurity E	N.D	Qualified
Related substances (HPLC)	Impurity A $\leq 0.10\%$	0.04%	Qualified
	Impurity C $\leq 0.10\%$	N.D	Qualified
	Any unspecified impurity $\leq 0.10\%$	N.D	Qualified
	Total Impurities $\leq 1.0\%$	0.06%	Qualified
Assay (HPLC)	98.0%~102.0% (Calculated on anhydrous and solvent-free basis)	99.93%	Qualified

*Means the document is under process
Product under patent is for R&D purpose.



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Particle size distribution	D0.9($\leq 50\mu\text{m}$)	Conforms	Conforms
Residual solvents (GC)	Dichloromethane $\leq 600\text{ppm}$	N.D	Qualified
	Ethyl acetate $\leq 5000\text{ppm}$	N.D	Qualified
	Ethanol $\leq 5000\text{ppm}$	805ppm	Qualified
	Toluene $\leq 890\text{ppm}$	537ppm	Qualified
	Methanol $\leq 3000\text{ppm}$	N.D	Qualified
	2-propanol $\leq 5000\text{ppm}$	N.D	Qualified
	Tetrahydrofurans $\leq 720\text{ppm}$	N.D	Qualified
	n-heptane $\leq 5000\text{ppm}$	N.D	Qualified
Conclusion	Acoording with the standard, it conformed		

Established by:

Reviewed by:

Inspected by:



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