



# 武汉福鑫化工有限公司

## Wuhan Fortuna Chemical Co.,Ltd

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### CERTIFICATE OF ANALYSIS

Product: Cefalexin Monohydrate

Lot No.: 12052011126

Mfg. date: Nov, 23, 2020

Quantity: 80kg

Exp. date: Oct, 2023

Items	Specifications	Results
Appearance	White to off-white crystalline powder	Off-white crystalline powder
Solubility	Slightly soluble in water, practically insoluble in alcohol, in chloroform, in ether.	Conforms
Identification	IR spectrum of sample must be complies with that of reference standard.	Conforms
	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.	Conforms
pH	3.0 ~ 5.5	4.9
Water	4.0%~8.0%	5.0%
Optical rotation (anhydrous substance)	+149° ~ +158°	+154°
Crystalline	Should meet the requirements	Conforms
Related substances	Any other impurity $\leq 1.0\%$	0.04%
	Total impurities $\leq 5.0\%$	0.13%
Dimethylformamide	$\leq 0.088\%$	Not detected
Methanol	$\leq 0.3\%$	0.01%
Acetone	$\leq 0.3\%$	0.05%
Methylene chloride	$\leq 0.06\%$	Not detected
Dimethylaniline	$\leq 20\text{ppm}$	Not detected
Bulk Density(g/ml)	—	0.30
Tapped Density(g/ml)	—	0.53
Sterility	Sterilized by Gamma-ray	Pass
Assay	Has a potency of 950 $\mu\text{g/mg}$ ~1030 $\mu\text{g/mg}$ (on anhydrous basis)	998 $\mu\text{g/mg}$
Particle size	90% pass 50micron	Pass
Conclusion	The product conforms to the standard of USP42.	

QC: Luo Xiaofeng

Tester: AT02

Re-tester: AT03