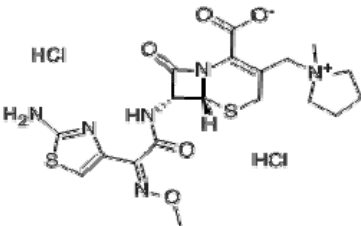


**HANGZHOU DINGYAN CHEM CO.,LTD**

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E-Mail:sales@dingyanchem.com,Web: www.dingyanchem.com

CERTIFICATE OF ANALYSIS**NO: DYC101607071**

Product name	Cefepime hydrochloride (USP37)
CAS Number	107648-80-6
Molecule Structure	
Molecule Formula	C ₁₉ H ₂₄ N ₆ O ₅ S ₂ ·2ClH
Batch number	20160201
Manuf date	2016-02-01
Testing date	2016-02-02

Items	Standard	Result
Appearance	White to yellowish powder	Almost white powder
Identification	TLC: Arginine appears as a dark red spot. The intensity and the R value of the spot from the Sample solution should correspond to those from the Standard solution	Complies
	The retention time of the major peak of the Sample solution should correspond to that of the Standard solution, as obtained in the Assay.	Complies
Particulate contamination	No visible foreign matter	Complies
Water	≤4.0%	2.1%
PH	4.0~6.0	5.6
Related substances	Cefepime related compound A ≤0.5%	0.0%
	Cefepime related compound C ≤0.5%	N.D
	Any individual unspecified impurity ≤0.5%	0.0%
	Total impurities ≤2.2%	0.2%
1-Methylpyrrolidine	≤1.0%	0.0%
Particulate matter	≥10um ≤6000 grains /g	140 grains /g
	≥25um ≤600 grains /g	4 grains /g
Bacterial endoxins	≤0.06USP EU/mg Not more than 0.06USP Endotoxin Unit/mg of cefepime	Complies

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Sterility	Should be sterile	sterile
Assay	Not less than 82.5% and not more than 91.1%(w/w) of cefepime on the anhydrous basis and nothing L-Arginine	86.4%
Cefepime content	Report the result (Hydrous)	53.0%
L-Arginine Assay	Report the result (Hydrous)	36.6%
Conclusion	The product complies referred above USP37 specification	

Hangzhou Dingyan Chem Co., Ltd.
QUALITY CONTROL: Freya
Quality Control
Signature(s)

CHECK: 姚仙娟

INSPECTOR: 刘清风

Add: Xiasha 571,19TH Street E-COMMERCE 4A601-602,Jiangan Area, Hangzhou, China