

## 瑾 岚 医 药 技 术 开 发 有 限 公 司

## JINLAN PHARM-DRUGS TECHNOLOGY CO., LIMITED Hangzhou ROYALL Import & Export Co.,Ltd.

## **CERTIFICATE OF ANALYSIS**

Product Name	Bortezomib	CAS NO.	179324-69-7
Quantity	57g	Batch Number	BL20120629001
Manufacture Date	2012.06.29	Expiry Date	2013.06.28
Report Date	2012.06.29	Analytical Method	In-house

Items	Specification	Results
Appearance	White or off-white crystalline powder	Conform
Water(KF)	0.1% Max	Conform
Residue on Ignition	0.1% Max	Conform
Specific rotation (C1.0,Methanol)	-43.0°~-48.0°	-48.2°
Heavy metal	Not more than 10 ppm	4ppm
	Methylene chloride : Not more than 0.0002%	ND
Residual Solvents (By GC)	Methanol : Not more than 0.002%	ND
Should be conforms ICH Q3C	Ethyl acetate: Not more than 0.005%	0.003%
	n - Hexane : Not more than 0.0002%	ND
	Total impurities: Not more than 0.2%	0.05%
Related Substances	Single impurity: NMT 0.1%	0.02%
Assay (HPLC)	Not less than 99.8%	99.95%
		S 2 L

Conclusion: The product conform with the respect to the above specifications.

We certify that the above mentioned product is in conformity with the specification.

Tested by: Wu Yan Checked by: Huang Guoli Approved by: Xu Fei

Add: 1113 Modern Star, #337 Shaoxing Road, Hangzhou, China Tel: 0086-571-85829052-801/802 Fax: 0086-571-85829053

Email: sales06@royalpharms.com Http://www.royalpharms.com