



石药集团中诺药业（石家庄）有限公司

CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd.

4.) Certificate of Analysis of API (Benzathine Benzylpenicillin):

CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO., LTD

Certificate of Analysis

PRODUCT: Benzathine Benzylpenicillin		
Batch No: 515507502		Sampling date: 2015.08
Weight : 215 BOU		Report Date: 2015.09
Date of expiry: 2019-09		Basis : BP 2015
Supplier: CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd Address: No.47 Fengshou Road, Shijiazhuang City, China		
ITEMS	SPECIFICATION	RESULTS
Character	White or almost white powder	White powder
Identification	A. The infrared absorption spectrum is concordant with the spectrum of benzathine	Complies
Acidity or alkalinity	Positive reaction	Complies
Related substance	Impurity C \leq 2.0%	0.15%
	Any other impurity \leq 1.0%	0.02%
Water	5.0%-8.0%	6.8%
Bacterial endotoxins	Less than 0.13 IU/mg	Less than 0.13 IU/mg
Sterility	Sterile	Sterile
Content of benzathine	24.0%-27.0% (anhydrous basis)	26.6%
Benzathine benzylpenicillin	96.0%-102.0% (anhydrous basis)	99.7%
Conclusion	It complies with the requirements of BP 2015 standards.	

Q.C. Manager: Jin Yinghui

Remark:

The API (Benzathine Benzylpenicillin) Batch No. 515507502 was evaluated against the Working Standard of the API Batch No.BP-2.5-151001.

The storage condition is below 25 °C.