

CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)
CO., LTD.

CERTIFICATION OF ANALYSIS

PRODUCT: BENZYL PENICILLIN BENZATHINE FOR INJECTION 1.2 MEGA		
Batch No.: 751160903		Manufacture Date: 2016-09
Quantity: 100,000 VIALS		Expiration Date: 2020-09
ITEMS	SPECIFICATION	RESULTS
Identification	Positive reaction	Positive reaction
Crystallinity	Meet the requirements	Meet the requirements
Bacterial endotoxins	Meet the requirements	Meet the requirements
PH	5.0-7.5	7.2
Sterility	Meet the requirements	Meet the requirements
Water	5.0%-8.0%	6.7%
ASSAY		
Benzathine content (anhydrous) (C ₁₆ H ₂₀ N ₂)	24.0% -27.0%	25.9%
Potency of the Penicillin G Benzathine	1090-1272 Units/mg	1152Units/mg
Labeled amount of penicillin	95%-110%	103.3%

Conclusion: Complies with the requirement of BP 2005 standards
(reference standard of benzathine benzyl penicillin)

Director of Division: 靳英会