



NORTH CHINA PHARMACEUTICAL GROUP SEMISYNTECH CO., LTD



DISTRIBUIDO POR
METAPHARMACEUTICAL
INDUSTRIAL SLU

19 NOV 2024

RP NO.E 924083122

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CERTIFICATE OF ANALYSIS

Product name: Benzylpenicillin, Procaine(Sterile)

Batch/Lot number: 924083122

Manufacture date: 2024-08-31

Packing: 20.00BOU/Drum

Report date: 2024-09-18

Quantity: 490.00BOU

Expiry date: 2027-07

Items	Specifications	Results
Characters	1) White or almost white, crystalline powder 2) Slightly hygroscopic 3) Slightly soluble in water, sparingly soluble in ethanol (96 percent),	1) Complies 2) ND 3) ND
Identification	IR spectrum complies with that of reference standard	Complies
pH	5.0 ~ 7.5 (50mg/15mL H ₂ O)	5.9
Related substances	Impurity A: $\leq 0.024\%$ Impurity B (sum of isomers): $\leq 0.4\%$ Impurity C (sum of epimers): $\leq 0.4\%$ Impurity D: $\leq 0.2\%$ Impurity E: $\leq 0.2\%$ Impurity F: $\leq 0.5\%$ Impurity G: $\leq 0.5\%$ Impurity H: $\leq 0.5\%$ Impurity I: $\leq 0.5\%$ Impurity J: $\leq 0.5\%$ Specified impurity I: $\leq 0.20\%$ Any other impurity: $\leq 0.2\%$ Total impurity 1: $\leq 2.0\%$ Total impurity 2: $\leq 2.0\%$	NDT 0.0% 0.0% 0.0% 0.0% 0.0% 0.0% 0.0% 0.0% 0.0% 0.05% ND 0.07% 0.12% ND
Water	2.8 ~ 4.2 %	3.2%
Residual solvents.	n-Butanol $\leq 5000\text{ppm}$ Ethyl acetate $\leq 5000\text{ppm}$	62ppm 5ppm
Bacterial endotoxins	$< 0.10\text{ IU/mg}$	$< 0.10\text{ IU/mg}$
Sterility	Meets the requirements	Meets the requirements
Assay	Procaine 39.0 ~ 42.0 % (calculated with reference to the anhydrous substance) Procaine Benzylpenicillin 96.0 ~ 102.0 % (calculated with reference to the anhydrous substance)	41.6% 100.4%

Conclusion:

Complies with Ph. Eur. 11th Edition standards.

Remark:

This batch has been manufactured under GMP conditions and meets the set quality specifications.

Delegated Q.P.

刘彦芳





NCPC

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Items	Specifications	Results
Potency(in house)	971u/mg ~1031u/mg	1015u/mg
Particle Size(in house)	10%	1.19µm
	50%	8.10µm
	90%	22.8µm

Conclusion:

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