



瑞阳制药股份有限公司
Reyoung Pharmaceutical Co., Ltd.

1052.276

CERTIFICATE OF ANALYSIS

Product name	Procaine Benzylpenicillin	Strength	Raw Materials
Batch No	21113009	Quality standard	BP2015
Mfg date	2021.12	Exp date	2024.11
Test date	2021.12.03	Report date	2021.12.19
Quantity	593.50 kg	Source	103 workshop

TESTS	SPECIFICATIONS	RESULTS
Appearance	White or almost white crystalline powder	White crystalline powder
Identification	A. Infrared absorption spectrophotometry	Complies
	B. Thin-layer chromatography	Complies
	C. Mix the contents of the tube by swirling; the solution is practically colourless. Place the test-tube on a waterbath for 1 min; a reddish-brown colour develops	Positive reaction
	D. Gives the reaction of primary aromatic amines	Positive reaction
Visible particulates	≤ 5	≤ 5
pH	5.0 to 7.5	6.07
Specific optical rotation	$+165^{\circ}$ to $+180^{\circ}$	176.7°
Related substances	Impurity A $\leq 0.024\%$	Not detected
	Other single impurity 1.0%	0.05%
Bacterial endotoxin	<0.10 IU /mg	<0.10 IU /mg
Water	2.8% to 4.2%	3.17%
Residual solvents	Methanol $\leq 0.3\%$	Not detected
	Normal butanol $\leq 0.5\%$	Not detected
	Ethyl acetate $\leq 0.5\%$	Not detected
Sterility	Should be sterile	Sterile
Assay	It contains 39.0 percent to 42.0 percent of Procaine, calculated on the anhydrous basis.	41.27%
	It contains 96.0 percent to 102.0 percent of Procaine penicillin, calculated on the anhydrous basis.	99.74%