



Shandong Lukang Pharmaceutical Co., Ltd.

CERTIFICATE OF ANALYSIS

PRODUCT NAME	Benzylpenicillin Potassium Sterile	REPORTING NO	0009
MFG. DATE	2024-03-30	BATCH NO	1022403007-1
EXP. DATE	2028-03-29	PACKING	9kg/bagX2bags/drum
REPORTING DATE	2024-08-21	QUANTITY	540.00kg(60bags)
DELIVERY QUANTITY	54KG/86.454BOU	TEL.	0537-2983117
MFG. SITE	88 Xinhua Road, Zoucheng Industrial Park, Zoucheng, Shandong, P.R. China		

Reference: EP 10.0

ITEMS	SPECIFICATION	RESULT	CONCLUSION
Characters	Appearance: White or almost white crystalline powder	White, slightly hygroscopic, crystalline powder.	Conform
	Solubility: Very soluble in water, practically insoluble in fatty oil and in liquid paraffin	Conform	Conform
Identification	Infrared absorption spectrophotometry	Conform	Conform
	It gives reaction (a) of potassium	Conform	Conform
Appearance of solution	Clear	< I	Conform
pH	5.5 - 7.5	6.6	Conform
Loss on drying	≤1.0%	0.1%	Conform
n-butanol (in-house)	≤0.2%	0.02%	Conform
Ethyl acetate (in-house)	≤0.2%	0.0001%	Conform
Visible particles (In-house)	Meet the requirement	Conform	Conform
Sub-visible particles (in-house)	≥10 μm: ≤3000 particles/g	442 particles/g	Conform
	≥25 μm: ≤300 particles/g	50 particles/g	Conform
Related substances	Impurity F: ≤2.0%	0.01%	Conform
	Impurity E: ≤1.0%	N.D.	Conform
	Impurity B: ≤0.5%	N.D.	Conform
	Impurity A: ≤0.2%	N.D.	Conform
	Impurity C: ≤0.2%	0.01%	Conform
	Impurity D: ≤0.2%	0.004%	Conform
	Impurity G: ≤0.2%	N.D.	Conform
	Impurity H: ≤0.2%	N.D.	Conform
	Any other impurity: ≤0.2%	0.04%	Conform
	Total impurities: ≤3.0%	0.14%	Conform
Sterility	Sterile	Conform	Conform
Bacterial endotoxins	<0.16 IU/mg	Conform	Conform
Assay (dried substance)	95.0% - 102.0% of C ₁₆ H ₁₇ KN ₂ O ₄ S	100.3%	Conform

Conclusion: The above results comply with the EP 10.0.

Remark:

Director of QC Dept.



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