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Certificate of Analysis

Name of product :	Procaine Hydrochloride EP	CAS No: [51-05-8]
Batch No.:	082 07 15	Batch size: 2000 kg
Country of origin : Czech Republic	Date of Manuf. 10 July 2015	Expiry date June 2020

Analytical	Results	Specifications Ph.Eur.8 (EP)
Characters	Corresponding	A white almost white, crystalline powder or colourless crystals, very soluble in water, soluble in ethanol
Identification		
Proof A	154.8 °C	154 to 158 °C
Proof B	Complies with test	Complies with test
Proof E	Complies with test	Complies with test
Appearance of solution	Complies with test	Clear, colourless
pH	5.69	5.0 to 6.5
Related substances	< 0.05%	Max. 0.05%
Heavy metals	< 5 ppm	Max. 5 ppm
Loss on drying	0.055 %	Max.0.5%
Sulphated ash	0.010 %	Max.0.1%
Assay (titrimetric)	99.97 %	99.0% to 101.0%
Supplementary tests Ph.Eur.8.,BP 2015CL 2009		
Residual solvents-only class 2 solvent Methanol and class 3 solvent Ethanol are likely to be present. Residual class 3 solvents are below 0.5%.		
- methanol	25 ppm	Max. 3000 ppm
- ethanol	634 ppm	Max. 5000 ppm
Impurity (GC)		
Diethylaminoethanol	< 100 ppm	Max. 300 ppm
Impurities (HPLC)		
Known Impurities		
4-aminobenzoic acid	0.028 %	Max. 0.1 %
Methyl 4-aminobenzoate	0.013 %	Max. 0.1 %
N-methyl Procaine Hydrochloride	0.085 %	Max. 0.1 %
Unknown Impurities		
Individual Unknown Impurities (Highest)	<0.010 %	Max. 0.10 %
Total unknown impurities	<0.010 %	Not specified
Total impurities	< 0.136 %	Max. 0.2 %
Assay (HPLC)	100.44 %	98.0% to 102.0%
Result: The product complies with Ph.Eur.8., BP 2015, CL 2009		
Date : 21 July 2015		Milan Kotyk QA manager