



Certificate of Analysis

Name of product :	Procaine Hydrochloride EP	CAS No: [51-05-8]
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Batch No.:	176 12 12	Batch size: 2000 kg
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Country of origin : Czech Republic	Date of Manuf. 19 December 2012	Expiry date November 2017
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Analytical	Results	Specifications Ph.Eur.7 (EP)
Description	Corresponding	White crystalline substance
Identification		
Proof A	155.5 °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	5.92	5.0 to 6.5
Related substances	< 0.05%	Max. 0.05%
Heavy metals	< 5 ppm	Max. 5 ppm
Loss on drying	0.090 %	Max.0.5%
Sulphated ash	0.044 %	Max.0.1%
Assay (titrimetric)	100.23 %	99.0% to 101.0%

Supplementary tests Ph.Eur.7.,BP 2007,ČL 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	18 ppm	Max. 3000 ppm
- ethanol	752 ppm	Max. 5000 ppm

Impurities (HPLC)

Unknown impurity-max.	<0.040 %	Max. 0.10 %
4-aminobenzoic acid	<0.020%	Max. 0.1 %
Methyl 4-aminobenzoate	<0.030 %	Max. 0.1 %
Total unknown impurities	<0.040 %	Not specified
Total impurities	<0.090 %	Max. 0.2 %

Impurity (GC)

Diethylaminoethanol	< 13 ppm	Max. 1000 ppm
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Result: The product complies with Ph.Eur.7., BP 2007, CL 2009

Date : 20 December 2012	Milan Kotyk QA manager
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