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Email : enquiries@norbrooksro.com

Certificate of Analysis

Name of product :	Procaine Hydrochloride EP	CAS No: [51-05-8]
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Batch No.:	085 04 16	Batch size: 2000 kg
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Country of origin : Czech Republic	Date of Manuf. 13 April 2016	Expiry date March 2021
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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	6.0	5.0 to 6.5
Related substances	< 0.05%	Max. 0.05%
Heavy metals	< 5 ppm	Max. 5 ppm
Loss on drying	0.030 %	Max.0.5%
Sulphated ash	0.010 %	Max.0.1%
Assay (titrimetric)	99.98 %	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	< 2 ppm	Max. 3000 ppm
- ethanol	330 ppm	Max. 5000 ppm

Impurity (GC)

Diethylaminoethanol	< 0.1 ppm	Max. 88 ppm
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Impurities (HPLC)

Known Impurities

4-aminobenzoic acid	0.013 %	Max. 0.1 %
Methyl 4-aminobenzoate	<0.010 %	Max. 0.1 %
N-methyl Procaine Hydrochloride	0.049 %	Max. 0.1 %

Unknown Impurities

Individual Unknown Impurities (Highest)	<0.005 %	Max. 0.10 %
Total unknown impurities	<0.005 %	Not specified
Total impurities	<0.077 %	Max. 0.2 %

Assay (HPLC)	100.25 %	98.0% to 102.0%
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Result: The product complies with Ph.Eur.8.6, BP 2016, CL 2009

Date : 22 April 2016	Milan Kotyk QA manager
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148319

3/4/2014

Invoice Amount:

Carrier

[illegible]

11/15/85:

206/96