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Certificate of Analysis

Name of product :	Benzocaine EP	CAS No : 94-09-7
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Batch No.:	079 07 08	Batch size: 2 000 kg
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Country of origin : Czech Republic	Date of Manuf. 15 July 2008	Expiry date June 2014
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Analytical	Results	Specifications Ph.Eur.7 (EP),BP 2013, CL 2009
Description	Corresponding	White fine crystalline substance
Identification		
Proof A (Melting Point)	89.7 °C	89 to 92 °C
Proof B	Complies with test	Complies with test
Appearance	Complies with test	Clear, colorless
Alkalinity or acidity	0.22 ml	Max.0.5ml
Loss on drying	0.005%	Max.0.5%
Sulphated ash	0.015 %	Max.0.1%
Assay of benzocaine (titrimetric)	100.02 %	99.0% to 101.0%

Supplementary tests Ph.Eur.7 (EP),BP 2013,CL 2009

Impurities (HPLC)	Analysis	Guarantee
-Unknown impurity max.	< 0.015 %	Max.0.10%
-4-aminobenzoic acid	< 0.015 %	Max.0.1%
-Methyl 4-aminobenzoate	< 0.015 %	Max.0.1%
Total unknown impurities	< 0.015 %	Not specified
Total impurities	< 0.045 %	Max.0.2%
-Residual solvents: Ethanol. Ethanol is the only solvent applied in the course of Benzocaine production	See loss on drying	Loss on drying is a predicable test for maximal potential ethanol content evidence

Result :The product complies with Ph.Eur.7 (EP), BP 2013, CL 2009

Date : 27 March 2013	Milan Kotyk QA manager
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