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Certificate of Analysis

Name of product :	Benzocaine EP	CAS No : 94-09-7
Batch No.:	040 03 13	Batch size: 2 000 kg
Country of origin : Czech Republic	Date of Manuf. 26 March 2013	Expiry date February 2018

Analytical	Results	Specifications Ph.Eur.7 (EP),BP 2013, CL 2009
Description	Corresponding	White fine crystalline substance
Identification		
Proof A (Melting Point)	89.6 °C	89 to 92 °C
Proof B	Complies with test	Complies with test
Appearance	Complies with test	Clear, colorless
Alkalinity or acidity	0.20 ml	Max.0.5ml
Loss on drying	0.025 %	Max.0.5%
Sulphated ash	0.034 %	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)		
Unknown impurity max.	<0.015 %	Max.0.10%
4-aminobenzoic acid	<0.050 %	Max.0.1%
Methyl 4-aminobenzoate	<0.015 %	Max.0.1%
Total unknown impurities	<0.015 %	Not specified
Total impurities	<0.080 %	Max.0.2%
Residual solvents -Only the class 3 solvent Ethanol is likely to be present. Loss on Drying is < 0.5%.		
Ethanol	0.025 %	Max.0.5%

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

Date : 3 April 2013

Milan Kotyk
QA manager

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

13L06-802

Director Técnico

28.11.14

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