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Certificate of Analysis

Name of product :	Benzocaine EP	CAS No : 94-09-7
Batch No.:	011 12 14	Batch size: 2 000 kg
Country of origin : Czech Republic	Date of Manuf. 31 December 2014	Retest date November 2019

Analytical	Results	Specifications Ph.Eur.8 (EP), BP 2014, CL 2009
Appearance	Corresponding	White or almost white, crystalline powder or colourless crystals
Solubility	Corresponding	Very slightly soluble in water, freely soluble in ethanol (96 per cent)
Identification		
Proof A (Melting Point)	89.1 °C	89 to 92 °C
Proof B	Complies with test	Complies with test
Appearance of solution	Complies with test	Clear, colorless
Acidity or alkalinity	0.29 ml	Max.0.5ml
Loss on drying	0.025 %	Max.0.5%
Sulphated ash	0.027 %	Max.0.1%
Assay	100.28 %	99.0% to 101.0%

Supplementary tests Ph.Eur.8 (EP), BP 2014, CL 2009

Impurities (HPLC)		
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 -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. 8 (EP), BP 2014, CL 2009

Date : 7 January 2015

Milan Kotyk
QA manager

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

ISC 19-804

Director Técnico

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