



Certificate of Analysis

Productname: **Benzocainum**
Number of analysis/Inspection Code: 1 / KEUR-69662B
Batchnumber: **10L08-B03-275229**
Reference code / No.:
Analysed according to: **PH.EUR.+**

FARMADENT d.o.o. Minarikova ul. 6 2000 Maribor Prejel: FUIJS DRAGO <i>[Signature]</i> Datum pregleda: 29.1.14. Pregledal: MAROLT Robert, mag. farm., spec. <i>[Signature]</i> Datum pregleda: 25.1.2014
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Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder	Conform		
Particle size	75% < 250 µm	79	%	Sieve analysis
Identification A	89 - 92	90	°C	Melting point
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear and colourless	Conform		5% m/V in alcohol
Acidity or alkalinity	Conform	Conform		
Loss on drying	<= 0,5	<0,1	%	In vacuo
Sulphated ash	<= 0,1	Conform	%	
Residual solvents	CPMP/ICH/283/95	Conform		
Assay Benzocaine	99,0 - 101,0	100,1	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

Release:
Drs. M.V. Garcia Alia
Pharmacist - QA Manager / QP

28-12-10

Expiration: 12-2015 ✓

Conclusion: APPROVED

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