



## Certificate of Analysis

FARMADENT d.o.o.  
Minarčkova ul. 6  
2000 Maribor  
Prejel: PUJS DRAGO  
Za:   
Datum prejema: 10.5.14  
Pregledal: MAROLT Robert, mag. farm. spec.  
FA   
Datum pregleda: 11.3.2014

Productname: **Benzocainum**  
Number of analysis/Inspection Code: 1 / KEUR-82567B  
Batchnumber: **12C21-B03-287134**  
Reference code / No.: 2471 / BZ-27/11-12  
Analysed according to: **PH.EUR7.4+ 3.17**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder	Conform		
Particle size	75% < 250 µm	90	%	Sieve analysis
Identification A	89 - 92	89	°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		Data producer
Assay Benzocaine	99,0 - 101,0	100,6	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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

06-04-12

Expiration: 03-2017

Conclusion: APPROVED

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