

## Analizni izvid / Certificate of analysis

## Calcii pantothenas

Serijska številka / Batch n<sup>o</sup>: LX0157-110004 ✓  
 Deklaracija / Corresponds to: Ph.Eur, FCC, USP

Datum analize / Date of analysis: 21/12/2011  
 Datum proizvodnje / Manufacturing date: 06/2011  
 Uporabno do / Expiry date: 06/2014 ✓

	Specifikacija / Specification Values	Rezultati / Batch Values
Lastnosti / Properties:	Bel, fin, sipek granuliran prašek. / White, fine, free flowing granulate powder.	Ustreza / Conforms
Istovetnost / Identification:	according to test	Ustreza / Conforms
Vsebnost / Assay:	98,0 – 101,0 % (dried substance)	100,3
Kalcij / Calcium (complex):	8,20 – 8,60 %	8,3
Videz raztopine / Appearance of solution:	according to test	Ustreza / Conforms
pH / pH:	6,8 – 8,0	6,9
Alkalnost / Alkalinity:	according to test	Ustreza / Conforms
Specifična optična sučnost / Specific optical rotation:	+ 25,5° to + 27,5°	+ 26,8
Klorid / Chloride:	≤ 200 ppm	Ustreza / Conforms
Težke kovine / Heavy metals:	≤ 20 ppm	Ustreza / Conforms
Svinec / Lead:	≤ 2 ppm	Ustreza / Conforms
Alkaloidi / Alkaloids:	No turbidity produced	Ustreza / Conforms
3-aminopropionska kislina / 3-aminopropionic acid:	≤ 0,5 %	0,14
Dušik / Nitrogen:	5,7 – 6,0	6,0
Diklorometan / Dichloromethane:	≤ 600 mg/kg	Ustreza / Conforms
Metanol / Methanol:	≤ 3000 mg/kg	Ustreza / Conforms
Izguba pri sušenju / Loss on drying:	≤ 3,0 %	2,3
Mikrobno onečiščenje / Microbial contamination:		
. total aerobic microbial count	≤ 1000 CFU/g	Ustreza / Conforms
. molds and yeasts	≤ 100 CFU/g	Ustreza / Conforms
. enterobacteria	≤ 10 CFU/g	Ustreza / Conforms
. Staphylococcus	Absent/10 g	Ustreza / Conforms
. E.Coli	Absent/10 g	Ustreza / Conforms
. Salmonella	Absent/25 g	Ustreza / Conforms
. Pseudomonas aeruginosa	Absent/10 g	Ustreza / Conforms

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 Minarikova ul. 6  
 2000 Maribor  
 Prejel: FUJS DRAGO  
 Datum prejema: 9.7.2013  
 Pregledal: MAROLT Robert, mag. farm. spec.  
 Datum pregleda: 10.7.2013

Opombe / Notes:

Mnenje / Opinion:

Po navedbah proizvajalca substanca ustreza zgoraj navedenim parametrom Ph.Eur 7, FCC, USP.  
 According to the manufacturers specifications the substance corresponds to the stated parameters Ph.Eur 7, FCC, USP.

Ines LOGAR mag.farm., spec.

Vodja službe za kontrolo kakovosti  
 Quality assurance manager

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Stran/Page 1/1

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