

Analizni izvid / Certificate of analysis

Zonisamide

Serijska številka / Batch n°: LC3157-110003
 Deklaracija / Corresponds to: /
 Proizvajalec / Manufacturer: Dipharma Francis sri

Datum analize / Date of analysis: 30/01/2012
 Datum proizvodnje / Manufacturing date: 08/2011
 Uporabno do / Expiry date: 08/2016

	Specifikacija / Specification Values	Rezultati / Batch Values
Lastnosti / Properties:	Bel ali skoraj bel kristaliničen prašek / White or almost white crystalline powder	Ustreza / Conforms
Istovetnost / Identification:	according to test	Ustreza / Conforms
Voda / Water:	≤ 0.50 %	0,1
Sulfatni pepel / Sulphated ash:	≤ 0.10 %	0,0
Tališče / Melting point:	162,0 – 166,0 °C	164,8
Težke kovine / Heavy metals:	≤ 10 ppm	< 10
Kloridi / Chlorides:	≤ 500 ppm	< 500
Sorodne snovi / Related substances:		
- non specific impurities	≤ 0,10 %	< 0,02
- sum of impurities	≤ 0,30 %	0,00
- triethylamine	≤ 0,10 %	0,00
Vsebnost / Assay:	98,0 – 102,0 %	100,0
Zaostala topila / Residual solvents:		
- acetonitrile	≤ 410 ppm	151
- methylene chloride	≤ 500 ppm	< 100
- ethyl acetate	≤ 500 ppm	< 100
- isopropanol	≤ 500 ppm	< 100
- toluene	≤ 500 ppm	< 100

Opombe / Notes:

Mnenje / Opinion:

Po navedbah proizvajalca substanca ustreza zgoraj navedenim parametrom.
 According to the manufacturers specifications, the product corresponds to the stated parameters.

Ines LOGAR mag.farm., spec.

Vodja službe za kontrolo kakovosti
 Quality assurance manager

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