

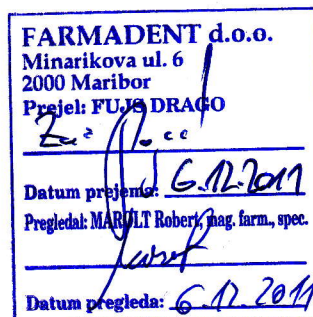
Analizni izvid / Certificate of analysis

Ephedrini hydrochloridum

Serijska številka / Batch n°: LX0262-110005
 Deklaracija / Corresponds to: Ph.Eur.
 Proizvajalec / Manufacturer: BASF Pharmachemikalien

Datum analize / Date of analysis: 01/12/2011
 Datum proizvodnje / Manufacturing date: 03/2011
 Uporabno do / Expiry date: 03/2016

	Specifikacija / Specification Values	Rezultati / Batch Values
Lastnosti / Properties:	Bel ali skoraj bel kristaliničen prašek ali brezbarvni kristali / White or almost white, crystalline powder or colourless crystals	Ustrezna / Conforms
Topnost / Solubility:	according to test	Ustrezna / Conforms
Tališče / Melting point:	~ 219 °C	219,5
Istovetnost / Identity:	according to test	Ustrezna / Conforms
Videz raztopine / Appearance of solution:	according to test	Ustrezna / Conforms
Kislost in alkalnost / Acidity and alkalinity:	according to test	Ustrezna / Conforms
Specifična optična sučnost / Specific rotation:	-33,5° / -35,5° (dried substance)	-34,0
Sorodne substance / Related substances:		
. impurity A:	≤ 0,2 %	< 0,1
. unspecified impurities:	≤ 0,1 %	Ustrezna / Conforms
. sum of impurities other than A:	≤ 0,5 %	< 0,05
Sulfat / Sulphat:	≤ 100 ppm	< 100
Izguba pri sušenju / Loss on drying:	≤ 0,5 %	< 0,1
Sulfatni pepel / Sulphated ash:	≤ 0,1 %	< 0,1
Vsebnost / Assay:	99,0 - 101,0 %	99,85
Velikost delcev / Particle size (below 0,3mm):	≥ 100 %	100



Opombe / Notes:

Mnenje / Opinion:

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

Ines LOGAR mag.farm., spec.

Vodja službe za kontrolo kakovosti
 Quality assurance manager

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