

Analizni izvid / Certificate of analysis

Ephedrini hydrochloridum

Serijska številka / Batch n°: LX0262-110006
 Deklaracija / Corresponds to: Ph.Eur.
 Proizvajalec / Manufacturer: BASF Pharmachemikalien

Datum analize / Date of analysis: 19/12/2011
 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	220
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)	-33,9
Sorodne substance / Related substances:		
. impurity A:	≤ 0,2 %	< 0,1
. unspecified impurities:	≤ 0,1 %	Ustrezna / Conforms
. sum of impurities other than A:	≤ 0,5 %	< 0,1
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 %	100,4
Velikost delcev / Particle size (bellow 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 7 th .

Ines LOGAR mag.farm., spec.
 Vodja službe za kontrolo kakovosti
 Quality assurance manager

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