

Analizni izvid / Certificate of analysis

Hyoscini-scopolamini hydrobromidum

Serijska številka / Batch n°: LX0325-100002
 Deklaracija / Corresponds to: Ph.Eur.
 Proizvajalec / Manufacturer: Boehringer Ingelheim Pharma

Datum analize / Date of analysis: 24/03/2011
 Datum proizvodnje / Manufacturing date: 12/2010
 Uporabno do / Expiry date: 11/2012

	Specifikacija / Specification Values	Rezultati / Batch Values
Lastnosti / Properties:	according to test	Ustreza / Conforms
Videz raztopine / Appearance of solution:	according to test	Ustreza / Conforms
Topnost / Solubility:	according to test	Ustreza / Conforms
Istovetnost / Identity:		
. melting point	188 – 193 °C	190,4
. test E	according to test	Ustreza / Conforms
. IR	according to test	Ustreza / Conforms
Čistoča / Purity:	according to test	Ustreza / Conforms
pH / pH:	4,0 – 5,5	4,6
Specifična optična sučnost / Specific rotation:	-24 °/-27°	-26,2
Sorodne substance / Related substances:	according to test	Ustreza / Conforms
Voda / Water:	10,0 – 13,0 %	10,5
Sulfatni pepel / Sulphated ash:	≤ 0,1 %	0,05
Vsebnost/ Assay:	99,0 – 101,0 %	100,7

FARMADENT d.o.o.
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 Prejel: FUJS DRAGO
 ZA: *[Signature]*
 Datum prejema: 15.9.11
 Pregledal: MAROLT Robert, mag. farm., spec.
[Signature]
 Datum pregleda: 13.9.2011

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.

Ines LOGAR mag.farm., spec.

Vodja službe za kontrolo kakovosti
 Quality assurance manager

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