

Analizni izvid / Certificate of analysis

FARMADENT d.o.o.
Minarikova ul. 6
2000 Maribor
Prejel: FUJS DRAGO

Atropini sulfas

Datum prejema: 5.9.11
Pregledal: MAROLT Robert, mag. farm., spec.

Datum pregleda: 5.9.2011

Serijska številka / Batch n^o: LX0109-090002 Datum reanalize / Date of reanalysis: 26/05/2011
Deklaracija / Corresponds to: Ph.Eur., BP Uporabno do / Expiry date: 05/2012
Proizvajalec / Manufacturer: Minsheng Group Shaoxing Pharmaceutical Datum proizvodnje / Manufacturing date: 03/2009

	Specifikacija / Specification Values	Rezultati / Batch Values
Lastnosti / Properties:	Bel ali skoraj bel, kristalen prašek ali brezbarvni kristali, zelo lahko topni v vodi, lahko topni v etanolu (96 odstotnem). / White or almost white, crystalline powder or colourless crystals, very soluble in water, freely soluble in ethanol (96 per cent).	Ustreza / Complies
Istovetnost / Identification:	v skladu s preskusom / it complies with the test	Ustreza / Complies
Vsebnost / Assay:	99,0 – 101,0 %*	100,6
pH / pH:	4,5 – 6,2	6,2
Optična sučnost / Optical rotation:	-0,50° to +0,05°	0,00
Sorodne substance / Related substances:		
. impurity E, H:	≤ 0,3 %	Ustreza / Complies
. impurity A, B, C, D, F, G:	≤ 0,2 %	Ustreza / Complies
. unspecified impurities:	≤ 0,1 %	Ustreza / Complies
. total impurities:	≤ 0,5 %	Ustreza / Complies
Voda / Water:	2,0 – 4,0 %	3,97
Sulfatni pepel / Sulphated ash:	≤ 0,1 %	0,04

Opombe / Notes: * brezvodna substanca / anhydrous substance

Mnenje / Opinion: Po preskušanih parametrih vzorec ustreza Ph.Eur.7th.
According to the tested parameters the sample corresponds to Ph.Eur.7th.

Ines LOGAR mag.farm., spec.

Vodja službe za kontrolo kakovosti
Quality assurance manager

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