

Analizni izvid / Certificate of analysis

Ranitidini hydrochloridum

Serijska številka / Batch n°: LX0683-100001 Datum analize / Date of analysis: 28/07/2010
 Deklaracija / Corresponds to: Ph.Eur. Datum proizvodnje / Manufacturing date: 05/2010
 Proizvajalec / Manufacturer: Union Quimico Famaceutica S.A. Uporabno do / Expiry date: 05/2013

	Specifikacija / Specification Values	Rezultati / Batch Values
Lastnosti / Properties:	Bel ali svetlo rumen, kristaliničen prašek, lahko topen v vodi, zmerno topen ali težko topen brezvodnem etanolu, zelo težko topen v metilen kloridu. Izkazuje polimorfnost. / White or pale yellow, crystalline powder, freely soluble in water, sparingly soluble or slightly soluble in anhydrous ethanol, very slightly soluble in methylene chloride. It shows polymorphism.	Ustreza / Conforms
Istovetnost / Identification:	according to test	Ustreza / Conforms
Vsebnost / Assay:	98,5 – 101,5 % (dried substance)	100,5
Videz raztopine / Appearance of solution:	according to test	Ustreza / Conforms
pH / pH:	4,5 – 6,0	5,08
Sorodne substance / Related substances:	according to test	Ustreza / Conforms
Težke kovine / Heavy metals:	≤ 20 ppm	Ustreza / Conforms
Izguba pri sušenju / Loss on drying:	0,75 %	Ustreza / Conforms
Sulfatni pepel / Sulphated ash:	≤ 0,1 %	Ustreza / Conforms

FARMADENT d.o.o. Minarikova ul. 6 2000 Maribor Prejeh: FELIS DRAGO	
za: <i>H</i>	
Datum prejema:	9.2.12
Pregledal:	MAROLT Robert, mag. farm., spec.
za <i>Bide</i>	
Datum pregleda:	9.2.2012

Opombe / Notes:

Mnenje / Opinion:

Po preskušanih parametrih vzorec ustreza Ph.Eur.6th.
 According to the tested parameters the sample corresponds to Ph.Eur.6th.

Ines LOGAR mag.farm., spec.

Vodja službe za kontrolo kakovosti
 Quality assurance manager

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