

Analizni izvid / Certificate of analysis

Ranitidini hydrochloridum

Datum prejema: 9.5.13

Pregledal: MAROLT Robert, mag. farm., spec.



Datum pregleda: 13.5.2013

Serijska številka / Batch n°: LX0683-110003 ✓

Deklaracija / Corresponds to: Ph.Eur.

Proizvajalec / Manufacturer: Uquifa

Datum analize / Date of analysis: 08/12/2011

Datum proizvodnje / Manufacturing date: 05/2011

Uporabno do / Expiry date: 05/2014 ✓

	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 polimorfno. / <i>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.</i>	Ustreza / Conforms
Istovetnost / Identification:	according to test	Ustreza / Conforms
Vsebnost / Assay:	98,5 – 101,5 % (dried substance)	100,75
Videz raztopine / Appearance of solution:	according to test	Ustreza / Conforms
pH / pH:	4,5 – 6,0	5,3
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 %	0,02
Sulfatni pepel / Sulphated ash:	≤ 0,1 %	0,03

Opombe / Notes:

Mnenje / Opinion:

Po preskušeni parametri 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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