

Analizni izvid / Certificate of analysis

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Ranitidini hydrochloridum

Serijska številka / Batch n°: **0030610**
Deklaracija / Corresponds to: **Ph.Eur.**
Proizvajalec / Manufacturer: **Union Quimico Farmaceutica S.A.**

	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



Opombe / Notes:

Datum analize / Date of analysis: 28/07/2010
Uporabno do / Expiry date: 05/2013
Datum proizvod / Manufacturing date: 05/2010

Mnenje/Opinion: Po preskušeni parametri vzorec ustreza zahtevam Ph.Eur.6th. /
According to the tested parameters the sample corresponds to Ph.Eur. 6th.

Ines Logar mag.farm.,spec.

Odgovorna oseba za sprostitve serije/
Responsible Laboratory Manager Quality Control

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Stran/Page 1/1

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