

# Analizni izvid / Certificate of analysis

## Ureum

Serijska številka / Batch n°: LX0619-130013 ✓  
 Deklaracija / Corresponds to: Ph.Eur.  
 Proizvajalec / Manufacturer: Kirsch Pharma GmbH

Datum analize / Date of analysis: 30/07/2013  
 Datum proizvodnje / Manufacturing date: 03/2013  
 Uporabno do / Expiry date: 03/2016 ✓

|                                           | Specifikacija / Specification Values                                                                                                                                                                                                                                                                                                              | Rezultati / Batch Values |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Lastnosti / Properties:                   | Bel ali skoraj bel kristaliničen prašek ali prozorni kristali, rahlo higroskopen, zelo lahko topen v vodi, topen v alkoholu, skoraj netopen v metilen kloridu. / White or almost white, crystalline powder or transparent crystals, slightly hygroscopic, very soluble in water, soluble in alcohol, practically insoluble in methylene chloride. | Ustreza / Conforms       |
| Istovetnost / Identification:             | v skladu s preskusom / it complies with the test                                                                                                                                                                                                                                                                                                  | Ustreza / Conforms       |
| Vsebnost / Assay:                         | 98,5 – 101,5 % *                                                                                                                                                                                                                                                                                                                                  | 99,8                     |
| Videz raztopine / Appearance of solution: | v skladu s preskusom / it complies with the test                                                                                                                                                                                                                                                                                                  | Ustreza / Conforms       |
| Alkalnost / Alkalinity:                   | v skladu s preskusom / it complies with the test                                                                                                                                                                                                                                                                                                  | Ustreza / Conforms       |
| Biuret / Biuret:                          | ≤ 0,1 %                                                                                                                                                                                                                                                                                                                                           | 0,05                     |
| Amonij / Ammonium:                        | ≤ 500 ppm                                                                                                                                                                                                                                                                                                                                         | < 500                    |
| Težke kovine / Heavy metals:              | ≤ 10 ppm                                                                                                                                                                                                                                                                                                                                          | < 10                     |
| Izguba pri sušenju / Loss on drying:      | ≤ 1,0 %                                                                                                                                                                                                                                                                                                                                           | 0,07                     |
| Sulfatni pepel / Sulphated ash:           | ≤ 0,1 %                                                                                                                                                                                                                                                                                                                                           | < 0,01                   |



|                   |                                                                                                                                            |
|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| Opombe / Notes:   | * sušena substanca / dried substance                                                                                                       |
| Mnenje / Opinion: | Po preskušanih parametri vzorec ustreza Ph.Eur.7.<br>According to the tested parameters the sample corresponds to Ph.Eur.7 <sup>th</sup> . |

Ines LOGAR mag.farm., spec.  
 Vodja službe za zagotavljanje kakovosti  
 Quality assurance manager

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