

Analizni izvid / Certificate of analysis

Theophyllinum

Serijska številka / Batch n°: LX3251-120001 ✓
 Deklaracija / Corresponds to: Ph.Eur.
 Proizvajalec / Manufacturer: BASF Pharmachemikalien

Datum analize / Date of analysis: 24/03/2012
 Datum proizvodnje / Manufacturing date: 11/2012
 Uporabno do / Expiry date: 02/2016 ✓

Specifikacija / Specification Values		Rezultati / Batch Values
Lastnosti / Properties:	Bel ali skoraj bel kristaliničen prašek, težko topen v vodi, zmerno topen v etanolu (96 odstotnem). Raztaplja se v raztopinah alkalijskih hidroksidov, v amoniaku in v mineralnih kislinah. / <i>White or almost white, crystalline powder, slightly soluble in water, sparingly soluble in ethanol (96 per cent). It dissolves in solutions of alkali hydroxides, in ammonia and in mineral acids.</i>	Ustreza / Conforms
Istovetnost / Identification:	v skladu s preskusom / <i>it complies with the test</i>	Ustreza / Conforms
Vsebnost / Assay:	99,0 – 101,0 % (dried substance)	100,75
Tališče / Melting point:	270 – 274 °C	273,4
Videz raztopine / Appearance of solution:	v skladu s preskusom / <i>it complies with the test</i>	Ustreza / Conforms
Kislost / Acidity:	v skladu s preskusom / <i>it complies with the test</i>	Ustreza / Conforms
Sorodne snovi / Related substances:	v skladu s preskusom / <i>it complies with the test</i>	Ustreza / Conforms
Težke kovine / Heavy metals:	≤ 20 ppm	< 20
Izguba pri sušenju / Loss on drying:	≤ 0,5 %	0,10
Sulfatni pepel / Sulphated ash:	≤ 0,1 %	< 0,1



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

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

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