

# Analizni izvid / Certificate of analysis

Datum prejema: 18.6.13

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

Datum pregleda: \_\_\_\_\_

## Morphini hydrochloridum

Serijska številka / Batch n°: LX0434-120006 ✓

Deklaracija / Corresponds to: Ph.Eur.

Proizvajalec / Manufacturer: S.A.L.A.R.S. S.p.a.

Datum analize / Date of analysis: 12/02/2013

Datum proizvod / Manufacturing date: 02/2012

Uporabno do / Expiry date: 01/2016 ✓

	Specifikacija / Specification Values	Rezultati / Batch Values
Lastnosti / Properties:	Bel ali skoraj bel kristaliničen prašek ali brezbarvne, svilnate iglice ali kubične mase, eflorescentne v suhi atmosferi. Topen v vodi, težko topen v etanolu (96 odstotnem), skoraj netopen v toluenu. / <i>White or almost white, crystalline powder or colourless, silky needles or cubical masses, efflorescent in a dry atmosphere. Soluble in water, slightly soluble in ethanol (96 per cent), practically insoluble in toluene.</i>	Ustreza / Conforms
Istovetnost / Identification:	v skladu s preskusom / <i>it complies with the test</i>	Ustreza / Conforms
Vsebnost / Assay:	98,0 – 102,0 % (anhydrous substance)	100,0
Videz raztopine / Appearance of solution:	v skladu s preskusom / <i>it complies with the test</i>	Ustreza / Conforms
Kislost ali alkalnost / Acidity or alkalinity:	v skladu s preskusom / <i>it complies with the test</i>	Ustreza / Conforms
Specifična optična sučnost / Specific optical rotation:	-110 / -115 (anhydrous substance)	-113
Sorodne snovi / Related substances:	v skladu s preskusom / <i>it complies with the test</i>	Ustreza / Conforms
Voda / Water:	12,5 – 15,5 %	13,2
Sulfatni pepel / Sulphated ash:	≤ 0,1 %	0,05

Opombe / Notes:

Mnenje / Opinion:

Po preskušanih parametrih vzorec ustreza Ph.Eur.7.  
*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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Obr.: 7512

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