

Analizni izvid / Certificate of analysis

Morphini hydrochloridum

Serijska številka / Batch n°: 10-00390
 Deklaracija / Corresponds to: Ph.Eur., BP
 Proizvajalec / Manufacturer: Johnson Matthey

Datum analize / Date of analysis: 10/06/2011
 Datum proizvod / Manufacturing date: 06/2010
 Uporabno do / Expiry date: 05/2014

	Specifikacija / Specification Values	Rezultati / Batch Values
Lastnosti / Properties:	Bel ali skoraj bel, kristaliničen prašek ali brezbarvne, svilnate iglice ali kubične mase, ki fluorescirajo v suhi atmosferi. / White or almost white, crystalline powder or colourless, silky needles or cubical masses, efflorescent in a dry atmosphere.	Ustreza / Conforms
Istovetnost / Identification:	according to test	Ustreza / Conforms
Vsebnost / Assay:	98,0 – 102,0 % (anhydrous substance)	99,4
Videz raztopine / Appearance of solution:	according to test	Ustreza / Conforms
Kislost ali alkalnost / Acidity or alkalinity:	according to test	Ustreza / Conforms
Specifična optična sučnost / Specific optical rotation:	- 110 to -115 (anhydrous substance)	-113,6
Sorodne snovi / Related substances:	according to test	Ustreza / Conforms
Voda / Water:	12,5 – 15,5 %	13,0
Sulfatni pepel / Sulphated ash:	≤ 0,1 %	Ustreza / Conforms
Mikrobno onečiščenje / Microbial contamination:		
. Total Plate count	≤ 100/g	2/g
. Yeast and Moulds	≤ 10/g	10/g
. bacterial endotoxins	≤ 17,5 EU/mg	< 0,008 EU/mg
Zaostala topila / Residual solvents:		
. ethanol	≤ 5000 ppm	1313
. methanol	≤ 3000 ppm	77
Velikost delcev / Particle size:	100 % through 400 micron	Ustreza / Conforms



Opombe / Notes:

Mnenje / Opinion:

Po navedbah proizvajalca substanca ustreza zgoraj navedenim parametrom Ph.Eur 7.
 According to the manufacturers specifications the substance corresponds to the stated parameters Ph.Eur 7.

Ines LOGAR mag.farm., spec.

Vodja službe za kontrolo kakovosti
 Quality assurance manager

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