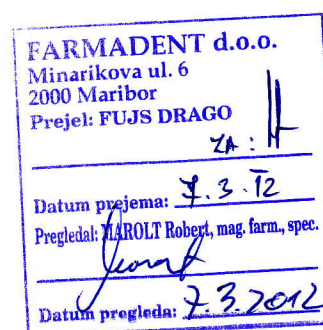


Analizni izvid / Certificate of analysis

Phenylephrini hydrochloridum

Serijska številka / Batch n°: LX0504-110002 Datum analize / Date of analysis: 06/01/2012
 Deklaracija / Corresponds to: Ph.Eur. Datum proizvodnje / Manufacturing date: 11/2011
 Proizvajalec / Manufacturer: Malladi Drugs & Pharmaceuticals Ltd. Uporabno do / Expiry date: 10/2016

	Specifikacija / Specification Values	Rezultati / Batch Values
Lastnosti / Properties:	Bel ali skoraj bel, kristaliničen prašek, lahko topen v vodi in v etanolu (96 odstotnem). Tališče okoli 143°C. / White or almost white, crystalline powder, freely soluble in water and in ethanol (96 per cent). mp: about 143 °C.	Ustreza / Conforms
Istovetnost / Identification:	v skladu s preskusom / it complies with the test	Ustreza / Conforms
Vsebnost / Assay:	98,5 – 101,0 % *	100,0
Videz raztopine / Appearance of solution:	v skladu s preskusom / it complies with the test	Ustreza / Conforms
Kislost ali alkalnost / Acidity or alkalinity:	v skladu s preskusom / it complies with the test	Ustreza / Conforms
Specifična optična sučnost / Specific optical rotation:	-43 to -47 *	- 46,5
Sorodne substance / Related substances:	v skladu s preskusom / it complies with the test	Ustreza / Conforms
Sulfati / Sulphates:	≤ 500 ppm	Ustreza / Conforms
Izguba pri sušenju / Loss on drying:	≤ 1,0 %	0,16
Sulfatni pepel / Sulphated ash:	≤ 0,1 %	0,06
Zaostala topila / Residual solvents:		
. isopropylalcohol	≤ 500 ppm	146
. methanol	≤ 500 ppm	225



Opombe / Notes: * sušena substanca / dried substance
 Mnenje / Opinion: Po preskušanih parametrih vzorec ustreza Ph.Eur.7.
 According to the tested parameters the sample corresponds to Ph.Eur.7th.

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

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