

Analizni izvid / Certificate of analysis

Phenylephrini hydrochloridum

Serijska številka / Batch n°: LX0504-080001
 Deklaracija / Corresponds to: Ph.Eur.
 Proizvajalec / Manufacturer: Malladi Drugs & Pharmaceuticals Ltd.

Datum analize / Date of analysis: 11/05/2010
 Datum proizvodnje / Manufacturing date: 02/2008
 Uporabno do / Expiry date: 01/2013

	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:	according to test	Ustreza / Conforms
Vsebnost / Assay:	98,5 – 101,0 % *	100,4
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:	-43 to -47 *	- 47
Sorodne substance / Related substances:	according to test	Ustreza / Conforms
Sulfati / Sulphates:	≤ 500 ppm	Ustreza / Conforms
Izguba pri sušenju / Loss on drying:	≤ 1,0 %	0,12
Sulfatni pepel / Sulphated ash:	≤ 0,1 %	< 0,1



Opombe / Notes:	* sušena substanca / dried substance
Mnenje / Opinion:	Po preskušanih parametrih vzorec ustreza Ph.Eur.6 th . According to the tested parameters the sample corresponds to Ph.Eur.6 th .

Ines LOGAR mag.farm., spec.

Vodja službe za kontrolo kakovosti
Quality assurance manager