

Analizni izvid / Certificate of analysis

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Erythromycinum

Serijska številka / Batch n°: **0030509**
Deklaracija / Corresponds to: **Ph.Eur.**
Proizvajalec / Manufacturer: **Metapharmaceutical S.L.**

	Specifikacija / Specification Values	Rezultati / Batch Values
Lastnosti / Properties:	Bel ali rahlo rumen prašek ali brezbarvni ali rahlo rumeni rahlo higroskopni kristali, težko topni v vodi (topnost pada z naraščajočo temperaturo), lahko topni v alkoholu, topni v metanolu. / White or slightly yellow powder or colourless or slightly yellow crystals, slightly hygroscopic, slightly soluble in water (the solubility decreases as the temperature rises), freely soluble in alcohol, soluble in methanol.	Ustreza / Conforms
Istovetnost / Identification:	according to test	Ustreza / Conforms
Vsebnost / Assay:		
• vsota / sum:	93,0 – 102,0 % (anhydrous substance)	96,65 %
• eritromicin B / erythromycin B:	≤ 5,0 %	0,5 %
• eritromicin C / erythromycin C:	≤ 5,0 %	0,25 %
Specifična optična sučnost / Specific optical rotation:	- 71 / -78 (anhydrous substance)	-74
Sorodne substance / Related substances:	according to test	Ustreza / Conforms
Tiocianat / Thiocyanate:	≤ 0,3 %	< 0,3 %
Voda / Water:	≤ 6,5 %	4,63 %
Sulfatni pepel / Sulphated ash:	≤ 0,2 %	< 0,1 %

Opombe / Notes:

Datum analize / Date of analysis: 22/10/2010
Uporabno do / Expiry date: 07/2009
Datum proizvod / Manufacturing date: 05/2012

Mnenje/Opinion: Po preskušeni parametri snovca ustreza Ph.Eur.6th. /
According to the tested parameters the sample corresponds to the Ph.Eur. 6th.

Ines Logar mag.farm.,spec.

Odgovorna oseba za sprostitve serije/
Responsible Laboratory Manager Quality Control

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Datum prejema: 5.7.2011
Pregledal: MAROLT Robert, mag. farm., spec.

Datum pregleda: 5.7.2011