

Analizni izvid / Certificate of analysis

Ethinylestradiolum

Serijska številka / Batch n°: LX0273-110002
 Deklaracija / Corresponds to: Ph.Eur.
 Proizvajalec / Manufacturer: Bayer Shering Pharma

Datum analize / Date of analysis: 22/05/2012
 Datum proizvodnje / Manufacturing date: 08/2009
 Uporabno do / Expiry date: 08/2012

	Specifikacija / Specification Values	Rezultati / Batch Values
Lastnosti / Properties:	Bel ali rahlo rumenkast kristalinični prašek. / White or slightly yellowish-white, crystalline powder.	Ustreza / Conforms
Istovetnost / Identification:	according to test	Ustreza / Conforms
Vsebnost / Assay:	97,0 – 102,0 % (dried substance)	99,7
Specifični optični zasuk / Specific optical rotation:	-27 ° to -30 °	-30
Sorodne substance / Related substances:	according to test	Ustreza / Conforms
Izguba pri sušenju / Loss on drying:	≤ 1,0%	< 0,1

FARMADENT d.o.o.
 Minarikova ul. 6
 2000 Maribor
 Prejel: FUJS DRAGO
 Datum prejema: 29.5.2012
 Pregledal: M. VOLT Robert, mag. farm., spec.
 Datum pregleda: 29.5.2012

Opombe / Notes: Brez TSE/BSE kontaminacije snovi med ali po proizvodnji izdelka. / No contamination with TSE/BSE-risk materials during or after the production process.

Mnenje / Opinion: Po navedbah proizvajalca substanca ustreza zgoraj navedenim parametrom Ph.Eur.7.
 According to the manufacturers specifications, the product corresponds to the stated parameter Ph.Eur.7th.

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

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