



Batch Certificate · Certificado de Lote · Сертификат Парии
Certificate of Analysis · Certificado de Análisis · Сертификат анализа

Bayer Pharma AG
Ernst-Schering-Str. 14, 59192 Bergkamen, Germany
☎ +49 2307 65-0

Art. No.: 00275784

No. 11217745

Date printed : 28.02.2012

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Estradiol benzoate, sieved

Batch No. : 81403700

Date of manufacture : 05.10.2011

Retest Date : 05.10.2016

Pharmacopeia : Ph. Eur., 7th Edition

appearance

off white crystalline powder or
colorless crystals

IR absorbance spectrum

matches reference spectrum

passes test

specific optical rotation

20°C

polarimetry

+55.0 - +59.0 °

calculated on the dried basis

+56.4 °

related substances

HPLC

17beta-estradiol (ZK5018) (EP impurity A)

<= 0.2 %

0.0 %

related substances

HPLC

17alpha-estradiol-3-benzoate (ZK28556) (EP Imp. E)

<= 0.3 %

0.1 %

related substances

HPLC

4-methyl-estradiol-3-benzoate (ZK118226) (EP Imp. B)

<= 0.3 %

0.2 %

related substances

HPLC

estrone benzoate (ZK4842) (EP impurity G)

<= 0.3 %

0.1 %

related substances

HPLC

estradiol-3,17-dibenzoate (ZK116176) (EP Imp. C)

<= 0.5 %

0.2 %



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related substances

HPLC

any other unspecified

<= 0.10 %

0.00 %

related substances

HPLC

sum

<= 1.0 %

0.7 %

loss on drying

gravimetry

<= 0.5 %

< 0.1 %

assay

UV/VIS absorption spectrum

estradiol-3-benzoate (ZK4902)

97.0 - 103.0 %

calculated on the dried basis

99.6 %

The batch corresponds to the quality specification and is released.

Results with values e.g. '0%' stands for results 'lower than LOQ'

Dr. Matthias Bohm

13.12.2011

Qualified Person / Quality Assurance Bergkamen. The following persons are empowered to sign by proxy: Dr. Andreas Große and Dr. Martin Krappe

This certificate of analysis was produced by a closed electronic data processing system and therefore bears no signature.