



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

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

Art. No. : 00165811

No.: 14209108

Certificate Order No.: SG11351044583

Date created : 22.01.2015

Estradiol, hemihydrate, micro 20, EP, USP

Testing Standard No. : S.4.2.01-01

dated : 11.04.2013

Test Specification No. : S.4.1.01-01

dated : 11.04.2013

Batch No. : 84201560

Date of manufacture : 07.05.2014

Retest Date : 07.05.2019

Destination : Germany

material

white or off-white, crystalline powder or colorless
crystals

passes test

IR absorbance spectrum

IR-spectroscopy

matches reference spectrum

passes test

appearance of solution

clarity

visual test

<= reference suspension I

< reference suspension I

specific optical rotation

polarimetry

+76.0 - +83.0 °

in dried substance

+80.6 °

appearance of solution

color

UV/VIS-spectroscopy

<= 0.020

0.001

volatile substances

GC

ethanol (ZK1550)

<= 2000 ppm

160 ppm

impurities

HPLC

estrone (EP Imp. A) (ZK5019)

<= 0.3 %

0.0 %



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impurities

HPLC

17-alpha estradiol (EP Imp. B) (ZK5046)

<= 0.3 %

0.0 %

impurities

HPLC

4-methyl estradiol (EP Imp. C) (ZK118225)

<= 0.3 %

0.2 %

impurities

HPLC

delta 9 (11)-estradiol (EP Imp. D) (ZK48124)

<= 0.1 %

0.0 %

impurities

HPLC

any unspecified impurity

<= 0.10 %

0.00 %

impurities

HPLC

sum

<= 0.5 %

0.2 %

sulfated ash

gravimetry

<= 0.1 %

< 0.1 %

heavy metals

color reaction

<= 0.002 %

< 0.002 %

water

Karl Fischer method

2.9 - 3.5 %

3.2 %



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assay

HPLC

17beta-estradiol (ZK5018)

97.0 - 102.0 %

99.4 %

in dried substance

particle size (microscopy)

<= 20 µm

100 % of particles

100 % of particles

particle size (microscopy)

<= 16 µm

>= 99 % of particles

100 % of particles

particle size (microscopy)

<= 8 µm

>= 95 % of particles

100 % of particles

particle size distribution

laser diffraction spectroscopy

100 %

<= 15.0 µm

8.8 µm

particle size distribution

laser diffraction spectroscopy

99 %

<= 12.5 µm

7.7 µm

particle size distribution

laser diffraction spectroscopy

95 %

<= 10.0 µm

5.2 µm

Bayer HealthCare



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particle size distribution

laser diffraction spectroscopy

50 %

$\leq 3.0 \mu\text{m}$

1.6 μm

particle size distribution

laser diffraction spectroscopy

$\leq 1.1 \mu\text{m}$

$\leq 40 \%$

33 %

Ph. Eur. monograph for estradiol hemihydrate

The quality complies with the
current monograph

The batch corresponds to the quality specification and is released.

The Testing Standard and Test Specification number may differ in the letter at the fifth position, if the document has been translated to any other language than german, i.e. 'E' stands for english and 'S' stands for spanish. Results with values '0%' stands for results 'lower than LOQ'

Product release date: 10.06.2014

This Certificate of Analysis was produced by a closed electronic data processing system and therefore bears an electronic signature. The following persons are empowered to sign: Dr. Matthias Bohm, Dr. Andreas Große, Dr. Martin Krappe



Electronically signed: Dr. Matthias Bohm, Qualified Person / Quality Assurance Bergkamen
Approval date / time: 22.01.2015 17:48:22