

Bayer HealthCare

Bayer Schering Pharma



Analysenzertifikat · Certificate of Analysis
Certificado de Análisis · Сертификат анализа

Bayer Schering Pharma AG
Ernst-Schering-Str. 14, 59192 Bergkamen, Germany

Art. No.: 00188201

No. 11200408

Date printed : 31.03.2011

Page : 1

Ethinylestradiol, micro 20

Testing Standard No. : K374D180

dated : 01.07.2001

Test Specification No. : K374D2B0

dated : 15.07.2004

Batch No. : 80303890

Date of manufacture : 03.09.2010

Retest Date : 03.09.2013

appearance

visual

white to faintly yellowish white crystalline powder

passes test

identification

IR absorbance spectrum

IR-spectroscopy

matches reference spectrum

passes test

melting range start

thermometry

USP, class Ia

181 - 185 °C

183 °C

melting range end

thermometry

USP, class Ia

181 - 185 °C

184 °C

specific optical rotation

polarimetry

-30 - -27 °

calculated on the dried basis

-30 °

clarity of solution

visual

clear or not more opalescent than reference

suspension I

clear

color of solution

visual

not more intense in color than reference solution

BY6

< BY6

volatile substances

GC

acetone (ZK56403)

<= 0.2 %

< 0.1 %

sulfated ash

gravimetry

<= 0.1 %

0.0 %

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loss on drying

gravimetry

<= 1.0 %

0.1 %

related substances

TLC

estrone (ZK5019)

<= 0.25 %

< 0.25 %

related substances

HPLC

6-keto-ethinylestradiol (ZK46494)

<= 0.20 %

0.00 %

related substances

HPLC

delta 9 (11)-ethinylestradiol (ZK51628)

<= 0.5 %

0.1 %

related substances

HPLC

delta 6-ethinylestradiol (ZK136231)

<= 0.20 %

0.06 %

related substances

HPLC

1-methyl-ethinylestradiol (ZK5453)

<= 0.15 %

0.02 %

related substances

HPLC

4-methyl-ethinylestradiol (ZK136709)

<= 0.20 %

0.06 %

related substances

HPLC

17beta-ethinylestradiol (ZK32637)

<= 0.25 %

0.02 %

related substances

HPLC

any other, single

< 0.10 %

0.02 %

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related substances

HPLC

total

<= 1.0 %

0.3 %

assay

HPLC

ethinylestradiol (ZK4944)

97.0 - 102.0 %

98.8 %

calculated on the dried basis

particle size (microscopy)

> 20 µm

0 particles

0 particles

particle size (microscopy)

>= 15 µm to <= 20 µm

<= 10 particles

0 particles

particle size (laser diffraction spectroscopy)

particle size distribution

100 %

<= 15.0 µm

7.5 µm

particle size (laser diffraction spectroscopy)

particle size distribution

99 %

<= 12.5 µm

7.1 µm

particle size (laser diffraction spectroscopy)

particle size distribution

95 %

<= 10.0 µm

5.4 µm

particle size (laser diffraction spectroscopy)

particle size distribution

50 %

<= 3.0 µm

1.9 µm

particle size (laser diffraction spectroscopy)

particle size distribution

<= 1.3 µm

<= 40 %

32 %

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

Dr. Matthias Bohm

20.01.2011

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.

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Pharmacopeia : Ph. Eur., 7th Edition

appearance

visual

white to faintly yellowish white crystalline powder

passes test

identification

IR-spectroscopy

matches the reference spectrum of the EP
reference standard

passes test

loss on drying

gravimetry

$\leq 1.0 \%$

0.1 %

related substances

HPLC

delta 9 (11)-ethinylestradiol (Imp. B) (ZK51628)

$\leq 0.5 \%$

0.2 %

related substances

HPLC

16-oxo-ethinylestradiol (Imp. H)

$\leq 0.2 \%$

0.0 %

related substances

HPLC

delta 6-ethinylestradiol (Imp. I) (ZK136231)

$\leq 0.2 \%$

0.1 %

related substances

HPLC

4-methyl-ethinylestradiol (Imp. K) (ZK136709)

$\leq 0.2 \%$

0.1 %

related substances

HPLC

estrone (Imp. C) (ZK5019)

$\leq 0.15 \%$

0.00 %

related substances

HPLC

6beta-hydroxy-ethinylestradiol (Imp. F) (ZK47751)

$\leq 0.15 \%$

0.00 %

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Pharmacopeia : Ph. Eur., 7th Edition

related substances

HPLC

each unspecified impurity

$\leq 0.10 \%$

0.00 %

related substances

HPLC

sum of impurities

$\leq 0.8 \%$

0.4 %

assay

potentiometric titration

ethinylestradiol (ZK4944)

97.0 - 102.0 %

calculated on the dried basis

100.1 %

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