

Bayer HealthCare



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

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

Art. No. : 64070931	No.: 14222157	Certificate Order No. : SGOBW044764	Date created : 09.02.2015
Estradiol valerate, micro 20, S96			
Testing Standard No. : S.4.1.901-02 EU	dated : 10.07.2012		
Test Specification No. : S.4.1.901-02 EU	dated : 10.07.2012		
Batch No. : 84404140			
Date of manufacture : 29.10.2014	Retest Date : 29.10.2019		
Destination : Germany			

appearance

Ph. Eur.

visual test

white or almost white, crystalline powder or
colourless crystals

passes test

IR absorbance spectrum

Ph. Eur.

IR-spectroscopy

matches reference spectrum

passes test

clarity of solution

Ph. Eur.

visual test

clear or not more opalescent than reference
suspension I

< opalescence suspension I

color of solution

Ph. Eur.

visual test

colorless or ≤ color reference solution B9

< B9

melting range start

thermometry

Ph. Eur.

143 - 150 °C

146 °C

melting range end

thermometry

Ph. Eur.

143 - 150 °C

147 °C



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specific optical rotation

20°C, Ph.Eur.

polarimetry

+41 - +47 °

+45 °

calculated on the dried basis

volatile substances

GC

methanol (ZK1555)

<= 0.1 %

0.0 %

acidity

visual titration

<= 0.5 %

0.1 %

calculated as valeric acid

loss on drying

Ph. Eur.

gravimetry

<= 0.2 %

< 0.1 %

related substances

HPLC

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

<= 0.5 %

0.0 %

related substances

HPLC

4-methyl-estradiol valerate (ZK118227) (EP impurity D)

<= 0.5 %

0.2 %

related substances

HPLC

delta9(11)-estradiol valerate (ZK168419) (EP impurity C)

<= 0.5 %

0.1 %

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related substances

HPLC

any other

<= 0.10 %

0.06 %

related substances

HPLC

total

<= 1.0 %

0.5 %

assay

UV/VIS-spectroscopy (Ph.Eur.)

estradiol-17-valerate (ZK5104)

97.0 - 103.0 %

99.9 %

calculated on the dried basis

assay

HPLC

estradiol-17-valerate (ZK5104)

98.0 - 101.0 %

99.8 %

calculated on the dried basis

particle size (microscopy)

> 30 µm

0 particles

0 particles

particle size (microscopy)

>= 20 µm and <= 30 µm

<= 5 particles

0 particles

particle size (laser diffraction spectroscopy)

particle size distribution

100 %

<= 15.0 µm

8.5 µm

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particle size (laser diffraction spectroscopy)

particle size distribution

99 %

<= 12.5 µm

7.6 µm

particle size (laser diffraction spectroscopy)

particle size distribution

95 %

<= 10.0 µm

5.6 µm

particle size (laser diffraction spectroscopy)

particle size distribution

50 %

<= 3.0 µm

1.8 µm

particle size (laser diffraction spectroscopy)

particle size distribution

<= 1.3 µm

<= 40 %

34 %

Ph. Eur. monograph for estradiol valerate

The quality complies with the
current monograph

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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 '0%' stands for results 'lower than LOQ'

Product release date: 28.11.2014

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



Die Angaben auf dem Analysenzertifikat entbinden den Käufer nicht von der Durchführung einer vollständigen analytischen Wareneingangskontrolle.

The results on the Certificate of Analysis do not absolve the buyer from a full analytical control.

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