HAPILA

Certificate of Analysis

This is to certificate that the following commodity meets the standards of HAPILA GmbH.

Estriol, micronized Ph. Eur.

Batch no:	207800.41.03.0414	Amount:	10.50 kg
Date of manufacture:	April, 2014	Specification no:	HPL-SF-207800.41.03
Date of release:	June 13, 2014	Current retest date:	April, 2016
Storage:	at room temperature	Next retest date:	April, 2019

Test	Specification	Result
Appearance (visual method)	white or almost white, crystalline powder	white crystalline powder
IR identification (Ph. Eur. 2.2.24)	conforms to *estriol CRS*	conforms
TLC identification (Ph. Eur. 2.2.27)	conforms to *estriol CRS*	conforms
Specific optical rotation (dried substance, Ph. Eur. 2.2.7)	+60 to +65°	+ 61.9°
Related Substances (HPLC, Ph. Eur. 2.2.29)		
Impurity A	≤ 0.5 %	< 0.05 %
Impurity B	≤ 0.5 %	< 0.05 %
Impurity C	≤ 0.5 %	< 0.05 %
Impurity D	≤ 0.5 %	< 0.05 %
Impurity E	≤ 0.5 %	0.08 %
Impurity F	≤ 0.5 %	< 0.05 %
Impurity G	≤ 0.5 %	< 0.05 %
Impurity H	≤ 0.15 %	< 0.05 %
Unspecified impurities each	≤ 0.10 %	< 0.05 %
Sum of impurities other than A	≤ 1.0 %	0.08 %
Loss on drying (Ph. Eur. 2.2.32)	≤ 0.5 %	0.04 %
UV assay (dried substance, Ph. Eur. 2.2.25)	97.0 – 103.0 %	98.1 %
Residual Solvents (GC, Ph. Eur. 2.4.24)		
Methanol	< 3000 ppm	< 1000 ppm
Acetone	< 5000 ppm	< 1000 ppm
Particle Size (laser light diffraction, volume distribution, Ph. Eur. 2.9.31)		
d_{95}	≤ 15 µm	10.4 µm
d_{100}	< 30 µm	24.0 µm

Hints:
The batch of drug substance (API) is analyzed according to the test methods and the results correspond to the requirements laid down in the valid CEP.

The retest period has been elongated to 36 months due to CEP No. R0-CEP 2013-277-Rev 02.

Reviewed:	Released:
NOV 10, 2017	NOV 10, 2017
Head of Production	Head of Quality Unit (QA/QC)

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