HAPILA

Certificate of Analysis

Retest

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, 2018

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 corresponds to the requirements laid down in the valid CEP

Reviewed: 2016-04-28

Head of Production

Released: 2016-04-28

Head of Quality Unit (QA/QC)

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