Lote: 0070220

HAPILA

Certificate of Analysis & Conformity

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

Estriol, micronized Ph. Eur.

Batch no:	207800.41.06.1219	Amount:	12.85 kg
Date of manufacture:	December, 2019	Specification no:	HPL-SF-207800.41.06
Date of release:	January 27, 2020	Date of retest:	December, 2022
Storage:	at room temperature		

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
HPLC identification (Ph. Eur. 2.2.29)	conforms to *estriol CRS*	conforms
Specific optical rotation (dried substance, Ph. Eur. 2.2.7)	+60 to +65°	+ 61.8°
Related Substances (HPLC, Ph. Eur. 2.2.29)		
Impurity A	≤ 0.2 %	< 0.05 %
Impurity D	≤ 0.2 %	< 0.05 %
Impurity E	≤ 0.3 %	0.27 %
Impurity F	≤ 0.5 %	< 0.05 %
Unspecified impurities each	≤ 0.10 %	< 0.05 %
Sum of impurities	≤ 1.0 %	0.27 %
Loss on drying (Ph. Eur. 2.2.32)	≤ 0.5 %	0.08 %
HPLC assay (dried substance, Ph. Eur. 2.2.29)	97.5 – 102.0 %	99.8 %
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	9.7 µm
d_{100}	< 30 µm	19.3 µm

THE CONNECTING LINK
TRANSO-PHARM
HANDELS-GMBH

HAPILA GmbH
Otto-Schott-Str.9 – D-07552 Gera – Germany – phone +49(0)365 20 58 69 10 - mail@hapila.de

HAPILA

Certificate of Analysis & Conformity

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

Estriol, micronized Ph. Eur.

Batch no:	207800.41.06.1219	Amount:	12.85 kg
Date of manufacture:	December, 2019	Specification no:	HPL-SF-207800.41.06
Date of release:	January 27, 2020	Date of retest:	December, 2022
Storage:	at room temperature		

Following relevant GMP aspects were taken into account before batch release of the Active Pharmaceutical Ingredient:

The batch of drug substance (API) is produced and analyzed according to the validated manufacturing process and the test methods laid down in the valid R0-CEP 2013-277-Revision 04.

Written procedures are established and followed for the review and approval of batch production and laboratory control records, including packaging and labeling, to determine compliance of the Active Pharmaceutical Ingredient with the established specification laid down in the valid CEP.

Batch production and laboratory control records of critical process steps are reviewed and approved by the quality units to be in compliance with the rules of GMP as stipulated in ICH Q7.

All deviations, investigations, and OOS reports are reviewed as part of the batch record review.

Comments/Remarks: none

Above mentioned batch is released for shipping.

Reviewed:	Released:
Jan 27, 2020	2020-01-27
Dr. Stefan Schüßler	Dr. Steffen Wittmann
Head of Production	Head of Quality Unit (QA/QC)

THE CONNECTING LINK
TRANSO-PHARM HANDELS-GMBH

HAPILA GmbH
Otto-Schott-Str.9 – D-07552 Gera – Germany - phone +49(0)365 20 58 69 10 - mail@hapila.de