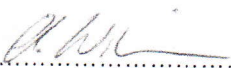
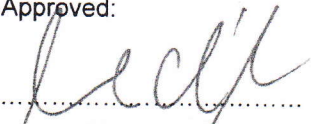


This is to certificate that the following commodity meets the standards of HAPILA GmbH.

Estriol, micronized Ph. Eur.

Batch no: 207800.41.03.0414 Amount: 1.01 kg
Date of manufacture: April, 2014 Specification no: HPL-SF-207800.41.02
Date of release: June 13, 2014 Date of retest: April, 2016
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 <i>estriol</i> CRS	conforms
TLC identification (Ph. Eur. 2.2.27)	conforms to <i>estriol</i> CRS	conforms
Specific optical rotation (dried substance, Ph. Eur. 2.2.7)	+60 to +65°	+ 62.8°
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 %	0.11 %
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 %	0.11 %
Loss on drying (Ph. Eur. 2.2.32)	≤ 0.5 %	0.18 %
UV assay (dried substance, Ph. Eur. 2.2.25)	97.0 – 103.0 %	99.6 %
Residual Solvents (GC, Ph. Eur. 2.4.24)		
Methanol	< 0.3 %	< 0.06 %
Acetone	< 0.5 %	< 0.02 %
Particle Size (laser light diffraction, volume distribution, Ph. Eur. 2.9.31)		
d ₉₅	≤ 15 µm	9.8 µm
d ₁₀₀	< 30 µm	23.0 µm

Responsible:	Approved:
 2014-08-12	 2014-08-12
Head of Quality control	Head of Quality assurance