



Product/sample name:

Estradiolum (17 alfa-); 500246

Client-code:

129

Project-code:

0119036

Batch number:

20F18-F01 DAC 2019/1

Analysis: Version:

1

Test	Test method	Specification	Result	Complies
Characters	Appearance	White to almost white powder	White powder	Yes
Identity B	2.2.24	Compared to reference	Conform (2x)	Yes
Optical rotation	2.2.7	+51 to +56	+ 55	Yes
Related substances	2.2.29	Impurity A \leq 0.2 % Impurity B \leq 0.15 % Impurity C \leq 0.2 % Impurity D \leq 0.3 % Other impurities \leq 0.10 % Total impurities \leq 1.0 %	0.1 % < 0.05 % Not detected 0.1 % < 0.05 % 0.2 %	Yes Yes Yes Yes Yes Yes
Loss on drying	2.2.32	≤ 0.5 %	< 0.1 %	Yes
Sulfated ash	2.4.14	≤ 0.1 %	< 0.1 %	Yes
Assay	2.2.29	97.0 - 102.0 %	99.7 %	Yes



QA-statement:

This study met the criteria for a valid test and was performed in compliance with the Good control Laboratory Practice as defined in the Guide to Good Manufacturing Practice for Medicinal Products in the European Community. The reported results adequately reflect the raw data of the study.

Conclusion:

The results do comply with the specifications

This certificate is approved by Manager QA on 13 August 2020

13 Aug 2020

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