



Zhejiang Xianju Pharmaceutical Co., Ltd
Certificate of Analysis

Record Code	Effective Date
AOP335-06R00	2021-01-01

Product	Ethinyl Estradiol	(1) Number of COA	2101-01
Batch No.	QC031-191101	Test Date	2021-01-07
Amounts	2.200kg	Manufacture Date	2019-11-28
According To	EP10.0 And Customer Standard	Retest Date	2024-11-28

【ITEM】	【SPECIFICATION】	【RESULT】
Appearance	White or slightly yellowish-white crystalline powder	Slightly yellowish-white crystalline powder
Identification	(A) Complies by IR	Conforms
Identification	(B) Complies by TLC	Conforms
Related Substances	Estradiol≤0.10%	Not detected
Related Substances	Impurity B≤0.5%	0.09%
Related Substances	Impurity H≤0.2%	Not detected
Related Substances	Impurity I≤0.2%	Not detected
Related Substances	Impurity K≤0.2%	Not detected
Related Substances	Impurity C≤0.15%	Not detected
Related Substances	Impurity F≤0.15%	Not detected
Related Substances	Unspecified impurity≤0.10%	0.06%
Related Substances	Total impurities≤0.8%	0.34%
Residual Solvents	Acetone≤5000ppm	183ppm
Residual Solvents	Tetrahydrofuran≤720ppm	Not detected
Residual Solvents	Iso-butanol≤5000ppm	Not detected
Residual Solvents	Toluene≤890ppm	Not detected
Loss on Drying	≤1.0%	0.3%
Particle Size (Volume Method)	D90≤20 μm	9 μm
Assay	Contains 97.5% to 102.0% of C ₂₀ H ₂₄ O ₂ calculated on the dried basis	100.8%

Conclusion: The Product Conforms To EP10.0 And Customer Standard.

Reported by: [Signature]
Date: 2021-01-09

Checked by: [Signature]
Date: 2021-01-09

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Record Code	Effective Date
AOP335-06R00	2021-01-01

Product	Ethinyl Estradiol	Number of COA	2101-02
Batch No.	QC031-191101.1	Test Date	2021-01-07
Amounts	2.260kg	Manufacture Date	2019-11-28
According To	EP10.0 And Customer Standard	Retest Date	2024-11-28

【ITEM】	【SPECIFICATION】	【RESULT】
Appearance	White or slightly yellowish-white crystalline powder	White crystalline powder
Identification	(A) Complies by IR	Conforms
Identification	(B) Complies by TLC	Conforms
Related Substances	Estradiol≤0.10%	Not detected
Related Substances	Impurity B≤0.5%	0.08%
Related Substances	Impurity H≤0.2%	Not detected
Related Substances	Impurity I≤0.2%	Not detected
Related Substances	Impurity K≤0.2%	Not detected
Related Substances	Impurity C≤0.15%	Not detected
Related Substances	Impurity F≤0.15%	Not detected
Related Substances	Unspecified impurity≤0.10%	0.06%
Related Substances	Total impurities≤0.8%	0.31%
Residual Solvents	Acetone≤5000ppm	155ppm
Residual Solvents	Tetrahydrofuran≤720ppm	Not detected
Residual Solvents	Iso-butanol≤5000ppm	Not detected
Residual Solvents	Toluene≤890ppm	Not detected
Loss on Drying	≤1.0%	0.2%
Particle Size (Volume Method)	D90≤20 μm	6 μm
Assay	Contains 97.5% to 102.0% of C ₂₀ H ₂₈ O ₂ calculated on the dried basis	100.8%

Conclusion: The Product Conforms To EP10.0 And Customer Standard.

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Checked by: [Signature]
Date: 2021-01-09



Record Code	Effective Date
AOP335-06R00	2021-01-01

Zhejiang Xianju Pharmaceutical Co., Ltd
Certificate of Analysis

Product	Ethinyl Estradiol	Number of COA	2101-03
Batch No.	QC031-191201	Test Date	2021-01-07
Amounts	2.300kg	Manufacture Date	2019-12-22
According To	EP10.0 And Customer Standard	Retest Date	2024-11-22

【ITEM】	【SPECIFICATION】	【RESULT】
Appearance	White or slightly yellowish-white crystalline powder	White crystalline powder
Identification	(A) Complies by IR	Conforms
Identification	(B) Complies by TLC	Conforms
Related Substances	Estradiol ≤ 0.10%	0.02%
Related Substances	Impurity B ≤ 0.5%	0.11%
Related Substances	Impurity H ≤ 0.2%	Not detected
Related Substances	Impurity I ≤ 0.2%	Not detected
Related Substances	Impurity K ≤ 0.2%	Not detected
Related Substances	Impurity C ≤ 0.15%	Not detected
Related Substances	Impurity F ≤ 0.15%	Not detected
Related Substances	Unspecified impurity ≤ 0.10%	0.05%
Related Substances	Total impurities ≤ 0.8%	0.33%
Residual Solvents	Acetone ≤ 5000ppm	165ppm
Residual Solvents	Tetrahydrofuran ≤ 720ppm	Not detected
Residual Solvents	Iso-butanol ≤ 5000ppm	Not detected
Residual Solvents	Toluene ≤ 890ppm	Not detected
Loss on Drying	≤ 1.0%	0.3%
Particle Size (Volume Method)	D90 ≤ 20 μm	7 μm
Assay	Contains 97.5% to 102.0% of C ₂₀ H ₂₈ O ₂ calculated on the dried basis	100.6%

Conclusion: The Product Conforms To EP10.0 And Customer Standard.

Reported by: *[Signature]*
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Checked by: *[Signature]*
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