



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

100.8%

Zhejiang Xianju Pharmacoutical Co., Ltd Certain Case of Amalysis

| | | 10227月月 | ¥ |
|--------------|------------------------------|----------------------|------------|
| Product | | oz (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 |
| 7 + m | | | |

| | | | 2024-11-20 |
|-----------------------|------------------------------------|---------------------|---|
| [ITEM] | I SPECIFICA | | [RESULT] |
| Appearance | White or slightly yellowish powder | n-white crystalline | 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% | | |
| Related Substances | Impurity C≤0.15% | | Not detected |
| Related Substances | Impurity F≤0.15% | 201 | Not detected |
| Related Substances | Unspecified impurity≤0.10% | | Not detected |
| Related Substances | Total impurities≤0.8% | 120, | 0.06% |
| Residual Solvents | Acetone≤5000ppm | | 0.34% |
| Residual Solvents | Tetrahydrofuran≤720ppm | | 183ppm |
| Residual Solvents | Iso-butanol≤5000ppm | | Not detected |
| Residual Solvents | Toluene≤890ppm | | Not detected |
| Loss on Drying | ≤1.0% | | Not detected |
| Particle Size (Volume | D90≤20 µ m | | 0, 3% |
| Method) | | | 9 µ m |
| | | | 6 |

Contains 97.5% to 102.0% of C20H21O2 calculated

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

on the dried basis

Reported by: 16th Date: 2021-01-09

Assay

Address: 15 West Fengxi Road, Modern Industrial Park, Xianju, Zhejiang, China

Email:zb@xjpharma.com

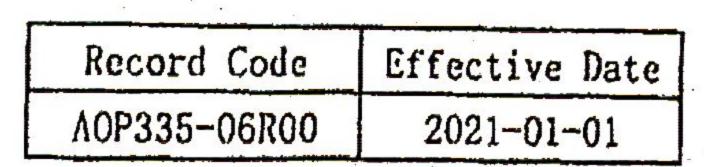
Telephone:0086-576-87731018

Checked by: 3007

Date: 2021-01-07







Zhejiang armaceutical Co., Ltd

| Product | Ethinyl Estradiol | Number 5 COA | |
|--------------|------------------------------|------------------|------------|
| 110000 | Cultify Estrautor | 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 |

| - | | | Language process | | |
|---------------------------------------|-----------------------|--|------------------|--------------|--------|
| | [ITEM] | [SPECIFICATION] | | [RESULT] | |
| # # # # # # # # # # # # # # # # # # # | Appearance | White or slightly yellowish-white crystalline powder | White | crystalline | powder |
| it. | Identification | (A) Complies by IR | 24 | Conforms | |
| | Identification | (B) Complies by TLC | | Conforms | 2 |
| 5 | Related Substances | Estradiol≤0.10% | 45. | Not detected | |
| 37 | Related Substances | Impurity B≤0.5% | | 0. 08% | 9 |
| | Related Substances | Impurity H≤0.2% | | Not detected | |
| | Related Substances | Impurity 1≤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% | 70 RI | 0.06% | |
| 9 | Related Substances | Total impurities≤0.8% | | 0.31% | |
| | Residual Solvents | Acetone≤5000ppm | | 155ppm | |
| | Residual Solvents | Tetrahydrofuran≤720ppm | | Not detected | |
| e . | Residual Solvents | Iso-butanol≤5000ppm | | Not detected | |
| # | Residual Solvents | Toluene≤890ppm | | Not detected | |
| | Loss on Drying | ≤1.0% | | 0. 2% | x . |
| | Particle Size (Volume | D90≤20 μm | | 6 µ m | |
| 8 | Method) | Comtains 07 50 to 100 00 -5 C 11 0 1 1 | | | · · · |
| 2 | Assay | Contains 97.5% to 102.0% of C20H24O2 calculated on the dried basis | | 100. 8% | |
| | | | | S | 12 |

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

Reported by: 2017
Date: WU-1/19

Checked by:

Address: 15 West Fengxi Road, Modern Industrial Park, Xianju, Zhejiang, China

Email:zb@xjpharma.com

Telephone:0086-576-87731018

Date:







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

Junju Larmaceutical Co., Ltd Zhejiang Certificate Analysis

| 39 | | (1) | |
|--------------|------------------------------|------------------|------------|
| 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 | powde |
| | | | Conforms | |
| Identification | (A) Complies by IR | 80 | Conforms | |
| Identification | (B) Complies by TLC | | Conforms | 100 |
| Related Substances | Estradiol≤0.10% | | 0.02% | ii. |
| Related Substances | Impurity B≤0.5% |) * | 0.11% | |
| Related Substances | Impurity H≤0.2% | | Not detecte | d |
| Related Substances | Impurity I≤0.2% | | Not detecte | d |
| Related Substances | Impurity K≤0.2% | | Not detecte | d |
| Related Substances | Impurity C≤0.15% | | Not detecte | d |
| Related Substances | Impurity F≤0.15% | | Not detecte | d |
| Related Substances | Unspecified impurity≤0.10% | | 0.05% | |
| Related Substances | Total impurities≤0.8% | | 0.33% | 5 |
| Residual Solvents | Acetone≤5000ppm | | 165ppm | |
| Residual Solvents | Tetrahydrofuran≤720ppm | | Not detecte | d |
| Residual Solvents | Iso-butanol≤5000ppm | | Not detecte | d |
| Residual Solvents | Toluene≤890ppm | 2. | Not detecte | d |
| Loss on Drying | ≤1.0% · | | 0.3% | |
| Particle Size (Volume Method) | D90≤20 μ m | | 7 µ m | * |
| Assay | Contains 97.5% to 102.0% of Cooling calculated on the dried basis | | 100.6% | (%) (2) |

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

Reported by: UHIL

Date: WU-1/-V9

Checked by:

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