



Zhejiang Xianju Pharmaceutical Co., Ltd  
Certificate of Analysis

Record Code	Effective Date
AOP350-03R01	2021-01-01

Product	Estradiol Hemihydrate	Number of Containers	2102-03
Batch No.	QC014-210101	Test Date	2021-01-29
Amounts	2.450kg	Manufacture Date	2021-01-03
According To	USP43, In-house And Customer Standard	Retest Date	2026-01-03

【ITEM】	【SPECIFICATION】	【RESULT】
Appearance	White or almost white crystalline powder	Almost white crystalline powder
Identification	A. Complies by IR	Conforms
Identification	B. UV: $\Delta E/ERS \leq 3.0\%$	0.6%
Melting range	173~179°C	177~179°C
Specific Rotation	+76° to +83°	+80.0°
Water	$\leq 3.5\%$	3.2%
Related Substances	Estra-1,3,5(10),9(11)-tetraene-3,17 $\beta$ -diol $\leq 0.3\%$	0.12%
Related Substances	Any individual impurity $\leq 0.10\%$	0.06%
Related Substances	Total impurities $\leq 1.0\%$	0.18%
Residual Solvents	Methanol $\leq 3000$ ppm	Not detected
Residual Solvents	Ethanol $\leq 5000$ ppm	313ppm
Assay	Contains 97.0% to 103.0% of $C_{18}H_{26}O_2$ calculated on the anhydrous basis	100.1%
Particle Size (Volume Method)	D100 < 15 $\mu m$	10 $\mu m$
Particle Size (Volume Method)	D90 < 10 $\mu m$	4 $\mu m$

Conclusion: The Product Conforms To USP43, In-house And Customer Standard.

Reported by:   
Date: 2021-02-02

Checked by:   
Date: 2021-02-02

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