

# Zhejiang Xianju Pharmaceutical Co., Ltd

XIANJU PHARMA

## Certificate of Analysis

Product	ESTRADIOL HEMHYDRATE	Number of CGA	G1(05)-1709-01
Batch No.	X1-170803	Manufacture Date	2017-09-01
Amounts (kg)	29.14	Release Date	2017-08-20
According To	USP40 IN-HOUSE AND CUSTOMER STANDARD	Retest Date	2022-08-20

ITEM	SPECIFICATION	RESULT
Appearance	White or almost white crystalline powder	Almost white crystalline powder
Identification	A. Complies by IR	Conforms
	B. UV: $\Delta E/E_{254} \leq 3.0\%$	1.5%
Melting point	173°C TO 179°C	177-179°C
Specific optical rotation	+75° TO +83°	+80.4°
Water	Not more than 3.5%	1.2%
Related substances	Estra-1,3,5(10),9(11)-tetraene-3,17 $\beta$ -diol not more than 0.3%	0.13%
	Individual unknown impurity not more than 0.10%	0.02%
	Total impurities not more than 1.0%	0.16%
Residual solvents	Methanol not more than 3000 ppm	Not detected
	Ethanol not more than 5000 ppm	243 ppm
Assay	Contains 97.0% to 103.0% of $C_{21}H_{24}O_2$ calculated on the anhydrous basis	99.7%
Particle size (Number method)	It should be 95% below 20 $\mu$ m	1.22 $\mu$ m

**CONCLUSION: THE PRODUCT CONFORMS TO USP40, IN-HOUSE AND CUSTOMER STANDARD.**

Reported by: [Signature]

Date: 2017-09-04

Checked by: [Signature]

Date: 2017-09-04

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2016-10-12

*Handwritten signatures and dates:*  
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