



CERTIFICATE OF ANALYSIS

PRODUCT NAME	Estradiol, USP (Hemihydrate)(Micronized)	
BATCH NUMBER	11242502	
MANUFACTURER CODE	ZZ2027	
MANUFACTURING DATE	11/29/2023	
EXPIRATION DATE	10/31/2028	

ANALYSIS	SPECIFICATION	RESULTS
ASSAY ON ANHYDROUS BASIS*	97.0 - 103.0 %	100.8 %
DESCRIPTION	White or creamy white, small crystals or crystalline powder. Is odorless, and is hygroscopic.	CONFORMS
IDENTIFICATION A <197A>*	IR: Reference to standard spectrum.	POSITIVE
IDENTIFICATION B <197U>*	UV: ≤ 3.0 % (280 nm)	0.2 % ; POSITIVE
MELTING RANGE <741> I*	173 ° - 179 ° C	176 ° - 178 ° C
SPECIFIC ROTATION <781S>*	+ 76 ° to + 83 °	+ 80 °
WATER <921> I*	≤ 3.5 %	3.3 %
CHROMATOGRAPHIC PURITY*	≤ 0.5 % (Individual impurity) ≤ 1.0 % (Total impurities)	NOT DETECTED NOT DETECTED
ELEMENTAL IMPURITIES <232>	Meets the requirements.	CONFORMS
RESIDUAL SOLVENTS <467>	Meets the requirements	CONFORMS
PARTICLE SIZE	To be reported	95 % <= 7 µm
SOURCE	Soy	
LABELING	The hemihydrate form is so labeled.	
SOLUBILITY	Practically insoluble in water; soluble in alcohol, in acetone, in dioxane, and in solutions of fixed alkali hydroxides; slightly soluble in chloroform; sparingly soluble in vegetable oils.	

QC APPROVED

DATE APPROVED: 11/26/125CERTIFIED BY: AN

THE ABOVEMENTIONED PRODUCT CONFORMS TO THE SPECIFICATIONS OF USP.

ENOVACHEM PHARMACEUTICALS REPACKAGES ACTIVE PHARMACEUTICAL INGREDIENT CHEMICALS PROVIDED BY OTHER SUPPLIERS. ENOVACHEM'S CERTIFICATE OF ANALYSIS REFLECTS TEST RESULTS THAT ARE A DIRECT TRANSCRIPTION OF INFORMATION PROVIDED ON THE SUPPLIER'S CERTIFICATE OF ANALYSIS. ORIGINAL AND SUPPLIER CERTIFICATE OF ANALYSIS HAS BEEN ATTACHED.

ORIGINAL MANUFACTURER INFORMATION: Zhejiang Xian ju Pharmaceutical Co., Ltd 15 West Fengxi Road, Modern Industrial Park, Xianju, Zhejiang, China

SUPPLIER INFORMATION: Medisca® 1-800-932-1039

6641 N Beltline Rd Unit 120 Irving, TX 75063

SUPPLIER LOT NUMBER HAS BEEN CHANGED FROM: 212017

TO BATCH NUMBER: 11242502

CERTIFICATE OF ANALYSIS

ESTRADIOL, USP (Hemihydrate) (Micronized)

Batch/Lot Number :	212017	This lot was manufactured by:
Manufacturing Date :	11/29/2023	ZHEJIANG XIANJU PHARMACEUTICAL CO., LTD. (FENGXI) 15 WEST FENGXI ROAD XIANJU, TAIZHOU, ZHEJIANG, 317300 CN
Expiration Date :	10/31/2028	
CAS:	35380-71-3	

TESTS	SPECIFICATIONS	RESULTS
ASSAY ON ANHYDROUS BASIS*	97.0 - 103.0 %	100.8 %
DESCRIPTION	White or creamy white, small crystals or crystalline powder. Is odorless, and is hygroscopic.	CONFORMS
IDENTIFICATION A <197A>*	IR: Reference to standard spectrum.	POSITIVE
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CHROMATOGRAPHIC PURITY*	≤ 0.5 % (Individual impurity) ≤ 1.0 % (Total impurities)	NOT DETECTED NOT DETECTED
ELEMENTAL IMPURITIES <232>	Meets the requirements.	CONFORMS
RESIDUAL SOLVENTS <467>	Meets the requirements.	CONFORMS
PARTICLE SIZE	To be reported	95 % <= 7 µm
SOURCE	Soy	
LABELING	The hemihydrate form is so labeled.	
SOLUBILITY	Practically insoluble in water; soluble in alcohol, in acetone, in dioxane, and in solutions of fixed alkali hydroxides; slightly soluble in chloroform; sparingly soluble in vegetable oils.	

LOT TESTED BY:

CED Analytical Laboratory Inc.
6641 N Beltline Rd Unit 120
Irving, TX 75063

PUBLISHED BY:



PUBLISHED DATE:

08/09/2024

ISSUE DATE:

08/09/2024

The above mentioned product conforms to the specifications of USP.

The above test results are a direct transcription of information provided to MEDISCA from the Certificate of Analysis provided by the manufacturer / supplier. Additional testing conducted by MEDISCA is represented by an asterisk. This lot was manufactured by M: ZZ2027.

All dates in this document are in format mm/dd/yyyy unless otherwise specified

This document has been electronically approved through MEDISCA's Quality Management System.



CERTIFICATE OF ANALYSIS

ESTRADIOL, USP (Hemihydrate) (Micronized)

Batch/Lot Number :	212017	This lot was manufactured by:
Manufacturing Date :	11/29/2023	ZHEJIANG XIANJU PHARMACEUTICAL CO., LTD. (FENGXI)
Expiration Date :	10/31/2028	15 WEST FENGXI ROAD
CAS:	35380-71-3	XIANJU, TAIZHOU, ZHEJIANG, 317300 CN

TESTS

PACKAGING AND STORAGE

*TESTED ON 08/09/2024

Lot number has been changed from
QC014-231104 to 212017.

SPECIFICATIONS

Preserve in tight, light-resistant containers. Store at 25°C,
excursions permitted between 15° and 30°C.

RESULTS

LOT TESTED BY:

CED Analytical Laboratory Inc.
6641 N Beltline Rd Unit 120
Irving, TX 75063

PUBLISHED BY:

PUBLISHED DATE:

08/09/2024

ISSUE DATE:

08/09/2024

The above mentioned product conforms to the specifications of USP.

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Zhejiang Xianju Pharmaceutical Co., Ltd
Certificate of Analysis

Record Code	Effective Date
AOP350-03R03	2023-03-15

Product	Estradiol Hemihydrate	Number of CO	2405-02
Batch No.	QC014-231104	Manufacture Date	2024-05-11
Amounts	74.730kg	Manufacture Date	2023-11-29
According To	USP 2020-05-01, In-house And Customer Standard	Retest Date	2028-11-29

【ITEM】	【SPECIFICATION】	【RESULT】
Appearance	White or almost white crystalline powder	Almost white crystalline powder
Identification	A. Complies by IR	Conforms
Identification	B. UV: $\Delta E/ERS \leq 3.0\%$	0.2%
Melting Range	173~179°C	177.5~179°C
Specific Optical Rotation	+76° to +83°	+80°
Water	$\leq 3.5\%$	3.2%
Residue On Ignition	$\leq 0.1\%$	0.06%
Related Substances	Estra-1,3,5(10),9(11)-tetraene-3,17 β -diol $\leq 0.3\%$	0.06%
Related Substances	Any other individual impurity $\leq 0.10\%$	0.04%
Related Substances	Total impurities $\leq 1.0\%$	0.10%
Residual Solvents	Methanol ≤ 3000 ppm	Not detected
Residual Solvents	Ethanol ≤ 5000 ppm	114ppm
Assay	Contains 97.0% to 103.0% of $C_{18}H_{24}O_2$ calculated on the anhydrous basis	100.7%
Particle Size (Volume Method)	$D_{95} < 10 \mu m$	7 μm

Conclusion: The Product Conforms To USP 2020-05-01, In-house And Customer Standard.

Reported by: 123456
Date: 2024-05-15

Checked by: 789012
Date: 2024-05-15

Address: 15 West Fengxi Road, Modern Industrial Park, Xianju, Zhejiang, China
Email: zb@xjpharma.com
Telephone: 0086-576-87731018

CERTIFICATE OF ANALYSIS

CED Sample ID 24-2822	Report Date 08/02/2024	Certificate No. 24-2822.00
Customer Information Medisca, Inc. 6641 N Belt Line Rd Suite 130 Irving, TX 75063 (800) 932-1039	Sample Information Estradiol USP (Hemihydrate) (Micronized) NDC No. 0869-BLK Lot No. 212017 Mfg. Lot No. QC014-231104	Customer Reference/ PO No. 142664 Sample Received Date 07/22/2024

The result(s) issued on this report only reflect the analysis of the sample submitted.

TEST	METHOD	SPECIFICATION/LIMITS	RESULT
Tap Density	USP <616>	Report result	0.310 g/mL
Comments			

Reviewed By *C. Cazzell* Courtney Cazzell, Quality Manager

08/02/2024

Date

Released By *Y. Idowu* Yemi Idowu, QC Specialist II

08/02/24

Date