



### 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: $\leq 3.0$ % (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*	$\leq 3.5$ %	3.3 %
CHROMATOGRAPHIC PURITY*	$\leq 0.5$ % (Individual impurity) $\leq 1.0$ % (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 % $\leq 7$ $\mu$ m
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: 11/26/25

CERTIFIED BY: cr

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

Manufacturing Date : 11/29/2023

Expiration Date : 10/31/2028

CAS: 35380-71-3

This lot was manufactured by:

ZHEJIANG XIANJU PHARMACEUTICAL  
CO., LTD. (FENGXI)  
15 WEST FENGXI ROAD  
XIANJU, TAIZHOU, ZHEJIANG, 317300  
CN

#### 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

IDENTIFICATION B <197U>\*

UV:  $\leq 3.0$  % (280 nm)

0.2 % ; POSITIVE

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173 ° - 179 °C

176 ° - 178 °C

SPECIFIC ROTATION <781S>\*

+ 76 ° to + 83 °

+ 80 °

WATER <921> I\*

$\leq 3.5$  %

3.3 %

CHROMATOGRAPHIC PURITY\*

$\leq 0.5$  % (Individual impurity)

NOT DETECTED

$\leq 1.0$  % (Total impurities)

NOT DETECTED

ELEMENTAL IMPURITIES <232>

Meets the requirements.

CONFORMS

RESIDUAL SOLVENTS <467>

Meets the requirements.

CONFORMS

PARTICLE SIZE

To be reported

95 %  $\leq 7$   $\mu$ m

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

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XIANJU, TAIZHOU, ZHEJIANG, 317300  
CN

#### TESTS

\*\*PACKAGING AND STORAGE\*\*

#### SPECIFICATIONS

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

#### RESULTS

\*TESTED ON 08/09/2024

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

#### 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:

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Zhejiang Xianju Pharmaceutical Co., Ltd  
Certificate of Analysis

Record Code	Effective Date
AQP350-03R03	2023-03-15

Product	Estradiol Hemihydrate	Lot No.	2405-02
Batch No.	QC014-231104	Issue 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℃	177.5~179℃
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 $\beta$ -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 $\leq 3000$ ppm	Not detected
Residual Solvents	Ethanol $\leq 5000$ 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)	D95 < 10 $\mu m$	7 $\mu m$

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

Reported by: 12/11/2024

Date: 2024-05-15

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

Checked by: 2024-05-15



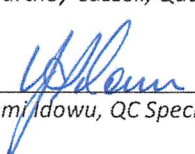
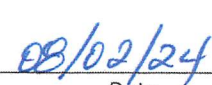
Date: 2024-05-15

## CERTIFICATE OF ANALYSIS

CED Sample ID 24-2822	Report Date 08/02/2024	Certificate No. 24-2822.00
Customer Information <b>Medisca, Inc.</b> 6641 N Belt Line Rd Suite 130 Irving, TX 75063 (800) 932-1039	Sample Information <b>Estradiol USP (Hemihydrate) (Micronized)</b> <b>NDC No. 0869-BLK</b> <b>Lot No. 212017</b> <b>Mfg. Lot No. QC014-231104</b>	Customer Reference/ PO No. <b>142664</b>
		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	 Courtney Cazzell, Quality Manager	 Date
Released By	 Yemi Idowu, QC Specialist II	 Date