



CERTIFICATE OF ANALYSIS

PRODUCT NAME	Testosterone, USP (Micronized)
BATCH NUMBER	11062501
MANUFACTURER CODE	ZZ1908
MANUFACTURING DATE	05/27/2024
EXPIRATION DATE	04/30/2027

ANALYSIS	SPECIFICATION	RESULTS
ASSAY ON DRIED BASIS*	97.0 - 103.0 %	99.0 %
DESCRIPTION	White or slightly creamy white crystals or crystalline powder. Is odorless and is stable in air.	CONFORMS
IDENTIFICATION A <197A>*	IR: Reference to standard spectrum.	POSITIVE
IDENTIFICATION B <197U>*	UV: Reference to standard spectrum.	POSITIVE
MELTING RANGE <741>*	153 ° - 157 °C	153 ° - 154 °C
SPECIFIC ROTATION <781S>*	+101° to +105°	+102°
LOSS ON DRYING <731>*	≤ 1.0 %	0.3 %
ELEMENTAL IMPURITIES <232>	Meets the requirements.	CONFORMS
RESIDUAL SOLVENTS <467>	Meets the requirements	CONFORMS
PARTICLE SIZE	To be reported.	90 % ≤ 20 µm
SOLUBILITY	Practically insoluble in water; freely soluble in dehydrated alcohol and in chloroform; soluble in dioxane and in vegetable oils; slightly soluble in ether.	
PACKAGING AND STORAGE	Preserve in well-closed containers. Store at 25°, excursions permitted between 15° and 30°C. Protect from light.	

QC APPROVED

DATE APPROVED: 11/06/25

CERTIFIED BY: ar

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: Hubei Zhuxi Humanwell Pharmaceutical Co., Ltd. Industrial park, Zhuxi County, Shiyan, Hubei 442300, China

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

6641 N Beltline Rd Unit 120 Irving, TX 75063

SUPPLIER LOT NUMBER HAS BEEN CHANGED FROM: 217146

TO BATCH NUMBER: 11062501

CERTIFICATE OF ANALYSIS

TESTOSTERONE, USP (Micronized)

Batch/Lot Number : 217146

Manufacturing Date : 05/27/2024

Expiration Date : 04/30/2027

CAS: 58-22-0

This lot was manufactured by:

HUBEI ZHUXI HUMANWELL
PHARMACEUTICAL CO. LTD.
INDUSTRIAL PARK ZHUXI COUNTY
SHIYAN, HUBEI, 442300
CN

TESTS

SPECIFICATIONS

RESULTS

ASSAY ON DRIED BASIS*

97.0 - 103.0 %

99.0 %

DESCRIPTION

White or slightly creamy white crystals or crystalline powder.
Is odorless and is stable in air.

CONFORMS

IDENTIFICATION A <197A>*

IR: Reference to standard spectrum.

POSITIVE

IDENTIFICATION B <197U>*

UV: Reference to standard spectrum.

POSITIVE

MELTING RANGE <741>*

153 ° - 157 °C

153 ° - 154 °C

SPECIFIC ROTATION <781S>*

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LOSS ON DRYING <731>*

≤ 1.0 %

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ELEMENTAL IMPURITIES <232>

Meets the requirements.

CONFORMS

RESIDUAL SOLVENTS <467>

Meets the requirements.

CONFORMS

PARTICLE SIZE

To be reported.

90 % ≤ 20 µm

SOLUBILITY

Practically insoluble in water; freely soluble in dehydrated
alcohol and in chloroform; soluble in dioxane and in vegetable
oils; slightly soluble in ether.

PACKAGING AND STORAGE

Preserve in well-closed containers. Store at 25°, excursions
permitted between 15° and 30°C. Protect from light.

*TESTED ON 01/24/2025

Lot number has been changed from
GT241101-1W1 to 217146.

LOT TESTED BY:

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

PUBLISHED BY:



PUBLISHED DATE:

01/24/2025

ISSUE DATE:

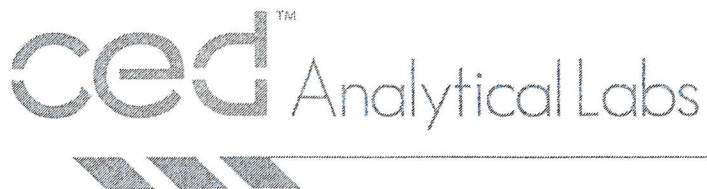
01/24/2025

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: ZZ1908.

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.



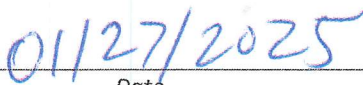
CERTIFICATE OF ANALYSIS

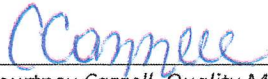
CED Sample ID 25-0040	Report Date 01/27/2025	Certificate No. 25-0040.00
Customer Information Medisca, Inc. 6641 N Belt Line Rd Suite 130 Irving, TX 75063 (800) 932-1039	Sample Information Testosterone USP (Micronized) NDC No. 0163-BLK Lot No. 217146 Mfg. Lot No. GT241101-1W1	Customer Reference/ PO No. 145252 Sample Received Date 01/06/2025

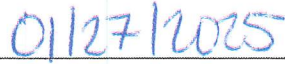
The result(s) issued on this report only reflect the analysis of the sample submitted.

TEST	METHOD	SPECIFICATION/LIMITS	RESULT
Tap Density	USP <616>	Report result	0.204 g/mL
Comments			

Reviewed By  Walter Anderson, QC Data Reviewer

Date 

Released By  Courtney Cazzell, Quality Manager

Date 

Hubei Zhuxi Humanwell Pharmaceutical Co., Ltd.

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[Http://www.zxhumanwell.com](http://www.zxhumanwell.com), E-mail: market@renfu.com.cn

CERTIFICATE OF ANALYSIS



人福医药

Product(品名): Testosterone

Batch No.(批号): GT241101-1W1

Quantity(数量): 500kg

Specification(规定): USP2024

Mfg. date(生产日期): 2024.05.27

Retest date(复验日期): 2027.05.26

Item (项目)	Specifications (标准)	Results (结果)
Description (性状)	White or slightly creamy white crystals or crystalline powder	White crystalline powder
Identification (鉴别)	IR: Comply with the reference spectrum UV: Comply with the reference spectrum	Conform
Melting point (熔点)	153°C ~ 157°C	153.5°C ~ 154.0°C
Loss on drying (干燥失重)	≤1.0%	0.09%
Specific optical rotation (比旋度)	+101° ~ +105°	+103.7°
Residual solvent (残留溶剂)	Methanol ≤3000ppm	Not detected
	Ethanol ≤5000ppm	Not detected
	Ethyl formate ≤5000ppm	Not detected
	Ethyl acetate ≤5000ppm	44ppm
	pyridine ≤200ppm	Not detected
Assay (dried substance) (含量)	97.0%~103.0%	99.5%
Particle Size (粒径)	90% ≤20μm	Conform

Conclusion: Complies with the requirements of USP2024

Report person: 柳婷婷

Date: 2024.11.29

QP: 侯梅

Date: 2024.11.29

