



CERTIFICATE OF ANALYSIS

PRODUCT NAME	Naproxen, USP
BATCH NUMBER	08112501
MANUFACTURER CODE	ZZ1101
MANUFACTURING DATE	03/24/2024
EXPIRATION DATE	02/28/2027

ANALYSIS	SPECIFICATION	RESULTS
ASSAY ON DRIED BASIS*	98.5 - 101.5 %	100.0 %
DESCRIPTION	White to off-white, practically odorless, crystalline powder.	CONFORMS
IDENTIFICATION A: <197A>*	IR: Reference to standard spectrum.	POSITIVE
IDENTIFICATION B: <197U>*	UV: <= 3 % (271 nm)	0.4 % ; POSITIVE
SPECIFIC ROTATION <781S>*	+83.0 ° to +89.5 °	+87.2 °
LOSS ON DRYING <731>*	≤ 0.5 %	0.03 %
ELEMENTAL IMPURITIES <232>	Meets the requirements	CONFORMS
CHROMATOGRAPHIC PURITY*	≤ 0.5 % (Individual impurity) ≤ 2.0 % (Total impurities)	NOT DETECTED NOT DETECTED
RESIDUAL SOLVENTS <467>	Meets the requirements.	CONFORMS
SOLUBILITY	Soluble in chloroform, in dehydrated alcohol, and in alcohol; sparingly soluble in ether; practically insoluble in water.	
PACKAGING AND STORAGE	Preserve in tight containers. Protect from light.	

QC APPROVED

DATE APPROVED: 11/20/25

CERTIFIED BY: AW

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 Charioteer Pharmaceutical Co., Ltd. Tongyuanxi, Dazhan, Xianju, Zhejiang Province, P.R. China, 317321 +86 576 87641661

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

6641 N Beltline Rd Unit 120 Irving, TX 75063

SUPPLIER LOT NUMBER HAS BEEN CHANGED FROM: 212565

TO BATCH NUMBER: 08112501

CERTIFICATE OF ANALYSIS

NAPROXEN, USP

Batch/Lot Number : 212565
Manufacturing Date : 03/24/2024
Expiration Date : 02/28/2027
CAS: 22204-53-1

This lot was manufactured by:

ZHEJIANG CHARIOTEER
PHARMACEUTICAL CO. LTD.
TONGYUANXI, DAZHAN, XIANJU
TAIZHOU, ZHEJIANG, 317321
CN

TESTS

SPECIFICATIONS

RESULTS

ASSAY ON DRIED BASIS*	98.5 - 101.5 %	100.0 %
DESCRIPTION	White to off-white, practically odorless, crystalline powder.	CONFORMS
IDENTIFICATION A: <197A>*	IR: Reference to standard spectrum.	POSITIVE
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	≤ 2.0 % (Total impurities)	NOT DETECTED
RESIDUAL SOLVENTS <467>	Meets the requirements.	CONFORMS
SOLUBILITY	Soluble in chloroform, in dehydrated alcohol, and in alcohol; sparingly soluble in ether; practically insoluble in water.	
PACKAGING AND STORAGE	Preserve in tight containers. Protect from light.	

*TESTED ON 08/23/2024

Lot number has been changed from
246022222 to 212565.

LOT TESTED BY:

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

PUBLISHED BY:



PUBLISHED DATE:

08/23/2024

ISSUE DATE:

08/23/2024

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: ZZ1101.

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

Zhejiang Charioteer Pharmaceutical Co., Ltd.

Address: Tongyuanxi, Dazhan, Xianju, Zhejiang Province, P.R. China, 317321

Tel: +86 576 87641661

Fax: +86 576 87641987

The product name	Naproxen		
Batch No.	246022222	Inspection Basis	Current USP
Manufacturing Date	2024.03.24	Retest Date	2027.03.23
Packing	25kg/drum	Amount	50kg
<u>The items and results of Inspection</u>			
Items	Results	Specifications	
[Characteristics]	White, crystalline powder	White to off-white, crystalline powder	
[Identification]			
A: Infrared Absorption	Conform	The infrared absorption spectrum is concordant with the reference spectrum	
B: Ultraviolet Absorption	Conform	Absorptivities at 271nm, calculated on the dried base, do not differ by more than 3%	
[Specific rotation]	+88.0°	+83.0° to +89.5°	
[Loss on drying]	0.13%	≤0.5%	
[Chromatographic purity](HPLC)			
Impurity D(in-house)	0.02%	≤0.10%	
Impurity E(in-house, Impurity C in EP)	<0.01%	≤0.10%	
Any other impurity	<0.01%	≤0.10%	
Total impurities	0.02%	≤1.0%	
[Assay] (On dry basis) It contains C ₁₄ H ₁₄ O ₃	99.6%	98.5% —101.5%	
[Residual solvent]			
Toluene	Conform	NMT 45ppm	
Methanol	Conform	NMT 50ppm	
Conclusion	Analyse according to Current USP, Conform		
QA Manager	<i>Zhang Xia</i>	Release Date	<i>2024.07.16</i>

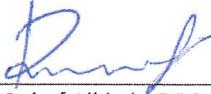
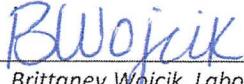
YICK-VIC CHEMICALS AND PHARMACEUTICALS
(HONG KONG) LIMITED

CERTIFICATE OF ANALYSIS

CED Sample ID 24-3109	Report Date 08/13/2024	Certificate No. 24-3109.00
Customer Information Medisca, Inc. 661 Route 3, Unit C, Plattsburgh, NY 12901 (800) 932-1039	Sample Information Naproxen USP Drum 1 NDC No. 0548-BLK Lot No. 212565 Mfg. Lot No. 24602222	Customer Reference/ PO No. 142851
		Sample Received Date 08/08/2024

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

TEST	METHOD	SPECIFICATION/LIMITS	RESULT
Description	Medisca Safety Data Sheet	White to off-white, practically odorless, crystalline powder.	Conforms
Identification A – Infrared Absorption	USP <197A>	Exhibits maxima only at the same wavelengths as that of the corresponding USP Reference Standard.	Conforms
Identification B – Ultraviolet Absorption	USP <197U>	Absorptivities at 271 nm, calculated on the dried basis, do not differ by more than 3%.	0.4%
Comments			

Reviewed By		08/13/2024
	Rahaf Alhirsh, QC Specialist I	Date
Released By		08-13-2024
	Brittany Wojcik, Laboratory Operations Manager	Date

CERTIFICATE OF ANALYSIS

CED Sample ID 24-3110	Report Date 08/13/2024	Certificate No. 24-3110.00
Customer Information Medisca, Inc. 661 Route 3, Unit C, Plattsburgh, NY 12901 (800) 932-1039	Sample Information Naproxen USP Drum 2 NDC No. 0548-BLK Lot No. 212565 Mfg. Lot No. 24602222	Customer Reference/ PO No. 142851
		Sample Received Date 08/08/2024

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

TEST	METHOD	SPECIFICATION/LIMITS	RESULT
Description	Medisca Safety Data Sheet	White to off-white, practically odorless, crystalline powder.	Conforms
Identification A – Infrared Absorption	USP <197A>	Exhibits maxima only at the same wavelengths as that of the corresponding USP Reference Standard.	Conforms
Identification B – Ultraviolet Absorption	USP <197U>	Absorptivities at 271 nm, calculated on the dried basis, do not differ by more than 3%.	0.1%
Comments			

<i>Reviewed By</i>	<i>Rahaf Alhirsh, QC Specialist I</i>	<i>08/13/2024</i>
<i>Released By</i>	<i>Brittaney Wojcik, Laboratory Operations Manager</i>	<i>08-13-2024</i>

CERTIFICATE OF ANALYSIS

CED Sample ID 24-3108	Report Date 08/23/2024	Certificate No. 24-3108.00
Customer Information Medisca, Inc. 661 Route 3, Unit C, Plattsburgh, NY 12901 (800) 932-1039	Sample Information Naproxen USP NDC No. 0548-BLK Lot No. 212565 Mfg. Lot No. 24602222	Customer Reference/ PO No. 142851
		Sample Received Date 08/08/2024

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

TEST	METHOD	SPECIFICATION/LIMITS	RESULT	
Description	Medisca Safety Data Sheet	White to off-white, crystalline powder.	Conforms	
Specific Rotation	USP <781S>	+83.0° to +89.5°	+87.2°	
Loss on Drying	USP <731>	NMT 0.5%	0.03%	
Assay – dried basis	USP Monograph*	98.5% - 101.5%	100.0%	
Chromatographic Purity	USP Monograph*	The Rf value of the principal spot in the chromatogram of the Test solution corresponds to that of the Standard solution.	Conforms	
		Individual Impurity	NMT 0.5%	None Detected
		Total Impurities	NMT 2.0%	None Detected
Comments: *USP Monograph effective 5/1/2020 to 07/31/2024.				

Reviewed By	<i>BWojcik</i> Brittaney Wojcik, Laboratory Operations Manager	Date	<i>08.23.2024</i>
Released By	<i>JLkann</i> Yemi Idowu, QC Specialist II	Date	<i>08/23/24</i>