Enovachem™
PHARMACEUTICALS

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: [signature]

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

Medisca®

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
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)	NOT DETECTED
	≤ 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

The items and results of Inspection

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	Zhang Xia	Release Date	2024.07.16

YICK-VIC CHEMICALS AND PHARMACEUTICALS
(HONG KONG) LIMITED

ced™ Analytical Labs

CERTIFICATE OF ANALYSIS

CED Sample ID	Report Date	Certificate No.
24-3109	08/13/2024	24-3109.00
Customer Information	**Sample Information**	**Customer Reference/ PO No.**
Medisca, Inc. 661 Route 3, Unit C, Plattsburgh, NY 12901 (800) 932-1039	**Naproxen USP Drum 1** **NDC No. 0548-BLK** **Lot No. 212565** **Mfg. Lot No. 246022222**	**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 *Rahaf Alhirsh, QC Specialist I* 08/13/2024 *Date*

Released By *Brittaney Wojcik, Laboratory Operations Manager* 08-13-2024 *Date*

ced™ Analytical Labs

CERTIFICATE OF ANALYSIS

CED Sample ID	Report Date	Certificate No.
24-3110	08/13/2024	24-3110.00
Customer Information	**Sample Information**	**Customer Reference/ PO No.**
Medisca, Inc. 661 Route 3, Unit C, Plattsburgh, NY 12901 (800) 932-1039	**Naproxen USP Drum 2** **NDC No. 0548-BLK** **Lot No. 212565** **Mfg. Lot No. 246022222**	**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			

Reviewed By *Rahaf Alhirsh, QC Specialist I* 08/13/2024 *Date*

Released By *Brittaney Wojcik, Laboratory Operations Manager* 08·13·2024 *Date*

ced™ Analytical Labs

CERTIFICATE OF ANALYSIS

CED Sample ID	Report Date	Certificate No.
24-3108	08/23/2024	24-3108.00
Customer Information	**Sample Information**	**Customer Reference/ PO No.**
Medisca, Inc. 661 Route 3, Unit C, Plattsburgh, NY 12901 (800) 932-1039	**Naproxen USP** **NDC No. 0548-BLK** **Lot No. 212565** **Mfg. Lot No. 246022222**	**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.				

BWojcik 08.23.2024

Reviewed By *Brittaney Wojcik, Laboratory Operations Manager* *Date*

08/23/24

Released By *Yemi Idowu, QC Specialist II* *Date*