

CERTIFICATE OF ANALYSIS

(Certificate No. KML009029-01)

Release Date: 16/02/2023

Re-test Date: 15/02/2026

N-Nitroso Levofloxacin EP Impurity B

Identification

Chemical Name :

(S)-9-Fluoro-3-methyl-10-(4-nitrosopiperazin-1-yl)-7-oxo-2,3-dihydro-7H-[1,4]oxazino[2,3,4-ij]quinoline-6-carboxylic acid

Alt. Name

: N-Nitroso Levofloxacin USP Related Compound A ; N-Nitroso N-Desmethyl Levofloxacin

CAT No.

: KML009029

CAS No.

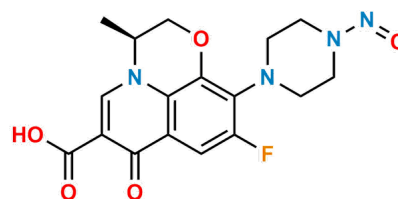
: 1152314-62-9

Molecular Formula

: C17H17FN4O5

Molecular Weight

: 376.3



Analytical Information

Batch No.

: LEV-N-NO-045-052

Solubility

: Acetonitrile

Description

: Light Yellow Solid

Mass

: Confirm

HPLC Purity

: 99.68 %

IR

: Confirm

Weight Loss By TGA

: 4.64 %

¹H NMR

: Confirm

% Potency

: 95.05 %

Additional Information

Long Term Storage

: Store at 2-8 deg. C for long term storage

Shipping Condition

: Product is stable to be Shipped at Room Temperature

% Potency = [100 - 4.64(Weight Loss By TGA)] x [99.68(HPLC Purity)]/100 = 95.05 %

Recommendation

: Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		08/05/2025
Reviewed & Approved By	Quality Control	Jatin Patel		08/05/2025

Attachments : COA, HPLC, MASS, ¹HNMR, IR and TGA