

CERTIFICATE OF ANALYSIS

(Certificate No. KMM006067-01)

Release Date: 10/10/2025

Re-test Date: 09/10/2028

Montelukast Sodium USPRS

Identification

Chemical Name :

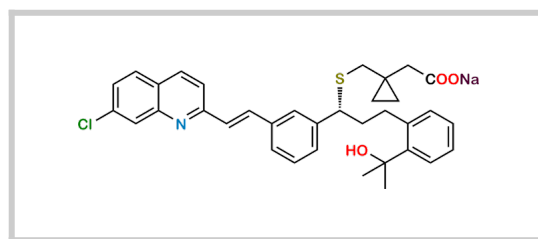
Sodium [1-[[[(1R)-1-[3-[(E)-2-(7-chloroquinolin-2-yl)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]sulfanyl]methyl]cyclopropyl]acetate (as per EP); Sodium 1-[[[(R)-m-[(E)-2-(7-chloro-2-quinolyl)vinyl]-α-[o-(1-hydroxy-1-methylethyl)phenethyl]benzyl]thio]-methyl]cyclopropaneacetate (as per USP)

CAT No. : KMM006067

CAS No. : 151767-02-1

Molecular Formula : C₃₅H₃₅ClNNaO₃S

Molecular Weight : 608.2



Analytical Information

Batch No. : M006067-102-330

Description : White Solid

HPLC Purity : 99.96 %

Weight Loss By TGA : 0.36 %

% Potency : 99.6 %

Solubility : ACN : Water (1:1)

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

¹³C NMR : Confirm

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 - 0.36(Weight Loss By TGA)] x [99.96(HPLC Purity)]/100 = 99.6 %

USP Catalog No & Lot No :-1446859 - R06240

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Bhargav Kathiriya		10/10/2025
Reviewed & Approved By	Quality Control	Viraj Akabri		10/10/2025

Attachments : COA, HPLC, MASS, ¹HNMR, ¹³C NMR, IR and TGA