CERTIFICATE OF ANALYSIS

(Certificate No. KMM006067-01)

Release Date: 10/10/2025 **Re-test Date:** 09/10/2028

Montelukast Sodium USPRS

Identification

Chemical Name:

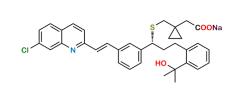
 $Sodium \ [1-[[[(1R)-1-[3-[(E)-2-(7-chloroquinolin-2-yl)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]sulfanyl]methyl]cyclopropyl]acetate (as per EP); Sodium 1-[[[(R)-m-[(E)-2-(7-chloro-2-quinolyl)vinyl]-\alpha-[o-(1-hydroxy-1-methylethyl)phenethyl]benzyl]thio]-methyl]cyclopropaneacetate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

CAT No. : KMM006067

CAS No. : 151767-02-1

Molecular Formula : C35H35ClNNaO3S

Molecular Weight : 608.2



Analytical Information

Description : White Solid **Mass** : Confirm **HPLC Purity** : 99.96 % IR : Confirm Weight Loss By TGA : 0.36 % 1H NMR : Confirm % Potency : 99.6 % **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