CERTIFICATE OF ANALYSIS

(Certificate No. KMM006067-01)

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

Montelukast Sodium USPRS

Identification

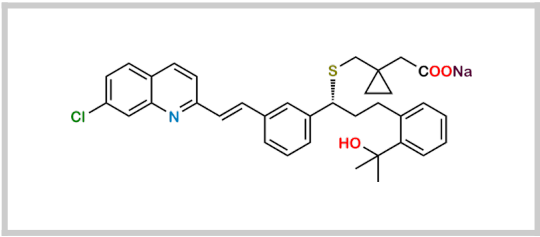
Chemical Name :
Sodium [1-[[[(1R)-1-[3-[(E)-2-(7-chloroquinolin-2-yl)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]sulfanyl]methyl]cyclopropyl]acetate (as per EP); Sodium 1-[[[(R)-m-[(E)-2-(7-chloro-2-quinolyl)vinyl]-α-[o-(1-hydroxy-1-methylethyl)phenethyl]benzyl]thio]-methyl]cyclopropaneacetate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