CERTIFICATE OF ANALYSIS

(Certificate No. KMO005009-01)

Release Date: 23/08/2025 **Re-test Date:** 22/08/2028

Ondansetron EP Impurity A

Identification

Chemical Name :
(3RS)-3-[(dimethylamino)methyl]-9-methyl-1,2,3,9-tetrahydro-4H-carbazol-4-one (as per EP)

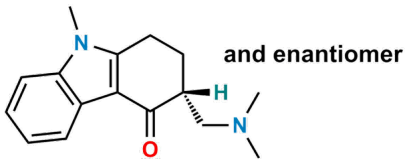
Alt. Name : Ondansetron USP Related Compound A

CAT No. : KMO005009

CAS No. : 153139-56-1

Molecular Formula : C16H20N2O

Molecular Weight : 256.3



Analytical Information

Batch No.	: O005009-102-236	**Solubility**	: Acetonitrile
Description	: Light Brown Solid	**Mass**	: Confirm
HPLC Purity	: 98.16 %	**IR**	: Confirm
Weight Loss By TGA	: 0.36 %	**1H NMR**	: Confirm
% Potency	: 97.81 %		

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 [98.16(HPLC Purity)]/100 = 97.81 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		25/08/2025
Reviewed & Approved By	Quality Control	Jatin Patel		25/08/2025

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