

CERTIFICATE OF ANALYSIS

(Certificate No. KMO005015-01)

Release Date: 23/08/2025

Re-test Date: 22/08/2028

Ondansetron EP Impurity G

Identification

Chemical Name :

(3RS)-3-[(1H-Imidazol-1-yl)methyl]-9-methyl-1,2,3,9-tetrahydro-4H-carbazol-4-one (as per EP)

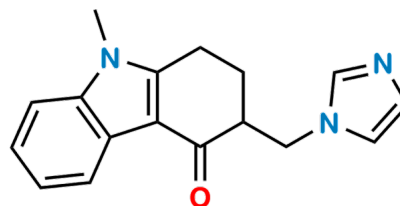
Alt. Name : Ondansetron USP Related Compound G

CAT No. : KMO005015

CAS No. : 99614-03-6

Molecular Formula : C₁₇H₁₇N₃O

Molecular Weight : 279.3



Analytical Information

Batch No. : O005015-102-235

Description : Off White Solid

HPLC Purity : 98.70 %

Weight Loss By TGA : 1.85 %

% Potency : 96.87 %

Solubility : Acetonitrile

Mass : Confirm

IR : Confirm

¹H 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 - 1.85(Weight Loss By TGA)] x [98.70(HPLC Purity)]/100 = 96.87 %

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