CERTIFICATE OF ANALYSIS

(Certificate No. KMO005012-01)

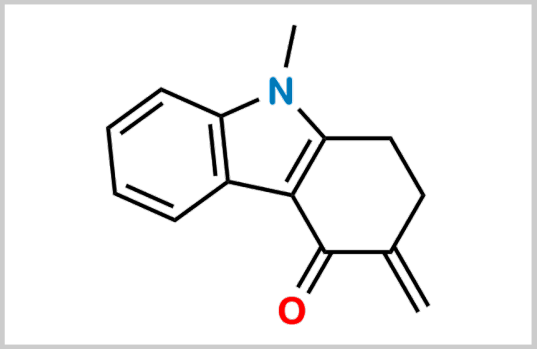
Release Date: 23/08/2025 **Re-test Date:** 22/08/2028

Ondansetron EP Impurity D

Identification

Chemical Name :
9-Methyl-3-methylene-1,2,3,9-tetrahydro-4H-carbazol-4-one

Alt. Name	: Ondansetron USP Related Compound D
CAT No.	: KMO005012
CAS No.	: 99614-64-9
Molecular Formula	: C14H13NO
Molecular Weight	: 211.3



Analytical Information

Batch No.	: O005012-102-232	**Solubility**	: Acetonitrile
Description	: Light Brown Solid	**Mass**	: Confirm
HPLC Purity	: 98.51 %	**IR**	: Confirm
Weight Loss By TGA	: 0.21 %	**1H NMR**	: Confirm
% Potency	: 98.3 %		

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 - 0.21(Weight Loss By TGA)] x [98.51(HPLC Purity)]/100 = 98.3 %

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