CERTIFICATE OF ANALYSIS

(Certificate No. KMO005016-01)

Release Date: 29/08/2025 **Re-test Date:** 28/08/2028

Ondansetron EP Impurity H

Identification

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

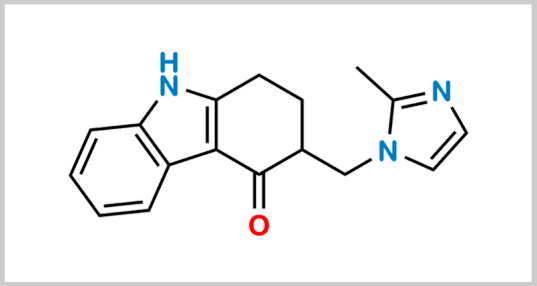
Alt. Name : N-Desmethyl Ondansetron (EP)

CAT No. : KMO005016

CAS No. : 99614-14-9

Molecular Formula : C17H17N3O

Molecular Weight : 279.3



Analytical Information

Batch No.	: O005016-102-246	**Solubility**	: ACN : Water (1:1)
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 98.19 %	**IR**	: Confirm
Weight Loss By TGA	: 2.60 %	**1H NMR**	: Confirm
% Potency	: 95.64 %		

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 - 2.60(Weight Loss By TGA)] x [98.19(HPLC Purity)]/100 = 95.64 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		29/08/2025
Reviewed & Approved By	Quality Control	Jatin Patel		29/08/2025

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