CERTIFICATE OF ANALYSIS

(Certificate No. KMM020004-01)

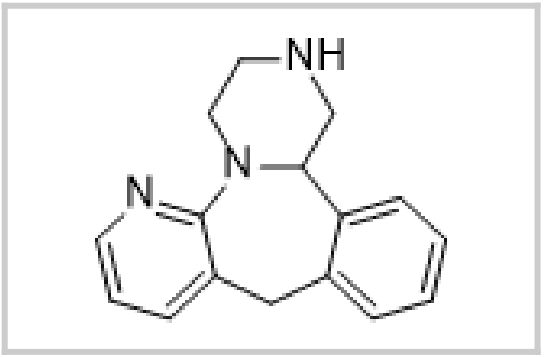
Release Date: 24/04/2024 **Re-test Date:** 23/04/2027

Mirtazapine EP Impurity D

Identification

Chemical Name :
1,2,3,4,10,14b-hexahydrobenzo[c]pyrazino[1,2-a]pyrido[3,2-f]azepine

Alt. Name	: Mirtazapine USP Related Compound A ; N-Desmethyl Mirtazapine
CAT No.	: KMM020004
CAS No.	: 61337-68-6
Molecular Formula	: C16H17N3
Molecular Weight	: 251.33



Analytical Information

Batch No.	: MIR-EP-IMP-D-073-182	**Solubility**	: Methanol
Description	: Light Brown Solid	**Mass**	: Confirm
HPLC Purity	: 98.02 %	**IR**	: Confirm
Weight Loss By TGA	: 4.83 %	**1H NMR**	: Confirm
% Potency	: 93.29 %	**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 - 4.83(Weight Loss By TGA)] x [98.02(HPLC Purity)]/100 = 93.29 %
-13CNMR added on 06.02.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		06/02/2025
Reviewed & Approved By	Quality Control	Jatin Patel		06/02/2025

Attachments : COA, HPLC, MASS, 1HNMR, 13CNMR, IR and TGA