CERTIFICATE OF ANALYSIS

(Certificate No. KMA010008-01)

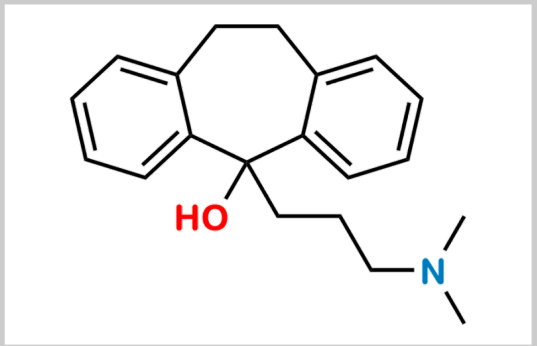
Release Date: 20/08/2024 **Re-test Date:** 19/08/2027

Amitriptyline Related Compound B

Identification

Chemical Name :
5-[3-(Dimethylamino)propyl]-10,11-dihydro-5H-dibenzo[a,d][7]annulen-5-ol (as per EP) ; 5-[3-(dimethylamino)propyl]-10,11-dihydro-5H-dibenzo[a,d]-cyclohepten-5-ol (as per USP)

Alt. Name	: Amitriptynol (USP) ; Amitriptyline USP Related Compound B
CAT No.	: KMA010008
CAS No.	: 1159-03-1
Molecular Formula	: C20H25NO
Molecular Weight	: 295.4



Analytical Information

Batch No.	: KMPS/AMI/B/010	**Solubility**	: Acetonitrile
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 97.98 %	**IR**	: Confirm
Weight Loss By TGA	: 3.01 %	**1H NMR**	: Confirm
% Potency	: 95.03 %		

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 - 3.01(Weight Loss By TGA)] x [97.98(HPLC Purity)]/100 = 95.03 %
-Re-tested on 20.08.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		04/04/2025
Reviewed & Approved By	Quality Control	Jatin Patel		04/04/2025

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