

CERTIFICATE OF ANALYSIS

(Certificate No. KMA010005-01)

Release Date: 11/12/2024

Re-test Date: 10/12/2027

Amitriptyline EP Impurity A

Identification

Chemical Name :

10,11-Dihydro-5H-dibenzo[a,d][7]annulen-5-one (as per EP)

Alt. Name

: Amitriptyline USP Related Compound A ; Dibenzosuberone (EP & USP)

CAT No.

: KMA010005

CAS No.

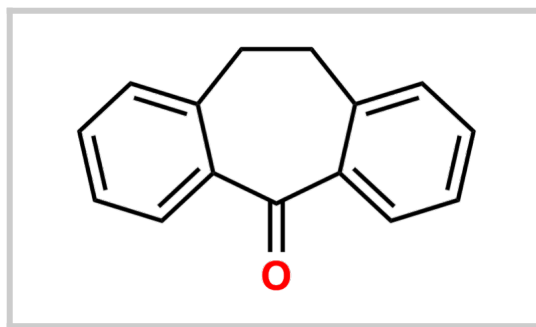
: 1210-35-1

Molecular Formula

: C₁₅H₁₂O

Molecular Weight

: 208.3



Analytical Information

Batch No.

: A010005-091-072

Solubility

: Water

Description

: Yellow Liquid

Mass

: Confirm

HPLC Purity

: 98.33 %

IR

: Confirm

Weight Loss By TGA

: 0.04 %

¹H NMR

: Confirm

% Potency

: 98.29 %

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 - 0.04(Weight Loss By TGA)] x [98.33(HPLC Purity)]/100 = 98.29 %

Recommendation

: Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		31/12/2024
Reviewed & Approved By	Quality Control	Jatin Patel		31/12/2024

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