

CERTIFICATE OF ANALYSIS

(Certificate No. KMD120006-01)

Release Date: 03/01/2026

Re-test Date: 02/01/2029

Diphenhydramine EP Impurity A

Identification

Chemical Name :

2-(Diphenylmethoxy)-N-methylethanamine (diphenhydramine impurity A)

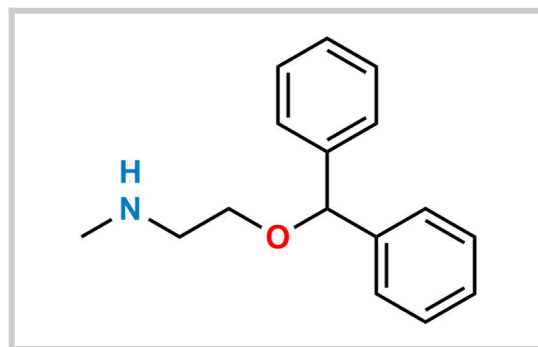
Alt. Name : N-Desmethyl Diphenhydramine ; N-Demethyldiphenhydramine

CAT No. : KMD120006

CAS No. : 17471-10-2

Molecular Formula : C₁₆H₁₉NO

Molecular Weight : 241.3



Analytical Information

Batch No. : D120006-114-087

Description : Light Yellow Semi Solid

HPLC Purity : 99.38 %

Weight Loss By TGA : 1.84 %

% Potency : 97.55 %

Solubility : Acetonitrile

Mass : Confirm

IR : Confirm

¹H 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 - 1.84(Weight Loss By TGA)] x [99.38(HPLC Purity)]/100 = 97.55 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		08/01/2026
Reviewed & Approved By	Quality Control	Jatin Patel		08/01/2026

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