

CERTIFICATE OF ANALYSIS

(Certificate No. KMC012011-01)

Release Date: 11/05/2024

Re-test Date: 10/05/2027

Cetirizine EP Impurity A

Identification

Chemical Name :

(RS)-1-[(4-Chlorophenyl)phenylmethyl]piperazine ;

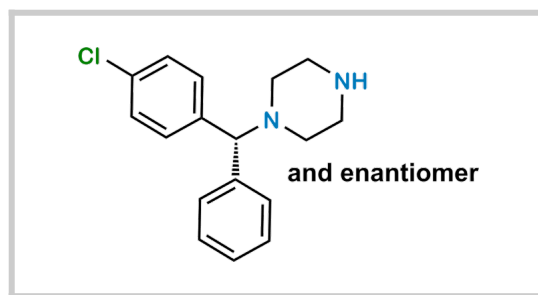
Alt. Name : Cetirizine CBHP Impurity (USP)

CAT No. : KMC012011

CAS No. : 303-26-4

Molecular Formula : C₁₇H₁₉ClN₂

Molecular Weight : 286.8



Analytical Information

Batch No. : CET-EPA-030-385

Description : Light Yellow Hygroscopic Solid

HPLC Purity : 94.14 %

Weight Loss By TGA : 1.53 %

% Potency : 92.7 %

Solubility : ACN : Water (1:1)

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 - 1.53(Weight Loss By TGA)] x [94.14(HPLC Purity)]/100 = 92.7 %

-Re-tested on 11.05.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		18/04/2025
Reviewed & Approved By	Quality Control	Jatin Patel		18/04/2025

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