

CERTIFICATE OF ANALYSIS

(Certificate No. KML026001-01)

Release Date: 11/05/2024

Re-test Date: 10/05/2027

Levocetirizine Chlorobenzhydryl Piperazine

Identification

Chemical Name :
(R)-1-((4-chlorophenyl)(phenyl)methyl)piperazine

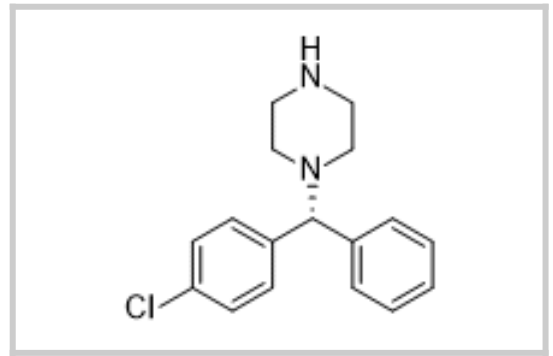
Alt. Name : Levocetirizine CBHP Impurity

CAT No. : KML026001

CAS No. : 300543-56-0

Molecular Formula : C₁₇H₁₉ClN₂

Molecular Weight : 286.80



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 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		11/05/2024
Reviewed & Approved By	Quality Control	Jatin Patel		11/05/2024

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA