

CERTIFICATE OF ANALYSIS

(Certificate No. KMC012018-01)

Release Date: 16/10/2022

Re-test Date: 15/10/2025

Cetirizine EP Impurity G

Identification

Chemical Name :

(R)-2-(4-((4-Chlorophenyl)(phenyl)methyl)piperazin-1-yl)ethan-1-ol Dihydrochloride ;

Alt. Name

: Cetirizine Ethanol Impurity ;
Cetirizine USP Related Compound G

CAT No.

: KMC012018

CAS No.

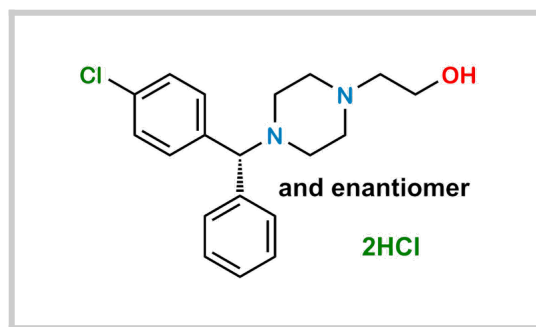
: 164726-80-1

Molecular Formula

: C₁₉H₂₃ClN₂O . 2HCl

Molecular Weight

: 330.86 . 2(36.5)



Analytical Information

Batch No.

: CET-EPG-030-305

Solubility

: ACN : Water (1:1)

Description

: Off White Solid

Mass

: Confirm

HPLC Purity

: 98.32 %

IR

: Confirm

Weight Loss By TGA

: 0.87 %

¹H NMR

: Confirm

% Potency

: 97.46 %

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 - 0.87(Weight Loss By TGA)] x [98.32(HPLC Purity)]/100 = 97.46 %

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, HPLC, MASS, ¹HNMR, IR and TGA