

CERTIFICATE OF ANALYSIS

(Certificate No. KMH006001-)

Release Date: 12/06/2024

Re-test Date: 11/06/2027

Hydroxyzine EP Impurity B

Identification

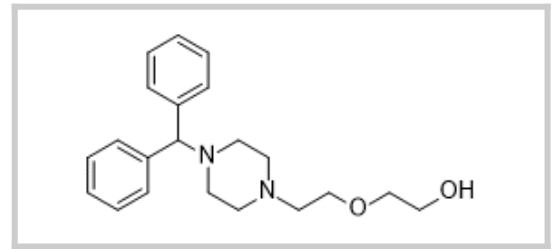
Chemical Name :
2-(2-(4-benzhydrylpiperazin-1-yl)ethoxy)ethanol

CAT No. : KMH006001

CAS No. : 3733-63-9

Molecular Formula : C₂₁H₂₈N₂O₂

Molecular Weight : 340.46



Analytical Information

Batch No. : HYD-EP-IMP-B-019-236

Description : Off White Solid

HPLC Purity : 98.97 %

Weight Loss By TGA : 0.81 %

% Potency : 98.17 %

Solubility : Methanol

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 - 0.81(Weight Loss By TGA)] x [98.97(HPLC Purity)]/100 = 98.17 %

Remarks : COA Re-generated on 13.06.2024

-Re-tested on 12.06.2024

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 13/06/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 13/06/2024 |

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