

CERTIFICATE OF ANALYSIS

(Certificate No. KML004023-01)

Release Date: 16/12/2024

Re-test Date: 15/12/2027

Labetalol EP Impurity E

Identification

Chemical Name :

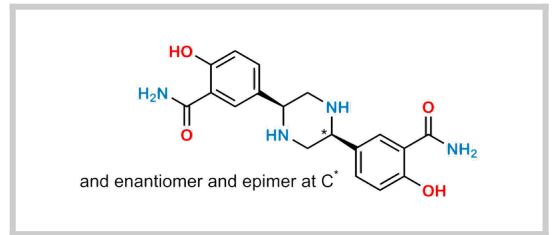
Mixture of 3 stereoisomers of 5,5'-piperazine-2,5-diylbis(2-hydroxybenzamide)

CAT No. : KML004023

CAS No. : NA

Molecular Formula : C₁₈H₂₀N₄O₄

Molecular Weight : 356.4



Analytical Information

Batch No. : L004023-091

Description : To be confirmed

HPLC Purity : NLT 95 %

Weight Loss By TGA : NLT 0.1 %

% Potency : 94.91 %

Solubility : To be confirmed

Mass : Should be Confirm

IR : Should be Confirm

¹H NMR : Should be 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 - 0.1(Weight Loss By TGA)] x [95(HPLC Purity)]/100 = 94.91 %

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 13/12/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 13/12/2024 |

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