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:

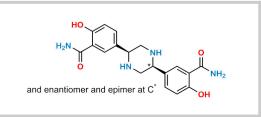
Mixture of 3 stereoisomers of 5,5'-piperazine-2,5-diylbis(2-hydroxybenzamide)

CAT No. : KML004023

CAS No. : NA

Molecular Formula : C18H20N4O4

Molecular Weight : 356.4



Analytical Information

Batch No. : L004023-091 **Solubility** : To be confirmed

Description : To be confirmed : Should be Mass

Confirm

HPLC Purity IR : Should be Weight Loss By TGA : NLT 0.1 %

Confirm

% Potency : 94.91 % 1H NMR : Should be

Confirm

Additional Information

: Store at 2-8 deg. C for long term storage **Long Term Storage**

: NLT 95 %

: Product is stable to be Shipped at Room Temperature **Shipping Condition % 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