

CERTIFICATE OF ANALYSIS

(Certificate No. KMC005019-01)

Release Date: 11/11/2024

Re-test Date: 10/11/2027

Carvedilol EP Impurity A

Identification

Chemical Name :

1-[[9-[2-hydroxy-3-[[2-(2-methoxyphenoxy)ethyl]amino]propyl]-9H-carbazol-4-yl]oxy]-3-[[2-(2-methoxyphenoxy)ethyl]amino]propan-2-ol (as per EP) ; 1-(4-(2-hydroxy-3-(2-(2-methoxyphenoxy)ethylamino)propoxy)-9H-carbazol-9-yl)-3-(2-(2-methoxyphenoxy)ethylamino)propan-2-ol (as per USP)

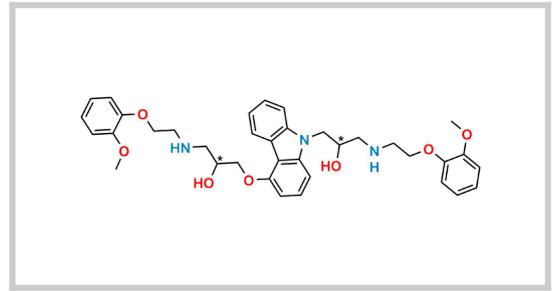
Alt. Name : Carvedilol USP Related Compound A

CAT No. : KMC005019

CAS No. : 1198090-73-1

Molecular Formula : C₃₆H₄₃N₃O₇

Molecular Weight : 629.7



Analytical Information

Batch No. : C005019-091-024

Description : Off White Solid

HPLC Purity : 95.69 %

Weight Loss By TGA : 0.91 %

% Potency : 94.82 %

Solubility : Acetonitrile

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 - 0.91(Weight Loss By TGA)] x [95.69(HPLC Purity)]/100 = 94.82 %

Recommendation : Released

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

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