

CERTIFICATE OF ANALYSIS

(Certificate No. KMB064001-01)

Release Date: 04/12/2024

Re-test Date: 03/12/2027

Betaxolol EP Impurity A

Identification

Chemical Name :

(2RS)-1-(4-Ethylphenoxy)-3-[(1-methylethyl)amino]propan-2-ol (as per EP)

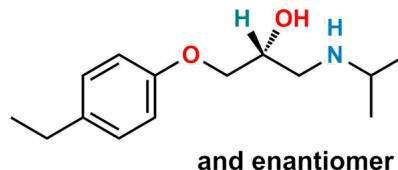
Alt. Name : Betaxolol USP Related Compound A

CAT No. : KMB064001

CAS No. : 67193-95-7

Molecular Formula : C₁₄H₂₃NO₂

Molecular Weight : 237.3



Analytical Information

Batch No. : B064001-091-063

Description : White Solid

HPLC Purity : 99.57 %

Weight Loss By TGA : 0.07 %

% Potency : 99.5 %

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 - 0.07(Weight Loss By TGA)] x [99.57(HPLC Purity)]/100 = 99.5 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		04/12/2024
Reviewed & Approved By	Quality Control	Jatin Patel		04/12/2024

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