

CERTIFICATE OF ANALYSIS

(Certificate No. KMF043009-01)

Release Date:

Re-test Date:

Fexofenadine EP Impurity C

Identification

Chemical Name :

(1RS)-4-[4-(hydroxydiphenylmethyl)piperidin-1-yl]-1-[4-(1-methylethyl)phenyl]butan-1-ol (as per EP)

Alt. Name

: Decarboxy Fexofenadine ;
Fexofenadine USP Related Compound
C

CAT No.

: KMF043009

CAS No.

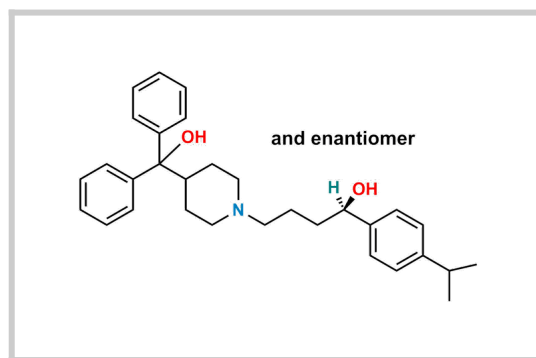
: 185066-37-9

Molecular Formula

: C31H39NO2

Molecular Weight

: 457.7



Analytical Information

Batch No.

: F043009-102

Solubility

: Methanol

Description

: Off white solid

Mass

: Confirm

HPLC Purity

: NLT 95.1 %

IR

: Confirm

Weight Loss By TGA

: NLT 0.1 %

¹H NMR

: Confirm

% Potency

: 95 %

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 [95.1(HPLC Purity)]/100 = 95 %

Recommendation

: Released

	Department	Name	Signature	Date
Prepared By	Analytical			
Reviewed & Approved By	Quality Control			

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