

CERTIFICATE OF ANALYSIS

(Certificate No. KMF004013-01)

Release Date: 28/09/2024

Re-test Date: 27/09/2027

FULVESTRANT EXTENDED IMPURITY C

Identification

Chemical Name :

7ξ-[9-[[9-[(4,4,5,5,5-pentafluoropentyl)sulfinyl]nonyl]sulfinyl]nonyl]estra-1,3,5(10)-triene-3,17β-diol (as per EP) ; Estra-1,3,5(10)-triene-3,17-diol,7-{9-[9-[(4,4,5,5,5-pentafluoro pentyl)sulfinyl]nonylsulfinyl]nonyl}-(7α,17β) (as per USP)

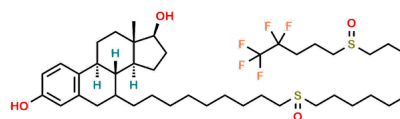
Alt. Name : Fulvestrant Extended

CAT No. : KMF004013

CAS No. : 2482852-42-4

Molecular Formula : C41H65F5O4S2

Molecular Weight : 781.1



Analytical Information

Batch No. : F004013-073-391

Solubility : Methanol

Description : Light Yellow Hygroscopic Semi Solid

Mass : Confirm

HPLC Purity : 98.47 %

IR : Confirm

Weight Loss By TGA : 0.26 %

1H NMR : Confirm

% Potency : 98.21 %

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 - 0.26(Weight Loss By TGA)] x [98.47(HPLC Purity)]/100 = 98.21 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		30/09/2024
Reviewed & Approved By	Quality Control	Jatin Patel		30/09/2024

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