

# CERTIFICATE OF ANALYSIS

(Certificate No. KMD014038-01)

Release Date: 09/06/2026

Re-test Date: 08/06/2029

## Duloxetine Lactose Adduct Impurity

### Identification

**Chemical Name :**

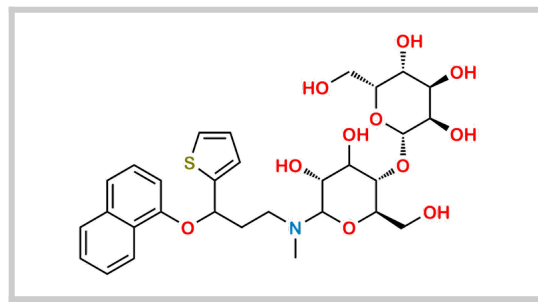
(2S,3R,4R,5R,6R)-2-(((2R,3S,5R)-4,5-Dihydroxy-2-(hydroxymethyl)-6-(methyl(3-(naphthalen-1-yloxy)-3-(thiophen-2-yl)propyl)amino)tetrahydro-2H-pyran-3-yl)oxy)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol

CAT No. : KMD014038

CAS No. : Not Available

Molecular Formula : C30H39NO11S

Molecular Weight : 621.7



### Analytical Information

Batch No. : D014038-136-006

Description : Light Yellow Solid

HPLC Purity : 98.43 %

Weight Loss By TGA : 2.55 %

% Potency : 95.92 %

Solubility : ACN : WATER (1:1)

Mass : Confirm

IR : Confirm

<sup>1</sup>H 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 - 2.55(Weight Loss By TGA)] x [98.43(HPLC Purity)]/100 = 95.92 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		09/06/2026
Reviewed & Approved By	Quality Control	Jatin Patel		09/06/2026

Attachments : COA, HPLC, MASS, <sup>1</sup>H NMR, IR and TGA