

# CERTIFICATE OF ANALYSIS

(Certificate No. KMQ001047-01)

Release Date: 21/07/2025

Re-test Date: 20/07/2028

## Quetiapine Impurity N

### Identification

**Chemical Name :**

2-[2-[4-[2-[2-[4-(Dibenzo[b,f][1,4]thiazepin-11-yl)piperazin-1-yl]ethoxy]ethyl]piperazin-1-yl]ethoxy]ethanol  
(as per EP)

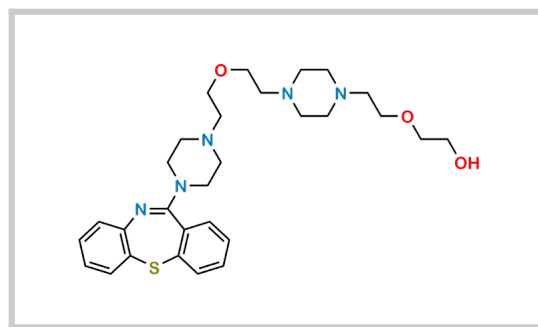
**Alt. Name** : Quetiapine Dipiperazine Diether  
Impurity

**CAT No.** : KMQ001047

**CAS No.** : 1800291-86-4

**Molecular Formula** : C29H41N5O3S

**Molecular Weight** : 539.7



### Analytical Information

**Batch No.** : Q001047-102-135

**Description** : Light Yellow Thick Syrup

**HPLC Purity** : 98.04 %

**Weight Loss By TGA** : 2.46 %

**% Potency** : 95.63 %

**Solubility** : Acetonitrile

**Mass** : Confirm

**IR** : Confirm

**<sup>1</sup>H NMR** : Confirm

**<sup>13</sup>C NMR** : Confirm

### Additional Information

**Long Term Storage** : Store at Ambient temperature for long term storage

**Shipping Condition** : Product is stable to be Shipped at Room Temperature

**% Potency** =  $[100 - 2.46(\text{Weight Loss By TGA})] \times [98.04(\text{HPLC Purity})]/100 = 95.63 \%$

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		25/07/2025
Reviewed & Approved By	Quality Control	Jatin Patel		25/07/2025

**Attachments** : COA, HPLC, MASS, <sup>1</sup>HNMR, <sup>13</sup>CNMR, IR and TGA