

## CERTIFICATE OF ANALYSIS

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## 1. Identification

Catalogue D288740 Number:

N-Des[2-(2-hydroxyethoxy)ethyl]

Product: Quetiapine Dihydrochloride

Structure:

2 HCI

CAS

111974-74-4 Number:

**Synonym:** 11-(1-Piperazinyl)-dibenzo[b,f][1,4]thiazepine

Dihydrochloride; DBTP; Norquetiapine;

Quetiapine EP Impurity B;

Molecular Formula:

C17H17N3S • 2HCl

Molecular weight:

295.4 + 2(36.46)

Source of Product:

N/A

Solubility:

DMSO (Slightly, Heated, Sonicated), Ethanol (Slightly, Heated), Methanol (Slight

**Purity:** 98%

Storage

Condition: -20°C

Lot

11-QIU-194-1 Number:

This Product Is Stable To Be Shipping Condition: Shipped At Room Temperature

2. Warning

Warning 1: Warning 2: Warning 3:

3. Analytical Information

Tests: Specifications: Results:

White to Pale Yellow Solid White to Off-White Solid **Appearance** 

**NMR** Conforms to Structure Conforms

%C: 53.91, %H: 5.58, %N: 11.05 Elemental Analysis Conforms

MS Conforms to Structure Conforms Chloride Content Report Result 19.5%

Water Content Report Result 4.7% by Karl Fischer **HPLC Purity** Report Result 99.65% (210 nm)

**Additional Information:** N/A

Purity is based on the analytical results of the tests performed. NMR and Elemental Analysis (if available) may have an accuracy of ± 2%. Isotopic purity is based on mass distribution observed. The contents of the specifications are subject to change without advance notice, and the specification values displayed here are the most up to date values.

4. Signatures

C of A Approved **Reviewed By Reviewed By Test Date Retest Date** By

**Evan Burns** Toni Rantanen Chanell Chu 8/26/2021 8/24/2025

Evan Burns