



## Certificate of Analysis

Product: **Quetiapine Oral Suspension 20mg/mL**

Lot Number: **1014201**

Licence: **PL00427/0240**

Chemistry Method Reference: **MFC-000092 V 2.0 (C6FAB)**

Test	Result	Comparative result (Units)
Description: off white suspension	Complies	Complies
Weight/mL	<b>1.042</b>	g/ml
pH	<b>5.4</b>	---
Assay of Quetiapine	<b>98.8</b>	%
Identification of Quetiapine (by UV & RT)	Complies	Complies
Assay of Methyl Hydroxybenzoate	<b>98.4</b>	%
Assay of Propyl Hydroxybenzoate	<b>98.4</b>	%
Identification of Methyl and Propyl Hydroxybenzoate (by RT)	Complies	Complies
Impurity G	<b>0.00</b>	%
Impurity B	<b>0.00</b>	%
Specified Unknown Degradation Product Unknown 1	<b>0.00</b>	%
Specified Unknown Degradation Product Unknown 2	<b>0.00</b>	%
Unknown degradants (each)	<b>0.00</b>	%
Total known and unknown degradants	<b>0.0</b>	%
Content Uniformity	Complies	Complies
Uniformity of mass of delivered dose	Complies	Complies
Viscosity	<b>1634</b>	cPs
Dissolution	<b>98</b>	%

### Comments and other tests:

Complies with Ph Eur chapter 5.1.4 – Microbiological Quality of Non - Sterile Pharmaceutical Preparations & Substances for Pharmaceutical Use

**CONCLUSION:** The product **Complies** with respect to the stated specification

**Date of Manufacture:** MAY/2024

**Date of Expiry:** MAY/2026

**Analyst(s)** R Manju J Laing

**Checked:** L Thornton – Sign and Date: LT 27 JUN 2024

**Approved for release:** [Signature]  
**H Pearson: QC Release and Compliance Officer**

**Date:** 27 Jun 2024

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