



Certificate of Analysis

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

Lot Number: **1014555**

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	1.042	g/ml
pH	5.5	---
Assay of Quetiapine	97.3	%
Identification of Quetiapine (by UV & RT)	Complies	Complies
Assay of Methyl Hydroxybenzoate	97.5	%
Assay of Propyl Hydroxybenzoate	97.2	%
Identification of Methyl and Propyl Hydroxybenzoate (by RT)	Complies	Complies
Impurity G	0.00	%
Impurity B	0.00	%
Specified Unknown Degradation Product Unknown 1	0.00	%
Specified Unknown Degradation Product Unknown 2	0.00	%
Unknown degradants (each)	0.00	%
Total known and unknown degradants	0.0	%
Content Uniformity	Complies	Complies
Uniformity of mass of delivered dose	Complies	Complies
Viscosity	1442	cP
Dissolution	93	%

Comments and other tests:

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

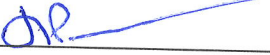
CONCLUSION: The product Complies with respect to the stated specification

Date of Manufacture: Aug/2024

Date of Expiry: Aug/2026

Analyst(s) M Raval S Kelemen

Checked: L Thornton – Sign and Date:  10 SEP 2024

Approved for release: 
H Pearson: QC Release and Compliance Officer

Date: 11-Sep-2024

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