



Certificate of Analysis

Product: Quetiapine Oral Suspension 20mg/mL

Lot Number: 1014311

Licence: 9103/DEC2023

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	5.4	---
Assay of Quetiapine	98.8	%
Identification of Quetiapine (by UV & RT)	Complies	Complies
Assay of Methyl Hydroxybenzoate	98.4	%
Assay of Propyl Hydroxybenzoate	98.4	%
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	1634	cP
Dissolution	98	%

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: pp Pearson 27 JUN 2024

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

Date: 27 Jun 2024

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