NIFTY LABS
PRIVATE LIMITED
(USFDA, EUGMP, MFDS, WHO-GMP)

CERTIFICATE OF ANALYSIS

Product Name : QUETIAPINE FUMARATE	**Reference** : EP
Batch No. : FQ0010224	**Mfg. Date** : FEBRUARY 2024
Batch Quantity : 355.87 Kg	**Retest Date** : JANUARY 2027
A.R Number : FQP-0009/24	**Date of Analysis:** 24.02.2024

S. No	TESTS	SPECIFICATIONS	RESULTS
1.0	Description	A white or almost white powder.	White powder
2.0	Solubility	Slightly soluble in water, in ethanol and in methanol.	Complies
3.0	Identification by IR	The Infra Red absorption spectrum of the sample should exhibit maxima only at the same wavelengths as that of a similar preparation of Quetiapine fumarate Standard.	Complies
4.0	Related substances by UPLC Impurity-G Impurity-N Unspecified Impurity Total Impurities	 Not more than 0.15% Not more than 0.15% Not more than 0.10% Not more than 0.5%	 ND 0.09% 0.06% 0.19%
5.0	Loss on drying	Not more than 0.5%	0.20%
6.0	Sulphated Ash	Not more than 0.1%	0.05%
7.0	Assay (On dried substance)	99.0% to 101.0%	100.4%
8.0	Fumaric acid	12.5% to 13.8%	13.0%
9.0	Residual Solvents by GC Methanol Ethanol Acetone Toluene	 Not more than 3000 ppm Not more than 5000 ppm Not more than 5000 ppm Not more than 890 ppm	 ND ND ND 62 ppm

Note: The product **Conforms** to the above specifications.
The product is non-sterile bulk.

Description	Prepared by	Reviewed by	Authorized by
Department	Quality Control	Quality Control	Quality Control
Designation	Sr. Executive	DGM	GM
Signature			
Date	30/09/24	30/09/24	30/09/24

Form No: F-01-03-NQC025