

RAMPEX LABS PVT. LTD., UNIT-2

24/02/2022

RAMPEX

CERTIFICATE OF ANALYSIS

Head Office: Plot No: 151, S.V.Co.Operative Industrial. Estate, Village Road, IDA-
Bollaram Sangareddy District, Telangana, India-502325

Phone: +91 8458279684, +91 9618020099 and +91 8886058585

Web: www.rampexlabs.com

Product	: OLANZAPINE	Customer Name	: Lakshmi farmachem Pvt. Ltd
Batch No.	: LAN/0030122	AR No.	: QC/FP/012/22
Quantity	: 10.0 Kg	Date of Mfg.	: January, 2022
Reference	: USP	Expiry/Re-test date	: December, 2026

Storage condition: Preserve in well closed containers and store at room temperature.

S.No.	Test	Specifications	Results
1.	Description	Yellow crystalline solid	Yellow crystalline solid
2.	Solubility	Soluble in n-propanol, sparingly soluble in Acetonitrile. Slightly soluble in methanol and dehydrated alcohol. Practically insoluble in water.	Complies
3.	Identification		
	By IR	IR absorption spectrum of test sample should corresponds to that of working standard.	Complies
	By HPLC	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation.	Complies
4.	Water content (% w/w)	Not more than 1.0	0.52
5.	Residue on ignition (% w/w)	Not more than 0.1	0.05

Approvals	Compiled by	Reviewed by	Approved by
Name	K.V.D.N. Rao	B. SAMBASIVARAO	D. Nagaraju
Designation & Dept.	Asst. Manager-QC	Manager-Q.C	DAM-QA
Sign & Date	<i>[Signature]</i> 27/03/2022	<i>[Signature]</i> 27/03/2022	<i>[Signature]</i> 27/03/2022

F-QC/SOP/016/01-07 & Effective date: 16/09/2021

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Works: Unit-2, Plot No: 34C, J.N. Pharmacy, Parawada Visakhapatnam, Andhra Pradesh

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Storage condition: Preserve in well closed containers and store at room temperature.

S.No.	Test	Specifications	Results
6.	Organic impurities by HPLC (%w/w)		
	a. Related compound-A	Not more than 0.10	Not detected
	b. Related compound-B	Not more than 0.10	0.01
	c. Chloromethyl Olanzapinium chloride (If present)	Not more than 0.15	Not detected
	d. Any individual unspecified Impurity	Not more than 0.10	0.02
	e. Total impurities	Not more than 0.4	0.03
7.	Assay (on anhydrous basis and solvent free basis (%w/w))	NLT 98.0 to NMT 102.0	100.3
8.	Additional tests		
8.1	Residual solvents by GC (ppm)		
	Methanol	Not more than 2000	81

Approvals	Compiled by	Reviewed by	Approved by
Name	K.V.D.N. Rao	B. SAMBASIVA RAO	D. Nagaraju
Designation & Dept.	Asst. Manager-QC	Manager-Q.C	QA M-QA
Sign & Date	<i>[Signature]</i> 17/03/2022	<i>[Signature]</i> 17/03/2022	<i>[Signature]</i> 23/03/2022

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Works: Unit-2, Plot No: 34C, J.N. Pharmacy Parawada, Visakhapatnam, A.P.

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S.No.	Test	Specifications	Results
	Acetone	Not more than 200	134
	Iso propyl alcohol	Not more than 100	Not detected
	1,4-Dioxane	Not more than 100	Not detected
	Toluene	Not more than 100	Not detected
	Dimethyl formamide	Not more than 100	Not detected
9.	Particle size (μ m) (In-House)		
	D (0.9)	Not more than 100	64.815

Remarks: The product conforms to above specifications

PO NO : PO220611
DATE : 24/02/2022
LC NO : MI62322000088
ISSUANCE DT : 17/03/2022

Approvals	Compiled by	Reviewed by	Approved by
Name	K.V.D.N. Rao	B. SAMBASIVARAO	D. Nagaraju
Designation & Dept.	Asst. Manager - Q.C.	Manager - Q.C.	DQM - QA
Sign & Date	17/03/2022	17/03/2022	23/03/2022

F-QC/SOP/016/01-07 & Effective date: 16/09/2021

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