



SWAPNROOP DRUGS & PHARMACEUTICALS

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CERTIFICATE OF ANALYSIS

Product Name	Amoxapine	CAS No:	14028-44-5
Batch No.	2605001	Manufactured by	Swapnroop Drugs & Pharmaceuticals
Date of Mfg.	MAY-2026	Date of Analysis	20/05/2026
Batch Quantity	-	Retest Date	APR-2031

Sr No	Test	Acceptance Criteria	Results
1	Description	White to yellowish crystalline powder.	Off-white crystalline powder.
2	Solubility	Freely soluble in chloroform, soluble in Tetrahydrofuran. Sparingly soluble in Methanol and in toluene. Slightly soluble in acetone. Practically insoluble in water.	Complies
3	Identification – By IR	The IR spectrum of sample should match with the IR spectrum of working standard	Complies
4	Identification – By HPLC	Retention time of major peak of the sample solution should corresponds to that of Standard solution as obtained in the Assay test by HPLC.	Complies
5	LOSS ON DRYING	NMT 0.5%	0.28%
6	RESIDUE ON IGNITION	NMT 0.1%	0.08%
7	ORGANIC IMPURITIES BY HPLC Chlorophenoxyaniline urea analog	NMT 0.10%	ND
8	ORGANIC IMPURITIES BY HPLC Amoxapine related compound G	NMT 0.15%.	0.065%
9	ORGANIC IMPURITIES BY HPLC Amoxapine related compound D	NMT 0.15%.	ND
10	ORGANIC IMPURITIES BY HPLC Chlorophenoxyaniline	NMT 0.10%	ND
11	ORGANIC IMPURITIES BY HPLC Chlorophenoxyaniline carbamate	NMT 0.10%	ND
12	ORGANIC IMPURITIES BY HPLC N-Carbamoyl amoxapine	NMT 0.10%.	ND
13	ORGANIC IMPURITIES BY HPLC Amoxapine dimer	NMT 0.10%.	ND
14	ORGANIC IMPURITIES BY HPLC Single individual impurity	NMT 0.10%.	0.074%
15	ORGANIC IMPURITIES BY HPLC Total impurities	NMT 0.50%	0.18%

Sr No	Test	Acceptance Criteria	Results
16	ASSAY BY HPLC	98.0% to 102.0% (On dried basis).	99.7%
17	PIPERAZINE CONTENT BY TLC	Should be not detected.	Complies
18	RESIDUAL SOLVENT BY GC Methanol	NMT 3000ppm	184ppm
19	RESIDUAL SOLVENT BY GC Acetone	NMT 5000ppm.	139ppm
20	RESIDUAL SOLVENT BY GC Methylene chloride	NMT 600ppm	ND
21	RESIDUAL SOLVENT BY GC Toluene	NMT 890ppm.	159ppm
22	MICROBIAL ANALYSIS Total microbial count	NMT 100CFU/gm	08 CFU/gm.
23	MICROBIAL ANALYSIS Total fungal count	NMT 10CFU/gm.	00 CFU/gm.
24	MICROBIAL ANALYSIS Escherichia coli	Should be absent	Absent
25	MICROBIAL ANALYSIS Salmonella spp.	Should be absent	Absent
26	MICROBIAL ANALYSIS Pseudomonas aeruginosa	Should be absent	Absent
27	MICROBIAL ANALYSIS Staphylococcus aureus	Should be absent	Absent

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By  Sonali Nirmal Date: 23/05/2026	Checked by  Dadarao Kakde Date: 23/05/2026	Approved By  Nayna Nehete Date: 23/05/2026 
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