



SWAPNROOP DRUGS & PHARMACEUTICALS

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CERTIFICATE OF ANALYSIS

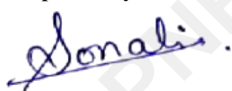
Product Name	Trazodone Hydrochloride USP	CAS No:	25332-39-2
Batch No.	2605001	Manufactured by	Swapnroop Drugs & Pharmaceuticals
Date of Mfg.	MAY-2026	Date of Analysis	20/05/2026
Batch Quantity	-	Retest Date	APR-2031

Sr No	Test	Acceptance Criteria	Results
1	Description	White to off-white crystalline powder.	Off white crystalline powder
2	Solubility	Sparingly soluble in chloroform and water.	Complies
3	Identification – By IR	The IR spectrum of the sample should compare with the IR of the working/reference standard of Trazodone Hydrochloride.	Complies
4	Identification – By HPLC	The retention of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay by HPLC.	Complies
5	Melting Point (°C)	Between 231°C-234°C	232.2°C
6	Loss on drying (% w/w)	Not more than 0.5%	0.3%
7	Residue on Ignition (% w/w)	Not more than 0.2%	0.03%
8	Organic Impurities by HPLC (% w/w) a) Triazolopyridinone	Not more than 0.10%	Not Detected
9	Organic Impurities by HPLC (% w/w) b) Trazodone N-oxide	Not more than 0.1%	Not Detected
10	Organic Impurities by HPLC (% w/w) c) Deschloro Trazodone	Not more than 0.1%	Not Detected
11	Organic Impurities by HPLC (% w/w) d) Trazodone Related Compound-C	Not more than 0.1%	Not Detected
12	Organic Impurities by HPLC (% w/w) e) Trazodone Related Compound-D	Not more than 0.1%	Not Detected
13	Organic Impurities by HPLC (% w/w) f) 4-Ethyl Trazodone	Not more than 0.1%	Not Detected
14	Organic Impurities by HPLC (% w/w) g) Trazodone isobutyl ether analog	Not more than 0.1%	Not Detected

Sr No	Test	Acceptance Criteria	Results
15	Organic Impurities by HPLC (% w/w) h) Bisperazine analog	Not more than 0.1%	Not Detected
16	Organic Impurities by HPLC (% w/w) i) Any Individual unspecified impurity	Not more than 0.10%	0.0001
17	Organic Impurities by HPLC (% w/w) j) Total impurities	Not more than 1.0%	0.0001
18	Limit of Trazodone Related compound -F and Cyclophosphamide Related compound -A	not more than 2.5 µg/g	Complies
19	Assay by HPLC (% W/W) (On dried basis)	Not less than 98.0% and not more than 102.0%	99.9%
20	Residual solvent by GC-HS (ppm) a) Acetone	Not more than 5000 ppm	Not Detected
21	Residual solvent by GC-HS (ppm) b) Toluene	Not more than 890 ppm	Not Detected
22	Residual solvent by GC-HS (ppm) c) 2-Propanol	Not more than 5000 ppm	Not Detected
23	Residual solvent by GC-HS (ppm) d) Ethyl Acetate	Not more than 5000 ppm	Not Detected
24	Residual solvent by GC-HS (ppm) e) Di isopropyl ether	Not more than 1000 ppm	Not Detected

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By  Sonali Nirmal Date:	Checked by  Dadarao Kakde Date:	Approved By  Nayna Nehete Date:
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