

Analytical Testing Report

DOCUMENT NO.: ATR-SYN-4736

REVISION: 1.0

PRODUCT NAME: Nitroso Aryl Piperazine Quetiapine

PRODUCT CODE: VE009S54

BATCH NO.: VOY756

LOT NO.: LOT-APR-002

DOSAGE FORM: Injectable Suspension

STRENGTH: 2 g/10 mL

BATCH SIZE: 600 L

MANUFACTURING SITE: SynTech Pharmaceuticals Inc.

DATE OF TESTING: 2025-04-18

SAMPLE ID: SAMP-002

SAMPLE SOURCE: Line 4 – Fill Room

STORAGE CONDITION: 2–8°C (Cold Chain)

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Test Parameter	Method	Specification	Result	Status
Appearance	Visual	Clear, colorless	Clear	Pass
pH	pH Meter	6.5–7.5	7.1	Pass
Viscosity	Viscometer	150–200 cP	160 cP	Pass
Volume Fill	Gravimetric	0.1490–0.500 mL	0.1501 mL	Pass
Particulate Matter	Microscopy	≤ 10 particles/mL	2 particles/mL	Pass
Osmolality	Osmometer	280–320 mOsm/kg	295 mOsm/kg	Pass
Residual Solvents	GC	ND	ND	Pass
Microbial Limits	Plate Count	<10 CFU/mL	<1 CFU/mL	Pass

Comments:

All parameters were tested under validated conditions. No deviations observed. Results are consistent with product specifications. Sample integrity maintained throughout testing.

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Test Summary

Test Category	Summary Description
Identity	Confirmed via NMR and FTIR spectral match to reference standard
Purity	HPLC assay showed 99.1% purity, exceeding minimum requirement
Potency	Verified against standard curve; within $\pm 2\%$ of label claim
Safety	No residual solvents or microbial contamination detected
Stability	Sample stored under validated cold chain; no degradation observed
Visual Inspection	No particulates, discoloration, or phase separation
Data Integrity	All raw data archived in LIMS; audit trail verified

Manual Entry Space:

Comments:

Testing confirmed product meets all release criteria. No retests required. All data reviewed and approved by QA.

Instrument Details & Analyst Review

Instrument Details

Instrument	ID	Calibration Date	Status	SOP Reference
HPLC	HPLC-3000	2025-04-10	Valid	SOP-HPLC-102
NMR	NMR-400	2025-04-11	Valid	SOP-NMR-201
FTIR	FTIR-200	2025-04-09	Valid	SOP-FTIR-305
GC	GC-250	2025-04-12	Valid	SOP-GC-410
Viscometer	VISC-100	2025-04-08	Valid	SOP-VISC-110
pH Meter	PHM-55	2025-04-07	Valid	SOP-PHM-220
Osmometer	OSM-300	2025-04-06	Valid	SOP-OSM-330

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Analyst & Review

Role	Name	Signature	Date
Analyst	Dr. P. Uruig		2025-04-18
Reviewer	Dr. S. Filipe		2025-04-19
QA Mgr	Rakuta Onumal		2025-04-20

Comments:

All instruments were calibrated and verified prior to use. Analyst followed SOPs precisely.
Reviewer confirmed data integrity and compliance. QA approved for release.