Sandpiper Pharma

Small Molecule Lyophilized Drug Product Specification

Test	Method	Purpose*	Acceptance
Appearance	Visual Inspection	R, S	Consistency with DP appearance prior to reconstitution
Appearance	Visual Inspection	R, S	Consistency with DP appearance following reconstitution
Identification	FT-IR	R	Consistency with reference spectrum
Identification	HPLC	R	Relative retention time of 0.980 to 1.020
Assay	HPLC	R, S	Target ± 10%.
Impurities	HPLC	R, S	Specified impurities: ≤ 0.5% Other impurities: ≤ 0.5% Total impurities: ≤ 2.0%
Uniformity of Dosage	USP <905>	R	L1 =15.0; L2 = 25.0
Visible Particles	USP <790>	R	Absence of particles of foreign matter following 100% visible inspection of manufactured vials; solution is essential free from particles or foreign matter following reconstitution
Subvisible Particles	USP <788>	R, S	Meets specifications on particles ≥ 25 µm and ≥ 10 µm
Residual Solvents	Headspace GC	R	Based on ICH guideline Q3C on impurities: guideline for residual solvents
Elemental Impurities	ICP-MS	R	Based on ICH guideline Q3D on elemental impurities; see also USP 232/233
Water Content	USP <921>	R, S	Report; develop data to establish acceptance criterion
Sterility	USP <71>	R, S	Sterile
Endotoxin	USP <85>	R	Based on ICH guideline Q4B on Bacterial Endotoxins Tests
pH	USP <791>	R, S	Following reconstitution; within acceptance range, typically target ± 2 pH units initially
Reconstitution Time	USP <1>	R, S	Less than target

Storage Condition	Temperature	N/A	Varies; selected to ensure long shelf life; typically room temperature, 5°C, or -20°C
Storage Container	Vial	N/A	N/A

* R = Release; S = Stability