Sandpiper Pharma

Small Molecule Drug Substance Specification

Test	Method	Purpose*	Acceptance
Appearance	Visual Inspection	R, S	Consistency with DS appearance
Identification	FT-IR	R	Consistency with reference spectrum
Identification	HPLC	R	Relative retention time of 0.980 to 1.020
Assay	HPLC	R, S	95.0% to 105.0%
Impurities	HPLC	R, S	Specified impurities: ≤ 0.5% Other impurities: ≤ 0.5% Total impurities: ≤ 2.0%
Chiral Purity	Chiral HPLC or SFC	R, S	Typically, ≥ 98.0%; chiral impurities must be controlled
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
Residue On Ignition	USP <281>	R, S	Consistent with drug substance
Water Content	USP <921>	R, S	Report; develop data to establish acceptance criterion
Polymorph	XRPD	R, S	Consistent with desired form
Bioburden	USP <61>	R, S	Based on EMA Guideline on the sterilisation of the medicinal product, active substance, excipient and primary container
Endotoxin	USP <85>	R	Based on ICH guideline Q4B on Bacterial Endotoxins Tests
Storage Condition	Temperature	N/A	Varies; selected to ensure long shelf life; typically, room temperature, 5°C, or -20°C
Storage Container	Multilayer Bag	N/A	N/A

* R = Release; S = Stability