Sandpiper Pharma

Antibody Drug Product Specification

Test	Method	Purpose*	Acceptance
Appearance	Visual Inspection	R, S	Consistency with DS appearance
Identity	Peptide Map	R	Consistency of retention times and masses of monitored peaks in sample compared to those in reference standard.
Identity and Impurities	cIEF	R, S	pI of main peak compares to reference standard; report pI and areas of additional peaks
Titer	Absorbance at 280 nm	R, S	Within acceptance range, typically, target ± 10% initially
Potency	Bioassay	R, S	Within acceptance range, typically, 100% ± 50% initially
Purity	RP-HPLC	R	Initially, report results only
Purity	CEC	R	Initially, report results only
Impurities	Reduced SDS-PAGE	R, S	2 major bands at same positions as reference standard; report weight of other bands observed
Impurities	Non-reduced SDS-PAGE	R, S	1 major band at same position as reference standard; report weight of other bands observed
Aggregation	SE-HPLC	R, S	Main peak typically ≥ 95.0% initially; aggregates < 5.0%
Subvisible Particles	HIAC	R, S	Limits on particles ≥ 10 µm and ≥ 25 µm
Endotoxin	USP <85>	R	Limit on EU/ml
Sterility	USP <71>	R, S	No growth
pH	USP <791>	R, S	Typically, within 0.2 pH units of target pH
Osmolality	Osmometer	R	Within acceptance range, typically target ± 50 mOsm/kg initially
Volume	USP <1>	R	Not less than target volume
Storage Condition	Temperature	N/A	Varies; selected to ensure long shelf life; typically, 5°C

Storage Container	Vial or Pre-Filled Syringe	N/A	N/A

* R = Release; S = Stability