



## Sandpiper Pharma

### Antibody Drug Substance Specification

Test	Method	Purpose*	Acceptance
Appearance	Visual Inspection	R, S	Consistency with DS appearance
Identity and Impurities	Reduced SDS-PAGE	R, S	2 major bands at same positions as reference standard; report weight of other bands observed
Identity and Impurities	Non-reduced SDS-PAGE	R, S	1 major band at same position as reference standard; report weight of other bands observed
Identity	Glycan Pattern	R, S	Initially, report results only
Potency	Titer by A280	R, S	Within acceptance range, typically, target $\pm$ 10% initially
Potency	Bioassay	R, S	Within acceptance range, typically, 100% $\pm$ 50% initially
Potency	Fc-ELISA	R	Within acceptance range, typically, target $\pm$ 40% initially
Potency	Fab-ELISA	R	Within acceptance range, typically, target $\pm$ 40% initially
Identity and Impurities	HIC-HPLC	R, S	Consistency of retention time with reference standard; no additional peaks.
Impurities	HCP-ELISA	R	Less than target
Impurities	rDNA	R	Less than target
Impurities	Protein A ELISA	R	Less than target
Impurities	Mycoplasma	R	Performed on harvest material prior to purification; no contamination
Impurities	In Vitro Viral	R	Performed on harvest material prior to purification; no contamination
Impurities	In Vivo Viral	R	Performed on harvest material prior to purification; no contamination
Aggregation	SE-HPLC	R, S	Main peak typically $\geq$ 95.0% initially; aggregates < 5.0%
Endotoxin	USP <85>	R	Limit on EU/ml
Bioburden	USP <61>	R, S	Less than CFU limit
pH	USP <791>	R, S	Typically, within 0.2 pH units of target pH

Conductivity	Conductivity Meter	R	Within acceptance range, typically target $\pm 20\%$ initially
Osmolality	Osmometer	R	Within acceptance range, typically target $\pm 50$ mOsm/kg initially
Storage Condition	Temperature	N/A	Varies; selected to ensure long shelf life; typically $-20^{\circ}\text{C}$ ; occasionally $-80^{\circ}\text{C}$
Storage Container	Multilayer Bag	N/A	N/A

\* R = Release; S = Stability