

Category	Test Identification	Acceptance criteria
Sterility	Aerobic culture	Negative
	Anaerobic culture	Negative
	Endotoxin (limulus ameocyte lysate)	<2 EU/mL
Purity	Residual moisture	<2%
Potency	Thrombin Generation Assay (Thrombinoscope)	Peak height 46-105nm
Identity	Flow cytometry	Annexin V 87-100%
		CD61 83-100%
Strength	Automated cell count	> 1.5 x 10 ⁹ particles/mL