Manufacturing step	Process stage	Critical control parameters	In-process controls	Key process parameters	Key process controls	Supporting documents
Site cleaning and preparation	Premises; equipment; utilities; documents.	Pressure difference; airborne particles.	Conductivity; total organic carbon; endotoxin; bioburden control.	Temperature; humidity.	µS/cm limit; TOC limit; cfu limit; particle limit.	Monitoring records (temperature, humidity); equipment cleaning, sanitization, sterilization; cleaning schedules, sanitation records, identification labels; pest control.
Raw materials	Controlled environment; cleaning, weighing, and documentation.	Quantity conformance.	Material weight.	Surface clearance.	Material weight; cfu limit; pest absence.	Weight records; cleaning records; cleaning schedules, sanitation records, identification labels; pest control.
Intermediate production	Stage 1. Lactic acid pretreatment.	Temperature; pressure.	Assay.	Temperature; volume.	Concentra-tion; racemization.	Sampling plans; laboratory tests; quality standard justification documents; humidity and temperature records; batch records;
	Stage 2. Pre-polymerization reaction.	Temperature.	Concentra-tion.	Pressure; volume.	Yield.	

	Stage 3.1. Depolymerization reaction compounding.	Temperature; pressure; weight.	None.	Stirrer velocity; volume.	Time.	control charts; equipment logs; cleaning records.
	Stage 3.2. Depolymerization reaction process.	Temperature.	Composition.	Pressure; volume.	Depolymerization yield.	
Isolation, purification	Stage 4. Lactide purification.	Temperature; pressure.	Assay; composition; impurities; microbiology.	Volume.	Separation quality; CFU limit; pathogen absence.	
	Stage 5. Polymerization reaction.	Temperature; weight.	Molecular weight; assay; impurities.	Volume; pressure; stirrer velocity.	Purity.	
Physical processing	Stage 6. Devolatilization.	Temperature; vacuum; time.	Drying; impurities.	Yield.		
	Stage 7. Milling.	Intensity.	Size; microbiology.	Size.		
Packaging, labeling	Stage 8. Packaging.	Labeling velocity.	Label and package quantity.	Clarity.	Waste and cross-contamination control.	Sampling plans; laboratory tests.