Table 1: Typical potential critical process parameters

Process Step	Equipment Type (Examples)	Potential Critical Process Parameters[a]	Potential Critical Attributes
Milling (particle size reduction)- Ref (2)	Oscillator (Frewitt) Screening mills/Cone mill (e.g. Comil) Impact/Hammer mill (e.g., Frewitt, Fitzpatrick)	• Impeller used & RPM • Screen size • Pressure • Temperature • Position- knives/hammer • Feeder speed • Gap for impeller	• Bulk density • Particle size distribution • De-agglomeration
	Separators (e.g. Russell Finex, Sweco)	• Vibrations setting • Screen size • Feeder speed	
Mixing- Convection[a] (low shear; No homogenization required)	Anchor/Sweep (e.g., Ross, FrymaKoruma, Lee, GEI, Waukesha Cherry)	• Mixing time • Type Blades, Sweep • Blade position • Anchor Speed • Pumping characteristics • Jacket (temperatures/heat transfer properties) • Heating and cooling rates • Temperature uniformity • Congealing temp/rate • Vacuum (if applicable) • Tank/kettle shape (e.g. bottom) • Order and method of addition	• Homogeneity, potency (active, preservative) • Viscosity • Density or specific volume • Appearance • Microbial quality (microbial limits, sterility, as applicable)
	Panetary Mixer (AMF, Hobart, Littleford Day)	• Mixing time • Type Blades • Mixer Speed • Order of addition • Similar to Anchor/sweep	
	Impeller (Lightnin, Ross)	• Mixing time • Type, angle, location of Blade • Mixer Speed • Order/Rate of addition- (Vortex) • Similar to Anchor/Sweep	

