

TABLE 23.8
List of Quality Attributes and Potential Process Parameters for a Wet Granulation Process

Process Step	Product Quality Attributes	Measure (Units)	Process Parameter (Variables)	Rationale
1. Blending	Blend uniformity	Analytical technique (% rsd)	Blender rpm	Impacts final drug product quality
	Potency	% theory	Time/revolution	
	Yield	kg	Order of addition	
	Specific volume	cc/g	Load size	
2. Milling	Particle size distribution	Sieve analysis (size)	Milling speed	Impacts dissolution and downstream processing; process understanding
	Yield	Loose density	Screen size	
	Specific volume	Tap density	Screen type	
	Appearance	kg cc/g Visual	Feed rate	
3. Granulation	Blend uniformity	Analytical technique (% rsd)	Granulating liquid addition rate, mix load	Impacts final drug product quality
	Specific volume	cc/g	Wet mass time	
	Particle size distribution	d50, d90, etc.	Quantity of granulating agent	
	Surface area	m ² /g	Impeller rpm	
	Yield	kg	Chopper speed	
4. Drying	Density	Density	Load size	Impacts final drug product quality and downstream processing
	Drying endpoint	Moisture content (% LOD)	Initial temperature	
	Throughput	Yield (kg)/unit time	Drying cycle profile	
	Granule flow	% rsd	Air flow/humidity	
	Segregation index	kg	Drying time	
	Yield	P-XRD	Cooling time	
5. Milling	Particle size distribution	Sieve analysis (size)	Milling speed	Impacts dissolution and downstream processing; process understanding
	Mill choking	Loose density	Screen size	
	Yield	Tap density	Screen type	
	Blend uniformity	Buildup kg Analytical technique (% rsd)	Feed rate Blender rpm	
6. Blending	Potency	% theory	Time/revolution	Impacts final drug product quality
	Yield	kg	Order of addition	
	Specific volume	cc/g	Load size	
7. Lubrication	Blend uniformity	Analytical technique (% rsd)	Blender rpm	Impacts final drug product quality
	Potency	% theory	Time/revolution	
	Yield	kg	Order of addition	
8. Compression	Specific volume	cc/g	Load size	Impacts final drug product quality
	Powder flow			
	Hardness	Tablet hardness tester (kp/KN)	Precompression force or thickness	
	Weight variation	Scale (mg)	Compression force or thickness	
	Friability	%	Granule feed rate	
Thickness	Inches	Penetration depth		
Disintegration	Time	Compression speed		
Dissolution	USP %Q in minutes			

(Continued)