




EMÜLSİYON VE SÜSPANSİYON KRİTİK ÜRETİM BASAMAKLARI

Table 5. Production Operations, Process Parameters and Quality Attributions for Emulsion Form (Revised from Lit. 31-33).

Pharmaceutical Operation	Sample Process Parameter	Potential Quality Attribute
Manufacturing	Granulator type and features	Humidity assignment
	Homogenizer features	Microbial limit
	Homogenization Process	Assay
	Duration	pH value
	Homogenizer rotation	Density
	Tank temperature	Viscosity
	Tank type and volume	Particle size and distribution
	Impeller type and localization	Appearance
	Feeding speed	Impurity
	Process temperatures	
	Cooling speed	
	Pumps and features	
	Rotor and stator clearance	
	Packing material cleaning machine criteria (bottle, etc.)	Appearance
Filling	Filling pumps and their features	Assay (Active ingredient and preservative if present)
		Filling weight/Volume uniformity
		Content uniformity
		pH
		Density
	Impurity	

Table 6. Production Operations, Process Parameters and Quality Attributes for Suspension Form (Revised from Lit. 32-34).

Pharmaceutical Operation	Sample Process Parameter	Potential Quality Attribute
Manufacture	Granulator type and features	Moisture determination
	Tank temperature	Content uniformity
	Tank type and volume	Microbial limit
	Impeller type and localization	Weight uniformity
	Product temperature	Dissolution profile
	Homogenizer features	Assay
	Homogenization process duration	pH value
	Homogenizer Rotation	Density
		Viscosity
		Particle size and distribution
		Sedimentation rate and speed
		Appearance
	Filtration	Filter type and size
Filter ΔP value		Assay (Active ingredient and preservative if present)
Integrity tests (Pre and post)		pH
Membrane filter capacity		Density
Filtration speed		Impurity
Secondary Filter and features		Microbial limit
Solution Viscosity		
Filtration duration		
Pumps and their features		
Filling	Bottle cleaning machines criteria	Appearance
	Filling pumps and their features	Assay (Active ingredient and preservative if present)
		pH
		Density
		Impurity
		Content uniformity
		Volume/Weight controls



THANK
YOU !