AMGEN®

Good manufacturing practice for large molecules and small molecule medicines

Large molecule

	Process		GMP requirements (Good Manufacturing Practice)
STEP 1	Cell line development	DNA - Cloning Transfection Select "best" cell	■ ■ ■
STEP 2	Cell expansion	Media pH, temp cell density	■ ■ ■
STEP 3	Cell culture	Bioreactor media pH, temperature	■ ■ ■
STEP 4	Harvest	Remove cells from product	■ ■ ■
STEP 5	Purification multiple steps	Remove impurities Highly selective resin Specific process conditions	■ ■ ■
STEP 6	Virus inactivation/removal	Dedicated steps to ensure virus killing or reduction	■ ■ ■
STEP 7	Filling	Filling method No human contact	■ ■ ■
STEP 8	Finishing	Lyophilization Syringe-fill	■ ■ ■
STEP 9	Packaging & storage	Controlled temperature Ensure no foaming No particles	
STEP 10	Quality assurance & characterization	Highly precise methods Reference standards	
STEP 11	Stability	Testing to ensure product remains stable through shelf life	

Small molecule

	Process		GMP requirements (Good Manufacturing Practice)
STEP 1	Reaction	Add ingredients pressure, temperaure	■
STEP 2	Weigh	Weigh API & inactive chemicals	■
STEP 3	Mix	Mixing speed, time	■
STEP 4	Compress (solid dosage) Filling (liquid dosage)	Pressure Filling method (no human contact)	■ ■
STEP 5	Packaging & storage	Room temperature	
STEP 6	Quality assurance & characterization	Easy methods	
STEP 7	Stability	Testing to ensure product remains stable through shelf life	

Good Manufacturing Practice (GMP)

- ■ Clean room & sterile equipment (prevention and control of potential bacterial contamination)
- ■ Virus segregation (prevention of potential virus contamination)
- ■ Segregation: Personnel and material