GMP Process Flow

Raw Material Receiving

- Quarantine
- Sampling
- Testing
- Review/release
- GMP storage

GMP Production

- Batch records
- In-process controls
- Operator/Witness
- QA oversight / intermediate release
- Deviations/OOS per SOP's

Release Testing

- Testing per specs
- Generation of CoA
- Release by Quality unit
- Deviations/OOS per SOP's

Stability testing

Laboratory / plant preparation

Developmental Runs

- Process development
- Analytical development
- Generation of Master Production Records (MPR's)
- Generation of specifications (R.M, intermediates, F.P.)

Package/Ship

- Package per batch record
- Label generated by QA
- Inspection of packaged material by QA
- GMP storage (secure, temp/humidity controlled)
- Ship material

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