

FACTORS DETERMINING SAFETY AND EFFECTIVENESS OF A DRUG PRODUCT

1. Components (Drug and Non-Drug)
2. Formula
3. Manufacturing (Compounding) Procedure
4. Assays, Tests, Inspections, Checks
5. Other In-Process Controls

CHART 2

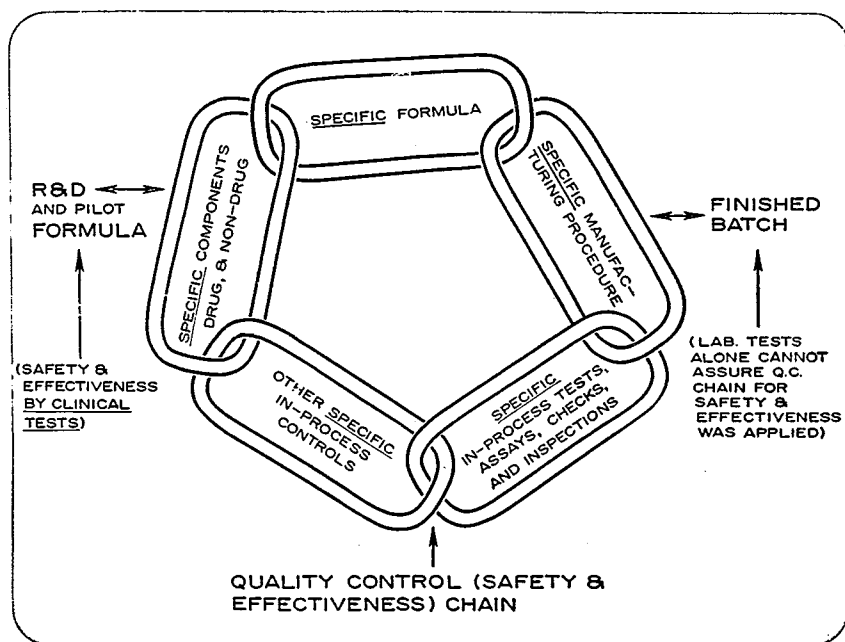


CHART 3