# PROCESS VALIDATION

# MASTER PLAN

# THE DOCUMENTATION

## VALIDATION PROTOCOL

- **⇒** PURPOSE of STUDY
- **⇒** RESPONSIBILITIES of PERSONNEL
- **⇒** FREQUENCY
- ⇒ PROCESS CRITICAL STEPS DEFINED
- **⇒** CRITICAL PARAMETERS SPECIFIED
- **⇒** SAMPLING PLAN
- **⇒** TESTING PLAN
- **⇒** ACCEPTANCE CRITERIA

# SAMPLING PLAN - Solid Dosage Forms

- **⇒** SEMISOLID DEAERATION Physical Tests Only
- ⇒ FINAL MIX Content Uniformity 3 Unit Dose Sampling
- ⇒ FILL & SHELL WEIGHTS- Monograph Testing (3-4 Intervals)
- **○** CAPSULE Monograph Testing



STEP

ONE

TWO

# **TESTING PLAN**

#### **IN-PROCESS** FINISHED PRODUCT

Content Uniformity (Final Blend)

Fill Weight **AVERAGE** HARDNESS (BAREISS) INDIVIDUAL WEIGHT AVERAGE WEIGHT

Weight Qualification Profile Assay (Capsule)

Content Uniformity (Capsules) Disintegration

Assay (Final Blend) Dissolution (Capsules)

Fill Moisture **Dissolution Profile** 

THREE

## VALIDATION REPORT

- Aim and Purpose of Study
- List of Raw Material used in MNF
- List of MNF Equipment (Pre-Qualified)
- Critical Process Steps Studied
- Results of Data Collected

- Acceptance Criteria Evaluation
- Analysis of Results (+ statistical)
- Validation Statement of Process
- Validation Recommendations
- Attachments (Batch Records & CoAs)

FOUR