1 Purpose

The purpose of this International Guideline is to describe the requirements for in-process testing and sampling during manufacture and packing.

2 Scope and Applicability

This Guideline is applicable to:
Any product including intermediates, bulk drugs and formulated products.
Any unit, its licensees, joint ventures and contractors.

3 Definitions

3.1 In-Process Testing/In-Process Controls

In-Process Testing/Controls is a test/control that is performed during manufacture, which provides added assurance that when finally tested by QC the product will meet it's predetermined specification and attributes.

4 Responsibilities

4.1 It is the responsibility of each unit manufacturing and/or packing products to put in place procedures that describe the In-process Testing and Sampling during manufacture and/or packing.

4.2 It is the responsibility of the unit conducting the audits of the joint-ventures licensees, and contractors to ensure that this International Guideline is adhered to.

5 Guideline

5.1 Planning

In-process controls should have the ability to identify when corrective actions are needed and control the performance of processing steps that cause variability in the quality characteristics of products including intermediates and APIs.

In-process control activities should be based on the Master Formula or the Chemistry Manufacturing and Control (CMC) Documentation and on local process capability.

Written in-process control instructions must contain information about for example sample size, sampling frequency, test methods and locally established control limits. Samples must be representative of the batch.

When possible, established statistical techniques should be applied and where appropriate, the test methods validated.

The instructions for in-process controls could be given in Batch Records, procedures or in separate in-process control records. The records must have

