1.7

ICH Q2A Guideline

Validation of Analytical Methods Definitions and Terminology

Comments for its Application

1. Introduction

This document presents a discussion for the characteristics for consideration during the validation of analytical procedures included as part of registration applications submitted within EU, Japan and USA.

The objective of validation of an analytical procedure is to demonstrate that it is suitable for its intended purpose.

2. Types of Analytical Procedures to be validated

- ☐ Identification tests
- ☐ Quantitative test for impurities content
- ☐ Limit tests for the control of impurities
- ☐ Quantitative tests of the active moiety in samples of drug products

2. Types of Analytical Procedures to be validated

- ☐ **Typical validation characteristics which should be considered:**
  - Specificity
  - Linearity
  - Quantitation limit
  - Detection limit
  - Range
  - Accuracy
  - Precision
    - Repeatability
    - Intermediate Precision

☐ **Revalidation may be necessary**

- changes in the synthesis of the drug substance
- changes in the composition of the finished product
- changes in analytical procedure

2. Types of Analytical Procedures to be validated

Validation characteristics	**Identification**	**Type of analytical procedure**		
		Quantitative test Impurity content	**Limit test for impurities**	**Assay - Dissolution - Content/ potency**
Specificity	x	x	x	x
Linearity		x		x
Quantitation limit		x	x	-
Detection limit		-	(x)	x
Range		x	-	x
Accuracy		x	-	x
Precision -Repeatability		x		x
- Intermediate precision		x		x

Robustness is not listed in the table but should considered at an appropriate stage in the development of the analytical procedure