1. INTRODUCTION

1.1. General Requirements for Stability Testing

The aim of stability testing is to ensure the quality, safety, and efficacy of drug products up to their expiration date. This means that all

Organoleptic
Physicochemical
Chemical
Microbial

test results must be within the shelf life tolerance ranges up to the end of the shelf life. Extensive studies are needed for this purpose. Stability testing accompanies the development of a medicinal product from the first preliminary trials with the drug substance up to continuous production. If the stability program is scientifically well founded, systematically structured and logically coordinated stability information will be continuously augmented and become increasingly reliable.

The overall stability program can be divided into six steps (1):

Step 1: Stress and acceleration tests with the drug substance
Step 2: Preformulation and formulation finding for
toxicological test samples
clinical samples
final dosage form
Step 3: Stress and acceleration tests with selected formulations
toxicological test samples
clinical samples
final dosage form
Selection of primary packaging materials
Step 4: Acceleration and long-term tests on drug substance and drug products up to marketing authorization
Step 5: Ongoing stability testing of drug substance, drug products
marketing authorization batches
production batches
Step 6: Follow-up stability tests on drug substance, drug products
continuous production
modifications during continuous production

Each stage covers eleven basic principles (2):

Selection of batches and samples
Test criteria
Analytical procedures
Specifications
Storage conditions
Testing frequency
Storage period
Number of batches
Packaging materials
Evaulation
Stability information