

**ACTD**

# ACTD

ACTD is ASEAN Common Technical Document.

This ASEAN Common Technical Dossier (ACTD) is a guideline of the agreed-upon common format for the preparation of a well-structured Common Technical Dossier (CTD) application which was submitted to ASEAN regulatory authorities for the registration of pharmaceuticals for human use.

ASEAN is a CTD document for South East Asian Countries. A bunch of 10 countries came together to lay down their own rules and regulations for dossier submission.

# ASEAN Countries

A bunch of 10 countries came together to join hands and lay down their own rules and regulations for dossier submission.

List of 10 ASEAN Countries:

1. Laos
2. Burma (Myanmar)
3. Brunei
4. Cambodia
5. Malaysia
6. Singapore
7. Thailand
8. Phillipines
9. Vietnam
10. Indonesia

# ACTD Objective

- To develop the harmonization scheme of Pharmaceuticals regulations of the ASEAN member countries, to complement and facilitate the objectives of ASEAN Free Trade Area, particularly the elimination of Technical Barriers to Trade posed by the regulations, without compromising on drug quality, efficacy and safety.

# ACTD Applications

ASEAN countries came together to simplify the trade and approval procedures for the drug products to be introduced in the market. The countries pay low excise and levy duties to trade their products in the ASEAN markets.

Hence, ACTD has following applications;

- For registration of pharmaceutical products in local market
- For registration of pharmaceutical product in international market
- For renewal of registration of pharmaceutical product

# ACTD Format

The ACTD consists of four parts. These four parts contain all the information required by the regulatory agencies to be submitted by the applicant.

## **Part 1: Table of Content, Administrative Data and Product Information:**

This part contains all the relevant information regarding the whole ACTD to provide basis details. A general introduction to the pharmaceutical product, its class, mode of action, etc.

## **Part 2: Quality Document:**

This part provides the overall summary and the study reports.

### **Part 3: Non-Clinical Document:**

Part III provides the non-clinical overview, written summaries and tabulated summaries. But for ASEAN countries, these study reports may not be required for Major Variation Products if the original product is already registered and approved in Reference Countries.

### **Part 4: Clinical Document:**

Part IV provides the Clinical overview and clinical summary. This document is not needed for generic products.

## **Part 1: Table of Content, Administrative Data and Prescribing Information**

Section A: Introduction

Section B: Table of Contents

Section C: Documents required for registration

## **Part 2: Quality Documents:**

Section A: Table of Contents

Section B: Quality Overall Summary

Section C: Body of Data

## **Part 3: Non-Clinical document**

Section A: table of Contents

Section B: Non-Clinical Overview

Section C: Non-Clinical Written and Tabulated Summary

1. Table of Contents
2. Pharmacology
3. Pharmacokinetics
4. Toxicology

Section D: Non-Clinical Study Reports

1. Table of Contents
2. Pharmacology
3. Pharmacokinetics
4. Toxicology

## **Part 4: Clinical Document**

Section A: Table of Contents

Section B: Clinical Overview

Section C: Clinical Summary

1. Summary of Biopharmaceutics and Associated Analytical Methods
2. Summary of Clinical Pharmacology Studies
3. Summary of Clinical Efficacy
4. Summary of Clinical Safety
5. Synopses of Individual Studies

Section D: Tabular Listing of all Clinical Studies

Section E: Clinical Study Reports

Section F: List of Key Literature References

# Conclusion

ACTD is a guideline for the preparation of well-structured CTD applications that would be submitted to ASEAN regulatory authorities for the registration of pharmaceuticals for human use.

ACTD has an advantage that it can be used for the whole region instead of a particular country. This harmonized format of ACTD facilitates the regulatory review.