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COMPARITIVE STUDY OF DOSSIER SUBMISSION PROCESS FOR DRUG PRODUCT IN USA, EU & INDIAN REGULATORY

Swapna.G*[1], Bindhu Madhavi .Ch[2], Anusha.P[1] , Rupa.T[1] , Mohini.D[1] , Venkkana.B[1],

[1]Assistant Professor, Nirmala college of Pharmacy, Atmakur(Vill), Mangalagiri (MD), Guntur Dist, Pin code -522503, Andhra Pradesh, India.

[2]Department of pharmaceutical Analysis & Quality Assurance, Nirmala College of Pharmacy, Atmakuru, Mangalagiri, Guntur district-522503. Andhra Pradesh, India.

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***Correspondence for Author**
Swapna Goday
Assistant Professor ,Nirmala college of Pharmacy, Atmakur(vill), Mangalagiri (md), Guntur Dist,Pin code - 522503, Andhra Pradesh, India

ABSTRACT

In this presentation we did individually study about the rule & regulations[1] which are followed for drug approval [2]process in USA, Europe & India. Data [3]in the dossier[4] gives the answer of following questions: What is the product? Is the quality [5]presented acceptable on grounds of Safety [6]and efficacy? Is the quality[7] presented reproducible? How long can the quality be maintained[8]? Quality must ensure consistency of safety and efficacy during the shelf life[9] of all batches Produced. And in last we did the comparative [10]study. This comparative study of dossier compilation given a brief idea about the difference in regulatory requirements[11] for drug approval process among USA, EU & India.

KEY WORDS: USA, EU & India.

INTRODUCTION

Dossier[12] is a file document submitted for the approval of drug product. It is submitted in form of CTD. CTD [13]is a harmonized format (template) for presenting data in the ICH regions Generic drug product[14] is comparable to an innovator drug product-

1. In dosage form
2. Strength
3. Route of administration
4. Quality
5. Use etc

The word dossier has its English meaning as a collection of or files of documents on the same subject, especially a file contains detailed information about a person or a topic.Any preparation for human use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient are called as pharmaceutical product for human use.

Process of reviewing & assessing the dossier of a pharmaceutical product containing its detailed data (administrative , chemistry , preclinical & clinical) and the permission granted by the regulatory agencies of a country with a view to support its marketing / approval in a country is called as marketing approval or product licensing.

Regulatory Guidelines For Dossier Submission In Usa

Dossier is submitted in CTD format.

CTD format

Aim

To harmonize the structure and format of registration documentation.

Benefits

Complete, well-organized submissions

Facilitates electronic submissions

Easier analysis acrosss applications etc.

Regional Admin Information Module-1 Nonclinical overview Clinical overview Clinical Summary Quality overall summary Quality Module-3 Nonclinical Studies Reports Module-4 Clinical Study Reports Module-5 The CTD Module-2 Not Part of CTD

The CTD is organized into five modules

Module 1 is region specific.

Modules 2, 3, 4, and 5 are intended to be common for all regions.

Module 1. Administrative Information

Should contain documents specific to each region;

E.g. application forms or the proposed label for use in the region.

Table of Contents of the Submission 1.2 Documents Specific to Each Region (for example, application forms, prescribing information,)

Module 2. CTD Summaries

Begin with a general introduction to the pharmaceutical (its pharmacological class, mode of action, proposed clinical use.

It contains 7 sections in the following order:

2.1 Common Technical Document Table of Contents (Modules 2-5)

2.2 CTD Introduction

2.3 Quality Overall Summary

2.4 Non-clinical Overview

2.5 Clinical Overview

2.6 Non-clinical Written and Tabulated Summaries

2.7 Clinical Summary

Module 3.

Quality

Table of Contents of Module 3Body of Data [Drug Substance, Drug Product & Regional information] Literature References.

Module 4.

Non-clinical Study Reports

Toxicology

Pharmacokinetics

Module 5.

Clinical Study Reports

1. Table of Contents of Module 5
2. Tabular Listing of All Clinical Studies
3. Clinical Study Reports (BA/BE)
4. Literature References

Regulatory Guidelines For Dossier Submission In Europe

Pharmaceutical companies of EU are use three approval procedures to market their pharmaceuticals

A centralized or

A decentralized or

Mutual recognition

Centralized procedure

Allows a pharmaceutical company to market its pharmaceutical product in all 25 member states without having to obtain separate approvals from each member state.

Decentralized procedure

An applicant can go directly to a national marketing authority to obtain permission to market its product in that member state and Then seek to have other member states accept the marketing approval of the first member state. Mutual recognition procedure (MRP)- Used in order to obtain marketing authorizations in several Member States where the medicinal product in question has received a marketing authorization in at least one Member State at the time of application.

Regulatory Guidelines For Dossier Submission In India

Drug & Cosmetic Act 1940 & Rules 1945

Regulates the import, manufacture, distribution & sale of drugs &cosmetics.

Schedule Y

Provides guidelines & requirements for clinical trials

CDSCO

A licensing authority for approval of new drug

proposed to be imported

Head office located in New Delhi & functioning under the control of directorate general of Health services, MHFW, Govt of India.

DCGI

Responsible for approval of new drug &

Clinical trials to be conducted in India

Appointed by Central Govt of India

Comparative Study Of Dossier Submission Process Of Drug Product In Usa, Eu, India:

A . ADMINISTRATIVE			
S.No. Requirements	**USA**	**EU**	**India**
1. Application	ANDA	MAA	MAA
2. Debarment Certification	Required	NA	NA
3. No. of copies	3	1	1
4. Approval time line	18 Month	12 Month	12 Month
5 Fees	No Fees	10-20 Lakh	50,000

6 Presentation eCTD&paper	eCTD & Paper	eCTD	

B. FINISHED PRODUCT CONTROL			
S.No. Requirements	**USA**	**EU**	**India**
1. Justification	ICHQ6A	ICHQ6A	ICHQ6A
2. Assay	90-100%	95-105%	90-110%
3. Disintegration	Not required	Required	Required
4. Color Identification	Not required	Required	Required
5. Water content	Required	Not Required	Required

C. MANUFACTURING & CONTROL			
S.No. Requiremen	**USA**	**EU**	**India**
1. No. of batches	01	03	1
2. Packaging	A min of 1,00,000 Units	Not Required	–
3. Process validation	Not required at the time of submission	Required	Required
4. Batch size	Min of 1,00,000 Units	Min of 1,00,000 Units	Not Specified.

D. STABILITY			
S.NO Requirement	**India**	**USA**	**EU**
1. No. of batches	01	02	01
2. Condition	25/60: 40/75	25/60: 40/75	30/35:0/70
3. Date & Time of submission	3 Month Accelerate & 3 Month Long term		6 Month Accelerate & 6 Month Long term 6 Month accelerated & 3 Month Long term
4. Container orientation	Inverted & Upright	Do not address	Do not address
5. Clause	21CFR Part 210 & 211 Volume4, EU guidelines for medicinal product		ICHQ1F
6. QP Certification	Not Required	Required	Required

S.No. Requirement	**USA**	**EU**	**India**
E. BIOEQUIVALENCE			
1 CRO	Audited by FDA	Audited by MHRA	CDSCO
2. Reserve sample	5 Times the sample required for analysis	No such requirement	–
3. Fasted/Fed	Must be as per OGD recommendation	NO such requirement	As CDSCO recommendation
4. Retention of samples	5 Year from the date of filing the application	No such requirement but usually followed 3 years from date of filing the application	

CONCLUSION

Significantly reduces the time and resources. Needed to compile applications for registration of human pharmaceuticals.Eases the preparation of electronic submissions .Facilitates regulatory reviews and Communication with the applicant by a standard .Document of common elements Simplifies exchange of regulatory information Between Regulatory Authorities.

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