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REVIEW ON REGULATORY SUBMISSION OF PHARMACEUTICAL PRODUCT IN INDIA

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ABSTRACT
The drug approval process is a regulatory framework that grants authorization to market pharmaceutical products through stages such as clinical trial applications, marketing authorization, and post-marketing surveillance. In India, the Drugs and Cosmetics Act governs this process, with State Authorities regulating manufacturing and distribution, and Central Authorities approving new drugs and overseeing clinical trials. The Central Drugs Standard Control Organization (CDSCO), under the Drugs Controller General of India (DCGI), ensures compliance, safety, efficacy, and quality of medicines. This guideline defines the standards and procedures for pharmaceutical approval in India to ensure safe and effective drug availability.

Key Words : Drug Regulation, CDSCO ,DCGI , Clinical Trials Marketing Authorization , Drugs and Cosmetics Act, Pharmaceutical Approval

Literature and review

Sr. No.	Year	Author	Country	Studies {Reference}
1	2018	Dr. V. G. Somani	*UK*	Defines procedures for drug approval, manufacturing, import, and clinical trials
2	2019	Gaur et al.	*US & EU*	Detailed rules for approval manufacturing, labelling compliance
3	2020	Sharma & Singh	*India*	Rules for new drug approval, clinical trials ethics committees forms
4	2021	Dr. Santosh indraksha	*Asia-Pacific*	Latest updates, clarification, news forms, policy changes {frequently updated}
5	2022	Dr. G. N. Singh	*India*	Explain drug approval workflow, roles of CDSCO, timelines online submission system for applications.

INTRODUCTION

India's drug regulatory system, governed by the Drugs and Cosmetics Act (1940) and Rules (1945), ensures the safe manufacture, import, and sale of pharmaceuticals. The Central Drugs Standard Control Organization (CDSCO), led by the Drugs Controller General of India (DCGI), oversees new drug approvals and clinical trials. Schedule Y, introduced in 1988 and revised in 2005, aligns India's clinical research standards with global norms, outlining requirements for Phase I–IV trials. Rules 122A–122E detail data and approval processes. State authorities manage manufacturing and sales, while central authorities regulate new drugs, ensuring safety, efficacy, and efficient review of submissions.

COMMON TECHNICAL DOCUMENT

A Common Technical Document (CTD) is a document that must be submitted to a regulatory body as part of a supporting list of leaflets with pharmaceutical registration applications in order to obtain market authorization. Mainly CTD tells about the format for the data it is common that RA (Regulatory Authority) expert knows the documents to be submitted while getting approval for any drug product. But CTD mainly talks about the organization of the information in order.

- Module 1: Administrative and prescribing information
- Module 2: Common Technical Document Summaries (Quality Overall summary)
- Module 3: Quality Data
- Module 4: Non- Clinical study reports
- Module 5: Clinical Study reports

Modules

- Module 1: Administrative and prescribing information
- Module 2: Common Technical Document Summaries (Quality Overall summary)
- Module 3: Quality Data
- Module 4: Non- Clinical study reports
- Module 5: Clinical Study reports Module 1:

It is variable part of CTD depends upon of individual country. Module 2:

It is summarizing the information that will be provided in the quality, nonclinical and clinical modules of the dossier. There is no single document that explain the content of Module 2 for the registration of pharmaceuticals for human use. The documents of Modules 3, 4 and 5, include a section on the information that must be provided in Module 2. It consists of 7 sub modules.

- Quality overall summary
- Nonclinical overview
- Clinical summary

Module 3:

It describes the format and organization of the chemical, pharmaceutical and biological data relevant to the application. It is consist of 3 sub- modules.

- Table of content
- Body of data
- Literature reference

Module 4:

It describes the format and organization of the nonclinical (pharma toxicological) data relevant to the application. It is consist of 3 sub-modules.

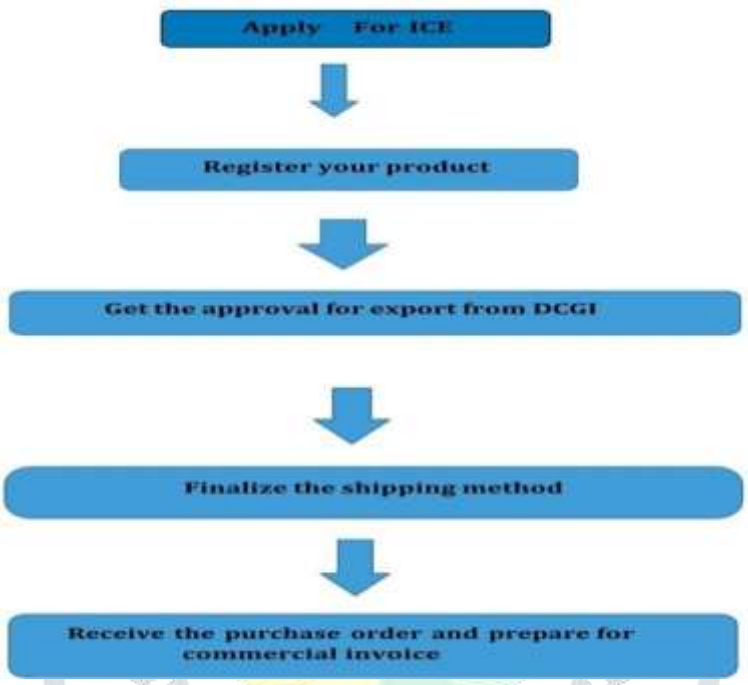
- Table of content
- Study report
- Literature reference

Module 5:

It describes the format and organization of the clinical data relevant to the application. It is consist of 4 sub- modules.

- Table of content
- Tabular listing of all clinical study
- Clinical study report
- Literature reference

Fig.no 1. FLOW CHART FOR EXPORT OF PHARMACEUTICAL PRODUCTS FORMS INDIA



PROCEDURE FOR EXPORT OF PHARMACEUTICAL PRODUCTS:

- Indian products need to be registered and approved prior to export. Export means selling of the drugs and pharmaceuticals to other countries without trade barrier and crossing the geographical frontier.

- Rules and acts responsible for import and export of pharmaceutical products:

- Drugs and Cosmetics act, 1940 and Rules, 1945.

- The Drugs (Prices Control) order, 1995.

- Medicinal and Toilet Preparation act, 1956

- Pharmacy act, 1948

- Narcotic and Psychotropic Substances act, 1985.

- Drugs and Magic Remedies act, 1954. Documents required for export of drugs from
- India:

- Covering letter.

- Purchase order
- Import export code Number (IEC) given by DGFT.
- Manufacturing license
- Performa invoice
- Custom clearance certificate
- Registration certificate
-

Functions

1. Ensuring Drug Safety, Efficacy, and Quality

Submissions allow the Central Drugs Standard Control Organization (CDSCO) to evaluate whether the product meets national safety and efficacy standards.

The Drug Controller General of India (DCGI) reviews clinical, preclinical, and manufacturing data.

2. Legal Authorization for Marketing

Regulatory submission is required to obtain marketing authorization (product approval). Without this approval, the product cannot be legally manufactured, imported, or sold in India.

3. Evaluation of Technical Data:

The submission includes Quality (CMC), Preclinical, and Clinical data for new drugs. CDSCO evaluates this data to confirm that the benefits outweigh the risks.

4. Control and Standardization

Ensures compliance with Drugs and Cosmetics Act, 1940 and Rules, 1945. Maintains uniformity in product quality, labeling, packaging, and storage standards.

5. Post-Marketing Surveillance

After approval, submissions support pharmacovigilance and post-marketing studies to monitor adverse drug reactions and long-term safety.

Data Requirements

- Quality Data – Drug substance and product specifications, stability studies.
- Nonclinical Data – Pharmacology and toxicology studies.
- Clinical Data – Human trials showing efficacy and safety.
- Labeling and Packaging Information – As per CDSCO and WHO guidelines.

Post-Approval Requirements

- After marketing authorization, manufacturers must:
- Submit Periodic Safety Update Reports (PSURs).
- Maintain pharmacovigilance systems.
- Report adverse drug reactions (ADRs)

Fig.2 Drug approval process in India

Conclusion

The regulatory submission process in India is a comprehensive and structured pathway designed toensure that all pharmaceutical products meet stringent standards of safety, efficacy, and quality. With CDSCO at the helm, and increasing adoption of global formats like CTD and eCTD, India's regulatory framework continues to evolve toward international harmonization and transparency

REFERENCE

1) Sahitya KS et al/ indian drug products in overseas market, J. Pharma. Sci &2020, Res. Vol. 12 (9), pg.1.

2) 2. Badjatya JK, Bodla R, Musyuni P. Export registration of pharmaceuticals in the rest of world countries, (J. Drug Delivery and Therapeutics) Jan-Feb,2013, Vol.3, pg.no.2,3,4,5.

3) Pooja M, Certificate of Pharmaceutical product COPP. www.rjpt online.org , 2015.

4) FDA, Types of drug master files. Available from: https://www.fda.gov/drugs-masterfiles-dmfs/types-drugs- master- files-dmfs , Accessed on 28 Feb 2020

5) Badjatya J K, Bodla R, Musyuni P. Export registration of pharmaceuticals in rest of world countries (ROW).

6) Senthil, Priyadharshini B. Regulatory process for import and export of drugs in india. 2015

7) International Conference in Harmonisation. Harmonised Tripartite Guideline: Immunotoxicity Studies

8) forHuman Pharmaceuticals S8. [Internet].ICH; 2005 [cited 2019 Sept 13]. Available from: http://www.ich.org/LOB/media/MEDIA17 06.pdf.

8). India export of pharmaceutical product from https://images.app.goo.gl/RuAcB8Dg5JYTzsJD7 https://www.google.com/imgres?imgurl= https://d3fy651gv2fhd3.cloudfront.net/ ch arts/india-exports-of- pharmaceutical products. ics.com/in ,2019.

9). Dr. Zeine C, Reference materials: Certificate of analysis. Available from: http://www.seishinsy oji.co.jp/files/libs/50/20160418114027148 9.pdf Accessed on 05 Feb 2020.

10. Yamini kanti S P et al, Filing of DMF in US, Canada and Europe. PDRAJ, Volume 2; issue (1). Available from: https://medwinpublishers.com/PDRAJ/PDRAJ16000108.p

11. Chakraborty S, eCTD submissions. Available from the: https://www.slideshare.net /saikatch/ ectd-submissions., Accessed on 06 March,2020.

12. IBEF, Infographic on the growth of pharmaceutical industry in India. Available from: https://www.ibef.org/industry/pharmaceuticalindia/infographic Accessed on- 05 Jan 2020.

13. ena et al. Regulatory requirements and ICH Guidelines on Carcinogeneticity testing of pharmaceuticals- A review on current status. Indian Journal of Pharmacology. 2005 Aug;37(4):209-22.

14. Kawabata TT, Evans EW. „Development of Immunotoxicity Testing Strategies for Immunomodulatory Drugs. 2012; 40(2):288-93