World Journal of Pharmaceutical Science and Research

www.wjpsronline.com

Research Article

ISSN: 2583-6579
SJIF Impact Factor: 6.916
Year - 2026
Volume: 5; Issue: 6
Page: 148-159

COMPARATIVE STUDY OF DRUG MASTER FILE (DMF) IN INDIA VS USFDA

Pranjali Amale*[1], Pro. Dr. B. V. Bakade[2], Pro. Dr. Anil Chandewar[3]

[1]Second Year M Pharmacy, Department of Regulatory Affairs, Pataldhamal Wadhwani College of Pharmacy, Yavatmal-445001.

[2]Associate Professor, Department of Pharmaceutics, Pataldhamal Wadhwani College of Pharmacy, Yavatmal-445001.

[3]Principal, Department of Pharmaceutical Chemistry, Pataldhamal Wadhwani College of Pharmacy, Yavatmal-445001.

Article Received: 14 April 2026 | | ***Article Revised: 05 May 2026*** | | ***Article Accepted: 25 May 2026***

***Corresponding Author: Pranjali Amale**
Second Year M Pharmacy, Department of Regulatory Affairs, Pataldhamal Wadhwani College of Pharmacy, Yavatmal-445001.
DOI: https://doi.org/10.5281/zenodo.20443517

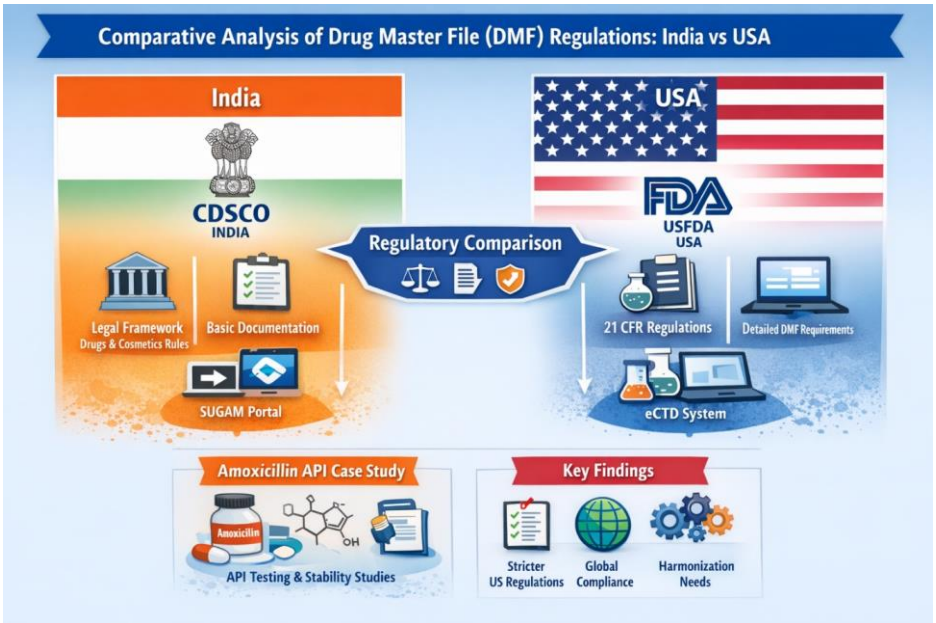
How to cite this Article: Pranjali Amale, Pro. Dr. B. V. Bakade, Pro. Dr. Anil Chandewar (2026) COMPARATIVE STUDY OF DRUG MASTER FILE (DMF) IN INDIA VS USFDA. World Journal of Pharmaceutical Science and Research, 5(6), 148-159.

ABSTRACT

The Drug Master File (DMF) is a confidential regulatory document submitted to drug regulatory authorities to provide detailed information regarding facilities, manufacturing processes, and raw materials used in pharmaceutical production. With globalization of pharmaceutical manufacturing and increasing international trade in Active Pharmaceutical Ingredients (APIs), understanding regulatory differences between major authorities has become essential. This research performs a comparative analysis of the DMF regulatory frameworks of the Central Drugs Standard Control Organization (CDSCO) of India and the United States Food and Drug Administration (USFDA). The study evaluates regulatory structure, documentation requirements, submission formats, review procedures, confidentiality mechanisms, and lifecycle management practices. A systematic literature review, regulatory document analysis, and comparative framework were used to analyze both systems. The results indicate that while CDSCO is progressing toward global regulatory harmonization through CTD adoption and digital platforms such as the SUGAM portal, the USFDA maintains a more mature, transparent, and scientifically rigorous DMF system supported by codified regulations under 21 CFR 314.420 and mandatory eCTD submissions. The study concludes that although CDSCO is evolving rapidly, further improvements in regulatory clarity, digital infrastructure, and lifecycle management are required to align fully with global standards.

KEYWORDS: Drug Master File (DMF), CDSCO, USFDA, eCTD; ICH Guidelines.

Graphical Abstract



1. INTRODUCTION

Pharmaceutical regulation plays a critical role in protecting public health by ensuring that medicines are safe, effective, and manufactured according to established quality standards. Over the past several decades, the pharmaceutical industry has evolved into a complex global network where drug substances, intermediates, excipients, and finished dosage forms may be manufactured by different organizations located in various countries.[1] This globalization of pharmaceutical manufacturing has created the need for regulatory systems that allow companies to submit detailed technical information while maintaining confidentiality of proprietary manufacturing processes.[2] One of the most important regulatory tools developed to address this challenge is the Drug Master File (DMF). A DMF is a confidential document submitted to regulatory authorities that contains detailed information regarding facilities, manufacturing processes, quality control procedures, stability data, and packaging systems associated with pharmaceutical substances.

These files enable regulatory agencies to evaluate the quality and safety of pharmaceutical components without requiring manufacturers to disclose sensitive proprietary information to third-party applicants.[3] The concept of the Drug Master File is widely used across the global pharmaceutical industry. In the United States, the USFDA has established a comprehensive DMF regulatory framework supported by clear regulatory guidelines and mandatory electronic submission systems. In India, the Central Drugs Standard Control Organization (CDSCO) regulates pharmaceutical products and has gradually introduced regulatory mechanisms for DMF submissions, particularly for Active Pharmaceutical Ingredients (APIs).[4] India is one of the world's largest producers of generic medicines and Active Pharmaceutical Ingredients. A large number of Indian pharmaceutical companies supply APIs to global pharmaceutical markets, including the United States and Europe. As a result, regulatory affairs professionals working in India must frequently prepare documentation that complies with both domestic and international regulatory standards.

Understanding the differences between CDSCO and USFDA DMF systems is therefore essential for successful global pharmaceutical regulatory submissions.[5] This research paper aims to provide a comprehensive comparative analysis of the DMF regulatory frameworks implemented by CDSCO and USFDA. The study evaluates regulatory structures, legal frameworks, technical documentation requirements, confidentiality mechanisms, digital submission infrastructure, and

lifecycle management systems. Additionally, the research includes an Amoxicillin API case study to illustrate the preparation of DMF documentation in practical pharmaceutical manufacturing scenarios.[6]

2. LITERATURE REVIEW

1. Akhilesh et al., (2014)

Discussed a Drug Master File (DMF) as a document containing complete information on Active Pharmaceutical Ingredients (API) or finished dosage forms, including chemistry, manufacturing, stability, impurity profile, packaging, and cGMP status. The study explains that DMF consists of two parts: the Applicant's (Open) Part, which contains information required for regulatory review, and the Restricted (Closed) Part, which contains confidential manufacturing information disclosed only to authorities. The paper highlights differences in terminology such as US-DMF and ASMF and emphasizes the structure, components, and importance of DMFs in regulatory submissions.

2. Gurram et al., (2017)

Reviewed a Drug Master File (DMF) as a confidential document submitted to regulatory authorities containing detailed information on manufacturing, processing, packaging, storage, and compliance with current Good Manufacturing Practices (cGMP).

US: DMFs are filed through New Drug Applications (NDA), Abbreviated New Drug Applications (ANDA), and Biologics License Applications (BLA).

Europe: DMFs are submitted via Marketing Authorization Applications (MAA) using centralized or decentralized procedures.

Canada: DMFs are filed through New Drug Submissions (NDS) for drugs and biologics.

Australia: DMF filing varies depending on the type of therapeutic product. The study compares DMF filing procedures across multiple regions and highlights differences in regulatory requirements and processes.

3. Anusha et al., (2017)

Discussed a Drug Master File (DMF) as a confidential document used to provide detailed information about manufacturing processes, facilities, packaging, and storage of pharmaceutical products. The study explains that DMFs can be used by the holder or by multiple parties to support regulatory applications and protect intellectual property while ensuring compliance with regulatory requirements. It also reviews different types of DMFs and important aspects of filing and processing.

Findings: The paper highlights the importance of DMFs in regulatory compliance and intellectual property protection.

4. Agarwal et al., (2018)

Discussed a Drug Master File (DMF) as a confidential document that provides detailed information about manufacturing, processing, and packaging of drugs for human or animal use. The study explains that DMF submission is voluntary and not a legal requirement under FDA regulations. It highlights that DMFs support various regulatory submissions including IND, NDA, ANDA, and amendments or supplements related to these applications. The paper emphasizes the importance of DMFs in supporting regulatory processes and protecting confidential information.

5. Kumar et al., (2018)[12]

Discussed a Drug Master File (DMF) as a confidential document submitted to regulatory authorities containing detailed information on API manufacturing, testing, and control. The study highlights that DMFs are widely used to support regulatory approval processes even though they are not mandatory.

It compares regulatory requirements across major agencies including FDA (USA), EMA (Europe), CDSCO (India), Ministry of Health, Labour and Welfare (Japan), and WHO. The paper emphasizes differences in DMF management across global regulatory authorities and highlights their importance in ensuring drug quality and compliance.

6. Kumar et al., (2018)[29]

Discussed a Drug Master File (DMF) as a confidential submission to regulatory authorities providing detailed information about facilities, processes, and materials used in manufacturing, processing, packaging, and storage of drugs. The study explains that there are different types of DMFs, with Type II (drug substance) and Type III (packaging material) being the most commonly used, while Type I has been phased out. It also highlights the role of DMFs in protecting intellectual property while complying with regulatory disclosure requirements.

Findings: The paper provides detailed insights into regulatory requirements and mechanisms of DMF submission.

3. RESEARCH METHODOLOGY

3.1 Research Design

The present research adopts a qualitative and comparative research design in order to analyze and evaluate the regulatory frameworks governing Drug Master Files (DMFs) in India and the United States. A comparative regulatory analysis approach was selected because the primary objective of the study is to identify similarities, differences, and regulatory gaps between the Central Drugs Standard Control Organization (CDSCO) and the United States Food and Drug Administration (USFDA).[7] The study focuses on regulatory structures, documentation systems, digital submission infrastructure, and confidentiality mechanisms used by these authorities. This design enables systematic evaluation of regulatory procedures and allows meaningful comparison between two internationally important pharmaceutical regulatory environments.

3.2 Data Collection Sources

The research is primarily based on secondary data sources obtained from reliable regulatory and academic publications.

Secondary data were considered appropriate for this study because regulatory frameworks and documentation standards are formally defined through official guidance documents and regulatory policies. The data used in this study were collected from several categories of sources including regulatory authority publications, international harmonization guidelines, scientific journals, and pharmaceutical regulatory textbooks.[9] The major sources of information used in this research include official guidance documents published by CDSCO and USFDA, regulatory policy documents, International Council for Harmonisation (ICH) guidelines related to Common Technical Document (CTD) and electronic CTD (eCTD), pharmaceutical regulatory affairs textbooks, peer-reviewed research articles related to pharmaceutical regulation, and publicly available regulatory databases. These sources provided comprehensive information regarding DMF submission procedures, technical documentation requirements, and regulatory review processes.

3.3 Literature Review Strategy

A structured literature review strategy was followed to ensure systematic identification and analysis of relevant regulatory information. Initially, regulatory guidelines related to Drug Master Files were identified from official websites of regulatory authorities and international regulatory organizations. Following identification, the literature was screened based on relevance to the objectives of the study. Documents that specifically addressed DMF preparation, regulatory submission procedures, confidentiality systems, and electronic regulatory infrastructure were prioritized.

After screening the documents, relevant regulatory parameters were extracted and categorized into thematic areas such as legal framework, technical documentation requirements, digital submission systems, confidentiality protection mechanisms, and lifecycle management practices. This structured literature review enabled comprehensive understanding of the regulatory systems and provided the foundation for the comparative analysis performed in this study.

3.4 Comparative Analysis Parameters

To perform an effective comparison between CDSCO and USFDA regulatory frameworks, several analytical parameters were defined. These parameters represent the core regulatory elements that influence Drug Master File submission, evaluation, and lifecycle management. The primary parameters used in the comparative analysis include regulatory authority structure, legal and regulatory framework governing pharmaceutical documentation, technical documentation requirements for DMF preparation, confidentiality protection and referencing mechanisms, digital submission infrastructure such as electronic Common Technical Document systems, and lifecycle management procedures for updating regulatory documentation. Each parameter was systematically evaluated for both regulatory authorities using available regulatory documentation. Differences and similarities were then analyzed to determine the level of regulatory maturity, efficiency, and global compatibility of the two systems.

3.5 Data Analysis Approach

The collected regulatory information was analyzed using qualitative comparative analysis. Descriptive analytical techniques were used to interpret regulatory guidelines and identify structural differences between the two regulatory frameworks. Tabular comparison methods were also used to present regulatory parameters in a structured format, making it easier to visualize differences in documentation requirements, digital systems, and legal frameworks. The analysis also incorporated interpretation of practical regulatory implications for pharmaceutical manufacturers, particularly those involved in global Active Pharmaceutical Ingredient (API) manufacturing and export. This analytical approach allowed the study to highlight regulatory challenges faced by manufacturers as well as opportunities for regulatory harmonization between CDSCO and USFDA systems.

3.6 Case Study Integration

In addition to comparative regulatory analysis, a case study approach was incorporated to demonstrate the practical application of Drug Master File documentation. The case study focuses on the Active Pharmaceutical Ingredient Amoxicillin, a widely manufactured beta-lactam antibiotic. The Amoxicillin case study illustrates typical DMF documentation elements including API specifications, analytical testing methods, impurity profiling, and stability studies. The inclusion of this case study helps bridge the gap between theoretical regulatory frameworks and real-world pharmaceutical manufacturing documentation. It also provides practical insight into how regulatory requirements are implemented during preparation of DMF submissions for globally marketed pharmaceutical substances.

4. RESULTS AND DISCUSSION

The results of the present study were obtained through a comparative evaluation of Drug Master File (DMF) regulatory systems implemented by the Central Drugs Standard Control Organization (CDSCO) in India and the United States Food and Drug Administration (USFDA). The comparison focused on regulatory structure, legal framework, technical documentation requirements, confidentiality mechanisms, digital submission systems, and practical DMF documentation through an Amoxicillin API case study. The findings are presented using comparative tables followed by interpretative discussion.

1. Comparison of Regulatory Authorities

The regulatory authorities responsible for pharmaceutical regulation in India and the United States differ in their organizational structure, operational scope, and global influence. The comparison is presented in Table 1.

Table 1: Comparison of Regulatory Authorities.

Parameters	CDSCO (India)	USFDA (USA)
Full Name	Central Drugs Standard Control Organization	United States Food and Drug Administration
Administrative Body	Ministry of Health and Family Welfare	Department of Health and Human Services
Major Review Center	Drug Controller General of India (DCGI)	Center for Drug Evaluation and Research (CDER)
Regulatory Structure	Semi-centralized	Highly centralized
Global Influence	Primarily national	Global regulatory leader

The results presented in Table 1 indicate that the USFDA operates within a highly centralized and specialized regulatory framework supported by dedicated review centers such as CDER. This structure enables efficient scientific review of pharmaceutical documentation including Drug Master Files. CDSCO, while functioning effectively within the Indian regulatory system, operates primarily at a national level and is still expanding its global regulatory influence.

These structural differences influence regulatory rigor, documentation expectations, and review processes for DMF submissions.

2. Legal Framework Governing Drug Master Files

The legal frameworks governing pharmaceutical regulation in India and the United States differ significantly in terms of regulatory clarity and documentation guidance.

Table 2: Legal Framework Comparison.

Parameters	CDSCO	USFDA
Primary Law	Drugs and Cosmetics Act, 1940	Federal Food, Drug and Cosmetic Act
Supporting Regulations	Drugs and Cosmetics Rules, 1945	Title 21 Code of Federal Regulations (21 CFR)
Dedicated DMF Guidelines	Limited	Clearly defined
Regulatory Enforcement	Developing	Highly structured

The results in Table 2 show that the USFDA regulatory system provides clearly defined legal provisions specifically addressing Drug Master Files under 21 CFR regulations. These regulations describe DMF types, submission procedures, confidentiality protections, and referencing systems. In contrast, India currently regulates pharmaceutical documentation primarily through the Drugs and Cosmetics Act and associated rules, which do not provide highly detailed standalone regulatory provisions specifically dedicated to DMFs. As a result, pharmaceutical companies submitting documentation to the USFDA must follow more structured regulatory requirements.

3. Technical Documentation Requirements

Technical documentation represents the most critical component of a Drug Master File submission. Regulatory authorities rely on this information to evaluate the quality, safety, and consistency of pharmaceutical substances.

Table 3: Technical Documentation Comparison.

Parameters	CDSCO Requirements	USFDA Requirements
Manufacturing Process	Moderate detail	Extensive process description
Analytical Method Validation	Required	Highly detailed validation
Impurity Profiling	Limited characterization	Comprehensive impurity analysis
Stability Data	Regional stability studies	ICH global stability studies
Process Validation	Basic documentation	Extensive validation data

The results summarized in Table 3 demonstrate that USFDA DMF submissions require significantly more comprehensive technical documentation compared to CDSCO submissions. USFDA regulations emphasize detailed impurity characterization, validated analytical methods, process validation reports, and comprehensive stability studies following ICH guidelines. Although CDSCO requires similar documentation, the level of detail may vary depending on the type of regulatory submission. This difference highlights the need for Indian pharmaceutical manufacturers targeting international markets to prepare extensive regulatory documentation.

4. Confidentiality Protection and Referencing Mechanisms

Confidentiality protection is one of the primary objectives of the Drug Master File system because pharmaceutical manufacturing processes often involve proprietary technologies.

Table 4: Confidentiality Systems.

Parameters	CDSCO	USFDA
Confidential Data Protection	Administrative mechanisms	Legally protected
Letter of Authorization	Accepted	Mandatory
Data Security	Limited digital control	Secure electronic systems
Cross Referencing	Possible	Structured system

The results presented in Table 4 indicate that the USFDA provides stronger regulatory protection for confidential manufacturing data through clearly defined legal provisions and secure electronic systems. Pharmaceutical companies referencing a DMF must obtain a Letter of Authorization from the DMF holder, allowing the regulatory authority to review confidential information. Although CDSCO also accepts letters of authorization, the regulatory framework governing confidentiality protection is less formalized compared to the USFDA system.

5. Digital Submission and Regulatory Infrastructure

Digital submission systems have significantly improved the efficiency of pharmaceutical regulatory processes.

Table 5: Digital Infrastructure Comparison.

Parameters	CDSCO	USFDA
Online Submission Portal	SUGAM	Electronic Submission Gateway
eCTD Requirement	Partial implementation	Mandatory
Submission Tracking	Limited	Advanced
Lifecycle Management	Developing	Fully structured

The results shown in Table 5 demonstrate that the USFDA has fully implemented the electronic Common Technical Document (eCTD) format for regulatory submissions, including Drug Master Files. This system allows efficient lifecycle management, document tracking, and regulatory review. CDSCO has introduced the SUGAM portal to support digital regulatory submissions; however, full implementation of standardized electronic documentation systems is still developing. Continued digital modernization will improve regulatory efficiency in India.

6. Amoxicillin API Case Study

A case study of Amoxicillin Active Pharmaceutical Ingredient (API) was analyzed to demonstrate practical DMF documentation requirements.

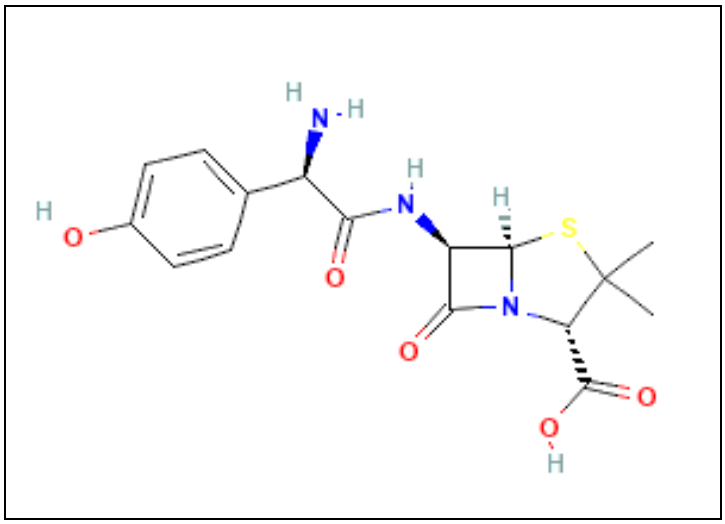


Figure 2: Amoxicillin.

Amoxicillin was selected purposefully due to its global therapeutic relevance, frequent DMF submissions and well-established pharmacopoeial standards, which allows meaningful comparison. Data was obtained from regulatory guidelines, official submission portals, Type II DMF dossiers, published regulatory updates and stakeholder consultation from industry experts engaged in antibiotic filings.

Table 6: Amoxicillin API Specifications.

Parameters	Specification
Chemical Class	Beta-lactam antibiotic
Appearance	White crystalline powder
Identification	IR / HPLC
Assay	95–102%
Water Content	≤ 2%
Impurity Limits	As per pharmacopeial standards

The results in Table 6 illustrate typical API specifications included in a Drug Master File. These specifications ensure that the API consistently meets pharmacopeial quality standards and remains suitable for pharmaceutical formulation.

Table 7: Stability Study Results.

Storage Condition	Duration	Observation
25°C / 60% RH	12 months	Stable
30°C / 65% RH	12 months	Stable
40°C / 75% RH	6 months	Slight degradation

Stability studies summarized in Table 7 demonstrate how environmental conditions influence the chemical stability of pharmaceutical substances. These studies are essential components of DMF documentation because they help determine the shelf life and recommended storage conditions of the API.

Table 8: Analytical Methods Used in Amoxicillin DMF.

Tests	Analytical Method
Identification	Infrared Spectroscopy
Assay	HPLC
Impurity Analysis	HPLC
Water Content	Karl Fischer Titration
Particle Size	Laser Diffraction

The analytical methods listed in Table 8 represent standard pharmaceutical quality control techniques used to ensure API purity, potency, and consistency. These validated analytical methods form a critical part of DMF submissions because they enable regulatory authorities to verify product quality.

7. Global Comparison of Master File Systems

Drug Master File systems are widely used across multiple international regulatory agencies.

Table 9: Global Master File Systems.

Region	Regulatory Authority	Master File Name
United States	USFDA	Drug Master File
Europe	EMA	Active Substance Master File
Japan	PMDA	Master File
Canada	Health Canada	Drug Master File
India	CDSCO	Drug Master File

The results presented in Table 9 demonstrate that master file systems are globally recognized regulatory tools for confidential pharmaceutical documentation. Although terminology and regulatory structures may vary, the fundamental purpose remains consistent across regulatory authorities.

The overall findings of this study indicate that while both CDSCO and USFDA utilize Drug Master File systems to regulate confidential pharmaceutical manufacturing documentation, the USFDA framework is significantly more structured and technologically advanced. The USFDA regulatory system provides clearer legal guidance, mandatory electronic submission infrastructure, and more extensive technical documentation requirements. In contrast, CDSCO operates an evolving regulatory system that is gradually aligning with international regulatory standards. Continued development of digital regulatory infrastructure and expansion of DMF-specific guidelines will further strengthen India's pharmaceutical regulatory framework.

5. FUTURE SCOPE

The present study focused on a comparative evaluation of Drug Master File (DMF) regulatory frameworks implemented by the Central Drugs Standard Control Organization (CDSCO) in India and the United States Food and Drug Administration (USFDA). Although the research provides important insights into regulatory structures, documentation requirements, and digital submission systems, several opportunities remain for further investigation and expansion of this work. One important direction for future research is the expansion of comparative analysis to include additional global regulatory authorities such as the European Medicines Agency (EMA), Health Canada, and Japan’s

Pharmaceuticals and Medical Devices Agency (PMDA). Including these regulatory systems would provide a broader understanding of global master file documentation practices and help identify international regulatory harmonization trends. Future studies may also focus on detailed analysis of Common Technical Document (CTD) and electronic Common Technical Document (eCTD) formats used in regulatory submissions. As electronic regulatory documentation systems continue to evolve, research on digital regulatory transformation, automated validation systems, and electronic lifecycle management could provide valuable insights for improving regulatory efficiency. Another potential research direction involves conducting case studies of additional Active Pharmaceutical Ingredients (APIs) beyond Amoxicillin.

Comparative analysis of multiple APIs would provide deeper understanding of practical challenges associated with DMF preparation, impurity profiling, stability studies, and analytical validation requirements. Future research may also investigate the regulatory challenges faced by Indian pharmaceutical manufacturers while preparing DMF submissions for international markets, particularly for regulatory agencies such as USFDA and EMA. Such studies could identify gaps in regulatory documentation practices and propose strategies for improving compliance with international regulatory standards. Finally, further work may explore the role of emerging technologies such as artificial intelligence, regulatory information management systems (RIMS), and digital quality management platforms in pharmaceutical regulatory documentation. Integration of these technologies has the potential to significantly enhance the efficiency, accuracy, and transparency of Drug Master File preparation and submission processes in the global pharmaceutical industry.

6. CONCLUSION

This study presented a comparative analysis of the Drug Master File (DMF) regulatory frameworks followed by the Central Drugs Standard Control Organization (CDSCO) in India and the United States Food and Drug Administration (USFDA). Drug Master Files are important regulatory documents that contain confidential information related to the manufacturing process, quality control, stability data, and packaging of pharmaceutical substances. These documents allow regulatory authorities to evaluate the safety, quality, and consistency of pharmaceutical products while protecting proprietary manufacturing information. The study found that the USFDA operates a more structured and well-established DMF regulatory system supported by clearly defined legal provisions and advanced electronic submission systems such as the electronic Common Technical Document (eCTD). These systems improve regulatory transparency, documentation management, and review efficiency. In contrast, CDSCO regulates pharmaceutical documentation through the Drugs and Cosmetics Act and has gradually introduced digital platforms such as the SUGAM portal, although the DMF framework is still evolving. The Amoxicillin API case study included in the research demonstrated the practical components of DMF documentation, including API specifications, analytical testing methods, and stability studies. Overall, the study concludes that strengthening regulatory guidance, expanding digital submission infrastructure, and aligning with international standards will improve the efficiency of the CDSCO regulatory system and support the global competitiveness of the Indian pharmaceutical industry.

7. CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest associated with this research work.

8. ACKNOWLEDGMENT

The authors express gratitude to academic mentors, regulatory professionals, and institutional support that contributed to the successful completion of this research work.

9. REFERENCES

1. Agarwal, P., & Badjatya, J. K., DMF filing in US, Europe and Canada. International Journal of Drug Regulatory Affairs, 2018; 3(4): 1–6. https://doi.org/10.22270/ijdra.v3i4.172
2. Sravanti, V. K. L., Bandla, R., & Reddy, R. K. J. (2021). Filing of DMF in the US, EU, and India and its comparative review. International Journal of Drug Regulatory Affairs, 2018; 9(1): 1–8. https://doi.org/10.22270/ijdra.v9i1.453
3. Kause, S., & Raut, P., Drug master file: A review. International Journal of Drug Regulatory Affairs, 2023; 11(2): 34–40. https://doi.org/10.22270/ijdra.v11i2.592
4. Patel, Y., & Pathan, A., Drug master file Electronic submission through eCTD: An overview. Trends in Drug Delivery, 2019; 6(1): 8–13. https://doi.org/10.37591/tdd.v6i1.447
5. U.S. Food and Drug Administration., Drug master files: Guidelines, 2020. https://doi.org/10.1016/j.drudis.2017.04.017 (Guidance documents describing DMF regulatory framework).
6. ICH., ICH harmonised guideline: Quality guideline Q7—Good manufacturing practice for active pharmaceutical ingredients, 2016. https://doi.org/10.1002/jps.2600740510
7. Creswell, J. W., & Creswell, J. D., *Research design: Qualitative, quantitative, and mixed methods approaches* (5th ed.), 2018. SAGE Publications.
8. Yin, R. K., *Case study research and applications: Design and methods* (6th ed.), 2018. SAGE Publications.
9. Hart, C., *Doing a literature review: Releasing the research imagination* (2nd ed.). SAGE Publications, 2018.
10. ICH., *ICH harmonised guideline: M4 – Organisation of the Common Technical Document for the registration of pharmaceuticals for human use*, 2016.
11. Booth, A., Sutton, A., & Papaioannou, D., *Systematic approaches to a successful literature review* (2nd ed.). SAGE Publications, 2016.
12. Snyder, H., Literature review as a research methodology: An overview and guidelines. *Journal of Business Research*, 2019; *104*: 333–339.
13. Kause, S., & Raut, P., Drug master file: A review. *International Journal of Drug Regulatory Affairs*, 2023; *11*(2): 34–40.
14. Sravanti, V. K. L., Bandla, R., & Reddy, R. K. J., Filing of DMF in the US, EU and India and its comparative review. *International Journal of Drug Regulatory Affairs*, 2021; *9*(1): 1–8.
15. Angell, M., *The truth about the drug companies: How they deceive us and what to do about it*. Random House, 2004.
16. Pisani, E., & Botchway, S., Regulatory harmonization and pharmaceutical trade. *Drug Discovery Today*, 2017; *22*(10): 1503–1507.
17. Brunton, L. L., Hilal-Dandan, R., & Knollmann, B. C., *Goodman & Gilman's the pharmacological basis of therapeutics* (13th ed.), 2018. McGraw Hill.
18. Rang, H. P., Dale, M. M., Ritter, J. M., Flower, R., & Henderson, G., *Rang and Dale's pharmacology* (9th ed.), 2019. Elsevier.
19. Zaidi, M., Zaidi, S. K., Bhutto, M., & Umer, M. Y., Amoxicillin And Clavulanic Acid–Induced Stevens–Johnson Syndrome: A Case Report. Excli Journal, 2017; 16: 748–751.

20. G. Indu, K. M.V.S R. Nagarjunnna. Drug Master File Filling In Us, Europe, Canada And Australia. Journal Of Pharmaceutical Research, 2017; 16(2): 160
21. P. Akhilesh, K. Pramod T. M. Dmf Filing In United States, Europe And Japan. World Journal Of Pharmacy And Pharmaceutical Sciences, 2014; 3(3): 323-27
22. S. Anusha, N.V.N Mounica .Processing And Submissiom Of Drug Master File. World Journal Of Pharmacy And Pharmaceutical Sciences, 2017; 6(3): 356-366
23. P. Kumar, B. Mangla, S. Singh. Drug Master File: Global Regulatory Issues And Challenges. European Journal Of Biomedical And Pharmaceutical Sciences, 2018; 5: 623-626.
24. K. Ashok, Hv. Nikhil, B. Rohinth. Regulatory Requirement And Filling Procedure Of Drug Master File In India Under Central Drug Standard Control Organization (Cdsco) In Comparison With South Korea. World Journal Of Advanced Research And Reviews, 2024; 23(3): 2960-2968.