Journal of Comprehensive Pharmaceutical Sciences
Online peer reviewed Journal I Published by COGNIX PRESS
Content available at www.cognixpress.in Online ISSN: 3139-5163

REVIEW ARTICLE
OPEN ACCESS

GMP CLEARANCE ROUTES AND PRODUCT CLASSIFICATION UNDER THAILAND'S REGULATORY FRAMEWORK FOR IMPORTED PHARMACEUTICALS: A DOCUMENTARY ANALYSIS OF REQUIREMENTS FOR INDIAN MANUFACTURING SITES

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Article History: 22.07.2026 Received: 11.08.2026 Revised: Accepted: 03.09.2026

ABSTRACT
The export of pharmaceutical products from India to Southeast Asian markets, particularly Thailand, has grown significantly due to India's cost-effective manufacturing capabilities, advanced chemical synthesis, and strong generic drug industry. However, entering the Thai pharmaceutical market requires strict compliance with regulatory requirements established by the Thai Food and Drug Administration (TFDA) under the Drug Act B.E. 2510 (1967) and its subsequent amendments, including Drug Act (No. 6) B.E. 2562. This study examines the regulatory framework governing pharmaceutical imports from India into Thailand, focusing on product classification, Pharmaceutical Inspection Co-operation Scheme (PIC/S) Good Manufacturing Practice (GMP) requirements, Site Master File (SMF) assessment, and ASEAN Common Technical Dossier (ACTD) submission procedures. It also evaluates stability testing requirements under ASEAN Climatic Zone IVb conditions (30°C ± 2°C / 75% RH ± 5% RH). Particular attention is given to regulatory challenges, including differences between India's Revised Schedule M and PIC/S GMP standards, product misclassification, dossier deficiencies, data integrity under ALCOA+ principles, computerized system validation, bioequivalence study requirements, and post-approval variations. The analysis highlights the importance of facility gap assessments, quality risk management, accurate regulatory documentation, and coordination with Thai Marketing Authorization Holders (MAHs). It emphasizes that compliance with TFDA requirements, regional harmonization standards, and international quality guidelines is essential for successful market entry. Overall, this study proposes a comprehensive regulatory compliance strategy to help Indian pharmaceutical manufacturers overcome regulatory barriers, reduce import delays, strengthen supply chain efficiency, and achieve sustainable commercial access to Thailand's pharmaceutical market.

Keywords: *Thailand Food and Drug Administration (TFDA); Good Manufacturing Practice (GMP); Indian Pharmaceutical Exports; ASEAN Common Technical Dossier (ACTD); Pharmaceutical Regulation; Product Classification.*

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INTRODUCTION

India is widely described as the 'pharmacy of the world,' supplying high-quality, cost-effective generic pharmaceuticals, active pharmaceutical ingredients (APIs), biologicals, and biosimilars to over 200 countries worldwide [1,8]. Within the vibrant Association of Southeast Asian Nations (ASEAN) economic community, Thailand represents one of the most strategic, highly regulated, and rapidly expanding destinations for Indian pharmaceutical exports [8,9]. Driven by universal healthcare coverage expansions under Thailand's Universal Coverage Scheme (UCS), a rapidly aging demographic profile, rising chronic non-communicable disease burdens, and increasing domestic demand for

affordable generic alternatives, Thailand's pharmaceutical import market offers substantial long-term commercial opportunities [2,8,10]. However, these lucrative market opportunities are counterbalanced by a complex, stringent, and continuously evolving regulatory framework administered by the Thai Food and Drug Administration (TFDA), operating under the overarching statutory authority of the Drug Act B.E. 2510 (1967) and its successive legislative amendments, including Drug Act (No. 6) B.E. 2562 (2019) [2,9].

For Indian pharmaceutical manufacturing sites, securing and maintaining market authorization in Thailand presents formidable regulatory challenges that demand deep institutional understanding and meticulous operational preparation [4, 8]. Unlike domestic Indian regulatory procedures historically governed by the Central Drugs Standard Control Organization (CDSCO) and State Licensing Authorities (SLAs) under Schedule M of the Drugs and Cosmetics Rules, 1945 [6], the TFDA enforces rigorous foreign inspection standards that demand strict adherence to the Pharmaceutical Inspection Co-operation Scheme (PIC/S) Good Manufacturing Practice (GMP) guidelines [3,4]. Having officially acceded to PIC/S in August 2016, the TFDA evaluates all overseas manufacturing sites against current PIC/S PE 009 standards [3,4]. Consequently, discrepancies in compliance mindsets, documentation architectures, quality management maturity, dossier formatting under the ASEAN Common Technical Dossier (ACTD) [5], and strict product classification protocols frequently result in application rejections, extensive deficiency queries, administrative bottlenecks, and costly port detentions [4,9,10].

Furthermore, the regulatory landscape governing imported pharmaceuticals in Thailand has undergone profound digital and procedural modernization in recent years [4,10]. The TFDA has progressively digitized its submission workflows through the SKYNET e-submission portal, instituted formal reliance pathways for Stringent Regulatory Authorities (SRAs), and intensified its scrutiny of data integrity (ALCOA+ principles), Quality Risk Management (QRM) [7], and continuous process verification across foreign manufacturing plants [3,4,9]. Simultaneously, India has initiated a major regulatory overhaul by notifying the Revised Schedule M in December 2023 [6], aiming to bridge the compliance divide with WHO-GMP and PIC/S standards. Despite this ongoing convergence, transitional friction remains acute for small, medium, and large Indian pharmaceutical exporters alike [6, 8].

To fully appreciate the complexity of this regulatory corridor, it is also necessary to examine the macroeconomic evolution of bilateral trade relations between India and Thailand [8]. While the India-Thailand Free Trade Agreement (FTA) and the broader ASEAN-India Trade in Goods Agreement (AITIGA) progressively reduced tariff barriers across chemical and pharmaceutical tariff lines, non-tariff barriers—specifically Technical Barriers to Trade (TBT) rooted in sanitary, phytosanitary, and stringent drug registration statutes—have assumed paramount significance [2,8,11]. Foreign manufacturers routinely discover that technical regulatory compliance represents a far more formidable market entry barrier than customs duties [8,9]. Navigating TFDA clearance routes therefore requires dedicated institutional resources, robust quality management systems, and a proactive posture toward international regulatory harmonization [3,7].

Despite the substantial commercial volume of the India-Thailand pharmaceutical trade corridor, there remains a pronounced gap in the academic and regulatory literature regarding a systematic, documentary analysis of how Indian manufacturing facilities can effectively navigate TFDA GMP clearance routes, statutory product classification mandates, and technical dossier requirements [4,8]. This article addresses this critical gap by conducting an exhaustive documentary analysis of Thai pharmaceutical regulations, evaluating the operational intersections between Indian manufacturing practices (CDSCO/Revised Schedule M) and TFDA PIC/S expectations, examining key technical dossier hurdles under the ACTD format, and proposing an actionable, multi-phase compliance roadmap for Indian pharmaceutical exporters [2,3,5,6].

2. MATERIALS AND METHODS

The present study is a descriptive, comparative regulatory review and documentary analysis carried out to understand the practical requirements for registering and exporting pharmaceutical products from Indian manufacturing sites to Thailand [2,4]. Instead of laboratory experimentation, regulatory affairs research relies on collecting, reviewing, and comparing official drug legislation, agency guidelines, and technical dossier formats across different national authorities. The goal of this methodology was to map out the step-by-step registration procedure in Thailand and identify the exact technical and GMP gaps that Indian pharmaceutical companies face during dossier submission and site clearance.

2.1 Collection of Regulatory Guidelines and Literature

The regulatory documents, official checklists, and literature required for this review were collected from official government portals and pharmaceutical databases. The primary data collection focused on four main regulatory sources: (a) Thailand's national drug laws, mainly the Drug Act B.E. 2510 (1967) and its latest amendment, Drug Act (No. 6) B.E. 2562 (2019), along with the Herbal Products Act B.E. 2562 (2019), accessed

through the official website of the Thai Food and Drug Administration (TFDA) [2]; (b) TFDA Drug Control Division guidelines and user manuals for the SKYNET electronic submission system, specifically covering overseas manufacturing site GMP clearance and modern drug registration [4]; (c) ASEAN harmonization guidelines downloaded from the ASEAN Secretariat portal, which include the ASEAN Common Technical Dossier (ACTD) format, the ASEAN Guideline on Stability Study of Drug Product, Bioequivalence (BE) study guidelines, and the ASEAN Variation Guidelines [5,12]; and (d) Indian and international GMP standards, specifically the Central Drugs Standard Control Organization (CDSCO) Revised Schedule M notification (G.S.R. 922(E), December 2023) [6], the PIC/S GMP Guide (PE 009-16) [3], and ICH Q9(R1) guidelines on Quality Risk Management [7].

2.2 Secondary Data and Industry Reports

In addition to official agency guidelines, secondary information was gathered from export reports published by the Pharmaceuticals Export Promotion Council of India (Pharmexcil) [8] to understand the current trade volume and common export hurdles between India and Southeast Asia. Practical regulatory articles, market entry guides, and review papers from regulatory databases (such as Google Scholar, PubMed, Artixio, Credevo, and PharmaTradz) were also reviewed [9,10,11]. Using keywords such as 'Thai FDA drug registration,' 'PIC/S GMP clearance Thailand,' 'ACTD dossier requirements,' and 'Revised Schedule M vs PIC/S,' relevant literature was shortlisted to see how official rules are actually applied during dossier screening.

2.3 Step-by-Step Comparative Analysis

After gathering the required guidelines, a direct, side-by-side comparison of the documents was performed across four practical areas of regulatory affairs:

(1) Product Classification: The definitions and categories under the Thai Drug Act were reviewed to see how prescription generics, OTC medicines, APIs, and borderline herbal/nutraceutical products are separated by the TFDA [2,9];

(2) GMP Clearance for Indian Sites: The requirements for foreign site approval in Thailand were broken down based on whether an Indian plant holds a PIC/S or Stringent Regulatory Authority (SRA) approval versus only a state/CDSCO WHO-GMP certificate [3,4]. Furthermore, the clauses of India's Revised Schedule M were compared point-by-point with PIC/S PE 009 to highlight common audit observations [3,6];

(3) Dossier Preparation (ACTD Format): The structure of ACTD Parts I to IV was studied, with particular attention given to Chemistry, Manufacturing, and Controls (CMC) data, real-time stability testing requirements for ASEAN Climatic Zone IVb (30°C ± 2°C / 75% RH ± 5% RH), and comparator bridging for bioequivalence studies [5,10,12]; and

(4) Post-Approval Maintenance: The timelines for answering TFDA deficiency letters and filing post-approval changes under ASEAN variation rules were summarized [4,5,10].

2.4 Scope and Limitations of the Study

Since several official circulars and ministerial notifications from the Ministry of Public Health in Thailand are originally published in the Thai language, this study relied on official English translations provided by the TFDA, ASEAN harmonization documents in English, and verified regulatory intelligence summaries [4,5,9]. Furthermore, because this work is based entirely on publicly available guidelines and documentary review rather than confidential company dossiers or internal TFDA review logs, the findings reflect standard statutory procedures and commonly reported industry challenges [8,10].

3. RESULTS

The documentary analysis yielded comprehensive, structured findings across the primary regulatory pillars governing Indian pharmaceutical imports into Thailand: Statutory Product Classification, Overseas PIC/S GMP Clearance Routes, and ACTD Technical Dossier Standardization [2,3,4,5].

3.1 Statutory Product Classification Frameworks and Categorization Challenges

The analysis demonstrates that the TFDA enforces a highly granular, multi-layered statutory classification system under the Drug Act B.E. 2510 and related health product statutes [2,9]. Before an Indian manufacturer or its local Thai representative can initiate GMP site clearance or product registration, the product must be accurately classified along two distinct axes: (a) the overarching health product category (Modern Drug, Traditional/Herbal Product, Food Supplement, Medical Device, or Cosmetic), and (b) the specific risk and dispensing classification within the Modern Drug regime [2,9,10].

Within the statutory definition of 'Modern Drugs' (pharmaceuticals intended for human use derived from chemical synthesis or biotechnology), the TFDA subdivides products into four dispensing and control categories:

(1) Specially Controlled Drugs (Ya Khum Phiset), which encompass high-risk therapeutics, prescription-only innovators, biologics, and drugs requiring intensive safety monitoring;

(2) Dangerous Drugs (Ya Antarai), which constitute the vast majority of standard prescription and pharmacist-dispensed generic pharmaceuticals exported from India

(such as antihypertensives, antibiotics, and bronchodilators);
(3) Non-Dangerous Drugs (Ya Samai Plan), which may be sold in licensed general drugstores without a pharmacist on duty; and
(4) Household Remedies (Ya Samai Prajam Ban), consisting of low-risk over-the-counter (OTC) preparations permitted for general retail distribution [2,9,10].
Furthermore, based on novelty and clinical history, registration applications are routed into New Drugs (New Chemical Entities, New Indications, or New Delivery Systems), New Generic Drugs (off-patent formulations requiring full bioequivalence and quality modules), or Biologics/Biosimilars [4,10].
A critical finding of the documentary review is that misclassification of borderline products is a primary cause of pre-submission rejection and port detention [9,10]. In Thailand, products containing vitamins, minerals, amino acids, or standardized botanical extracts frequently straddle the legal boundaries between the Drug Act B.E. 2510, the Herbal Products Act B.E. 2562, and the Food Act B.E. 2522 [2,9]. When an Indian manufacturer formulates a nutraceutical or herbal combination that exceeds TFDA daily allowance thresholds for food supplements or makes explicit therapeutic or prophylactic claims, the TFDA strictly applies the pharmaceutical statutory regime [2,9]. Similarly, Active Pharmaceutical Ingredients (APIs) exported from India to Thailand for local formulation are regulated as raw material drugs, requiring pre-import notifications, Certificates of Analysis (CoA), and alignment with recognized pharmacopoeias (USP, BP, EP, or Thai Pharmacopoeia) alongside Drug Master File (DMF) or Certificate of Suitability (CEP) verification [4,11].

Table 01: Summary of Thai FDA product classifications and registration requirements for imported pharmaceuticals

Category / Classification	Statutory / Regulatory Basis	Primary Control & Registration Requirements
Specially Controlled Drugs	Drug Act B.E. 2510	Prescription-only; strict hospital/clinic control; full ACTD Modules 1-5; mandatory safety monitoring program (SMP) for new drugs [2,10].
Dangerous Drugs	Drug Act B.E. 2510	Dispensed by licensed pharmacist; primary category for Indian generic exports; requires ACTD Modules 1-3 and Module 5 BE studies [2,5,10].
Non-Dangerous & Household Drugs	Drug Act B.E. 2510	OTC / general retail distribution; abridged clinical requirements; strict Thai consumer labeling and warning mandates [2,9].
Category / Classification	**Statutory / Regulatory Basis**	**Primary Control & Registration Requirements**
Active Pharmaceutical Ingredients (APIs)	TFDA Import Notifications	Pre-import declaration via local licensee; open/closed part DMF or EDQM CEP; pharmacopoeial compliance (USP/BP/EP/TP) [4,11].
Borderline / Herbal / Combination	Drug Act & Herbal Products Act B.E. 2562	Mandatory pre-classification consultation; defaults to stringent modern drug regime if therapeutic claims or high active doses exist [2, 9].

3.2 PIC/S GMP Clearance Routes for Overseas (Indian) Manufacturing Sites

Under TFDA regulations instituted to harmonize with PIC/S standards, no foreign pharmaceutical product can be registered or imported into Thailand unless its overseas manufacturing site holds a valid TFDA GMP Clearance approval [3,4]. This requirement applies universally to finished dosage form (FDF) manufacturers, primary and secondary packaging sites, and external quality control testing laboratories [4,9]. The documentary analysis identifies three distinct clearance pathways, a condensation of the route cases defined in the notification and its annexes, and stringent evidentiary requirements that Indian manufacturing plants must navigate:
1. Mandatory Local Licensee Representation: A foreign pharmaceutical manufacturer in India has no legal standing to file regulatory applications directly with the TFDA [2, 4]. The Indian manufacturer must execute a formal legal mandate appointing a Thai-registered corporate entity holding a valid Drug Importation License (Nor.Yor.1) to act as the local Marketing Authorization Holder (MAH) and importer of record [2, 4, 9]. The local MAH submits all GMP clearance documents through the TFDA SKYNET electronic system and

assumes full statutory liability for product quality, batch recalls, and pharmacovigilance within Thailand [4, 9].

2. Documentary Evidence & Equivalence Pathways: The TFDA routes foreign GMP clearance applications into three evaluation tracks based on the regulatory pedigree of the certifying authority [3,4,9]: (a) The PIC/S & SRA (Stringent Regulatory Authority) Reliance Pathway, applicable when the Indian manufacturing facility holds a current GMP certificate and inspection report issued by a PIC/S Participating Authority (e.g., US FDA, EMA, UK MHRA, TGA Australia, Health Canada, or PMDA Japan). This route qualifies for an expedited documentary desk review [3,4]; (b) The WHO-GMP / Non-PIC/S Documentary Evaluation Pathway, which applies to the majority of Indian manufacturing sites certified solely by Indian CDSCO/State FDAs under WHO-GMP Certificate of Pharmaceutical Product (CoPP) schemes. Under this route, the TFDA conducts an exhaustive technical audit of the facility's Site Master File (SMF), quality management documentation, validation master plans, and recent CDSCO inspection reports to verify complete equivalence with PIC/S PE 009 standards [3,4,6]; and (c) The On-Site Physical Inspection Pathway, triggered when documentary evidence is insufficient, when a site manufactures high-risk sterile or biological products without SRA/PIC/S certification, or when historical compliance discrepancies exist. In such cases, TFDA inspectors travel to India to conduct a rigorous physical audit of the plant at the applicant's expense [4,9].

3. Core GMP Clearance Dossier format: To pass the TFDA desk review, the Indian manufacturing site must provide a comprehensive, authenticated documentation package [4,9]. This includes a legalized GMP certificate or CoPP, a complete Manufacturing License issued by the relevant Indian State/Central authority, a PIC/S-compliant Site Master File (SMF) no older than two years (complete with high-resolution architectural layouts showing personnel and material flows, HVAC pressure cascade diagrams, and water system schematics), a comprehensive list of products manufactured on the specific production line, and full inspection reports from the most recent regulatory audit accompanied by closed Corrective and Preventive Action (CAPA) evidence [3,4,9].

3.3Dossier Requirements, ACTD Harmonization, and Stability Protocols

Once the Indian manufacturing site's GMP clearance is initiated or secured, the product registration dossier must be compiled and submitted via the TFDA e-CTD/SKYNET portal in strict accordance with the ASEAN Common Technical Dossier (ACTD) format [4,5,10]. Unlike the five-module ICH CTD structure used in the US and EU, the ACTD organizes technical data into four parts: Part I (Administrative Data and Product Information), Part II (Quality / CMC Document), Part III (Non-Clinical Document), and Part IV (Clinical Document) [5,9,10].

Table 02: ASEAN Common Technical Dossier (ACTD) structure and TFDA focus areas.

ACTD Part / Equivalent Module	Core Documentary Components	Key TFDA Technical Compliance Focus
Part I (Module 1)	Administrative Data & Product Information	Application forms, legalized CoPP, Free Sale Certificate, Loa/PoA, Thai-language outer/inner labels, and Patient Information Leaflets (PIL) [4, 5, 9].
Part II (Modules 2.3 & 3)	Quality / Chemistry, Manufacturing & Controls (CMC)	Drug substance (S1-S7) and Drug product (P1-P9) data: master batch records, process validation on 3 commercial batches, analytical validation, and Zone IVb stability [5, 10, 12].
Part III (Modules 2.4, 2.6 & 4)	Non-Clinical Document (Toxicology & Pharmacology)	Mandatory for New Chemical Entities (NCEs) and biologics; generally waived for established generic products registered via abridged pathways [5, 10].
Part IV (Modules 2.5, 2.7 & 5)	Clinical Document & Bioequivalence (BE) Reports	Clinical efficacy trials for innovators; in vivo Bioequivalence (BE) studies and comparative dissolution profiles against the Thai comparator product for generics [5, 9, 10].

3.4 Stability Testing under ASEAN Climatic Zone IVb and Bioequivalence Mandates

Within Part II (Quality) and Part IV (Clinical) of the ACTD dossier, the documentary analysis reveals two major technical hurdles that frequently delay Indian generic drug approvals in Thailand: Climatic Zone IVb stability compliance and Bioequivalence (BE) study design [5, 10, 12]. First, Thailand strictly enforces the ASEAN Guideline on Stability Study of Drug Product, which designates the region as Climatic Zone IVb (hot and very humid climate) [5, 12]. Consequently, Indian manufacturers must submit long-term real-time stability data generated at 30°C ± 2°C and 75% RH ± 5% RH (minimum 12 months at submission, covering at least three primary batches) alongside accelerated stability data at 40°C ± 2°C and 75% RH ± 5% RH for 6 months [12]. Because domestic Indian stability protocols historically permitted testing under Zone III or Zone IVa (30°C / 65% RH or 70% RH) conditions, dossiers submitted with non-Zone IVb stability data—or lacking stability studies conducted in the exact container-closure system (e.g., Alu-Alu or high-barrier PVdC blisters) intended for commercial marketing in Thailand—are summarily issued deficiency letters [10, 12].

Second, for generic oral solid dosage forms (particularly immediate-release and modified-release prescription drugs classified as Dangerous Drugs), the TFDA mandates full in vivo Bioequivalence (BE) studies in accordance with ASEAN BE guidelines [5, 9, 10]. A critical compliance requirement is the selection of the Reference Listed Drug (RLD) / Thai comparator product. Indian manufacturers frequently conduct BE studies using an Indian or European reference product to support multi-country filings. To be accepted by the TFDA, the applicant must provide rigorous bridging data—including qualitative and quantitative composition evidence, manufacturing site verification, and multi-media comparative dissolution profiles (pH 1.2, 4.5, and 6.8)—proving that the foreign reference product used in the BE study is identical to the innovator product registered in Thailand [5, 10]. Furthermore, the clinical and bioanalytical sites in India conducting the BE study must adhere strictly to Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) standards recognized by the TFDA [4, 10].

3.5 Labeling, Packaging, and Thai Language Statutory Mandates

The analysis of ACTD Part I requirements highlights uncompromising statutory mandates regarding product labeling, serialization, and package inserts under the Drug Act B.E. 2510 [2, 4, 9]. All imported pharmaceutical products distributed in Thailand must incorporate mandatory Thai-language text on their commercial labels and Patient Information Leaflets (PILs), including the drug category designation (e.g., 'Ya Antarai' printed in red bold Thai script inside a rectangular border), the Thai registration number, storage conditions reflecting Zone IVb parameters, active ingredient strengths, batch numbers, manufacturing and expiry dates, and statutory warning statements mandated by the Ministry of Public Health [2, 9]. Discrepancies between the artwork approved in Part I of the ACTD dossier and the physical commercial stock arriving at Thai customs ports result in immediate shipment detention and potential import license suspension [2, 4, 9].

4. RESULTS AND DISCUSSION

The findings of this documentary analysis underscore that while India's pharmaceutical manufacturing sector possesses unmatched production scale, active ingredient self-sufficiency, and cost advantages, successfully commercialising products in the Thai market requires a strategic paradigm shift from volume-driven export execution to precision-based regulatory engineering [1, 2, 8].

4.1 Navigating the Schedule M to PIC/S Transition

A primary insight emerging from the analysis is the operational friction caused by transitional compliance standards between Indian domestic manufacturing schedules and international PIC/S benchmarks [3, 6]. Although the Indian government's notification of the Revised Schedule M [6] represents a landmark step toward global regulatory convergence, regulatory maturity on the plant floor cannot be achieved merely by updating standard operating procedures on paper. TFDA reviewers evaluating Indian Site Master Files and inspection histories focus heavily on empirical evidence of quality culture—specifically scrutinizing computerized system validation (CSV), audit trail review practices, environmental monitoring trend analyses, and scientific root-cause investigations for Out-of-Specification (OOS) results [3,4, 6]. Consequently, Indian manufacturers that lack prior US FDA, EMA, or PIC/S inspection credentials must execute comprehensive, independent mock PIC/S gap audits and remediate all facility and QMS vulnerabilities prior to submitting GMP clearance applications to the TFDA [3, 4, 9].

4.2 Strategic Management of Local MAH Partnerships and Deficiency Timelines

Furthermore, the statutory prohibition against foreign entities holding direct marketing authorizations or import licenses in Thailand creates a critical structural dependency on local Thai Marketing Authorization Holders (MAHs) [2, 4, 9]. Whether an Indian pharmaceutical company incorporates a wholly owned Thai subsidiary (which itself must secure a local drug

importation license and employ qualified Thai resident pharmacists) or partners with a third-party Thai distributor, the local MAH controls the interface with the TFDA SKYNET portal [4, 9, 11]. During the technical evaluation of both GMP clearance packages and ACTD dossiers, the TFDA enforces strict statutory clock-stops, typically granting only 30 to 60 calendar days to respond to formal deficiency letters (often limited to a maximum of two clarification rounds) [4, 10]. Any administrative lag, translation inaccuracy, or technical miscommunication between the Indian plant's regulatory affairs team and the local Thai MAH can result in automatic application rejection and forfeiture of regulatory fees [9, 10]. Establishing robust, legally binding Quality Technical Agreements (QTAs) and service-level agreements with experienced Thai regulatory partners is therefore indispensable [7, 9, 11].

4.3 Quality Risk Management and Supply Chain Economics

From an economic and supply chain perspective, the cost of regulatory non-compliance in the India-Thailand pharmaceutical corridor far outweighs the investment required for upfront compliance readiness [7, 8]. When a dossier is rejected due to missing Zone IVb stability data, inadequate BE bridging justifications, or expired GMP certificates, the resulting 12-to-24-month delay in market entry erodes first-mover generic advantages and locks up working capital [8, 10, 12]. By embedding ICH Q9(R1) Quality Risk Management principles [7] across the entire export development lifecycle—starting with formulation packaging selection (opting for high-barrier Alu-Alu blisters capable of withstanding 30°C/75% RH), executing Zone IVb stability studies from day one [12], and maintaining a living, PIC/S-compliant Site Master File [3]- Indian pharmaceutical exporters can drastically compress TFDA review timelines and achieve predictable commercial launches [8, 9, 10].

4.4 Post-Approval Lifecycle Maintenance and ASEAN Harmonisation Outlook

Finally, regulatory compliance does not conclude upon the issuance of a TFDA product registration certificate and GMP clearance [4, 5]. Under the ASEAN Variation Guidelines adopted by the TFDA, any post-approval change at the Indian manufacturing site-including major variations (MaV) such as adding an alternate API source, modifying batch sizes, or relocating manufacturing equipment, as well as minor variations requiring prior approval (MiV-PA) or notification (MiV-N)-must be formally filed and approved before modified batches are exported to Thailand [4, 5, 10]. Moreover, foreign GMP clearances must be proactively renewed prior to expiration to prevent customs blocks on active commercial shipments [4, 9]. Looking forward, while ASEAN member states continue to deepen mutual recognition arrangements (MRAs) and reliance mechanisms, the TFDA's growing use of digital dossier screening and stringent post-market pharmacovigilance means that only manufacturers with institutionalized regulatory excellence will thrive in Thailand's evolving healthcare ecosystem [2, 4, 8].

5. CONCLUSION

Navigating Thailand's regulatory framework for imported pharmaceuticals is a rigorous, multi-dimensional undertaking that demands seamless alignment with the Thai Drug Act B.E. 2510, PIC/S Good Manufacturing Practice (GMP) standards, and ASEAN Common Technical Dossier (ACTD) specifications [2, 3, 5]. As this documentary analysis demonstrates, Indian pharmaceutical manufacturing sites seeking to capture growth opportunities in the Thai market must look beyond domestic baseline compliance to institutionalise global quality benchmarks [1, 6, 8].

By accurately establishing statutory product classifications prior to submission, bridging operational gaps between India's Revised Schedule M and PIC/S PE 009 expectations, generating robust real-time stability data under ASEAN Climatic Zone IVb conditions (30°C / 75% RH), and forging tightly coordinated partnerships with qualified local Thai Marketing Authorization Holders, Indian exporters can systematically eliminate the primary triggers of TFDA deficiency letters and port detentions [2, 3, 6, 9, 12]. Ultimately, treating regulatory compliance as a core strategic pillar rather than an administrative afterthought will not only accelerate time-to-market in Thailand but also strengthen India's standing as a premier, reliable supplier of high-quality medicines across the broader ASEAN region [1, 8].

FUNDING

This study received no external funding.

INFORM CONSENT AND ETHICAL STATEMNT

Not Applicable

AUTHOR CONTRIBUTION

All authors are contributed equally.

ACKNOWLEDGEMNET

Not Declared

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