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KEY GMP AND GCP REQUIREMENTS FOR GENERIC DRUG REGULATIONS IN BRICS, MIST, AND ICH COUNTRIES: A COMPARATIVE REVIEW

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ABSTRACT

Plant-derived medicines are licensed under regulatory categories that sit between traditional herbal preparations and fully synthetic new chemical entities, yet the data requirements attached to their market authorisation differ markedly across jurisdictions, and those differences are themselves inconsistent. BRICS nations — Brazil, Russia, India, China, and South Africa — together with MIST economies — Mexico, Indonesia, South Korea, and Turkey — collectively accounted for roughly 20% of global pharmaceutical sales by 2019 and are projected to represent over 30% by 2025. Despite sharing this growth trajectory, the Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) frameworks these countries apply to generic drug registrations diverge across dossier format, local language obligations, bioequivalence study design, and the degree of alignment with internationally harmonized standards. This review compares the key GMP and GCP requirements for generic drug approval across BRICS, MIST, and ICH-member nations, drawing on primary regulatory texts and peer-reviewed literature retrieved from PubMed, ScienceDirect, the International Journal of Drug Regulatory Affairs, and official agency websites. The analysis finds that ICH-member countries maintain the most coherent and predictable approval frameworks, while substantial heterogeneity persists within and across the BRICS and MIST groupings. South Korea and Turkey, both full ICH and PIC/S members, most closely mirror Western regulatory norms within MIST, whereas Russia, Indonesia, and China retain requirements that depart from international consensus. Within BRICS, India and Brazil have advanced furthest toward harmonization. The review closes by identifying actionable convergence opportunities and proposing concrete measures to improve GMP/GCP alignment and, in turn, generic medicine access and patient safety.

KEYWORDS: GMP, GCP, generic drugs, BRICS, MIST, ICH, CDSCO, ANVISA, NMPA, PIC/S, bioequivalence, regulatory harmonization.

1. INTRODUCTION

Generic drugs underpin affordable medicine supply across every healthcare system. In the United States, generics fill close to 90% of all prescriptions yet account for only around 18% of total drug expenditure, illustrating the economic leverage they provide.[12] The strategic weight of generics is even greater in lower- and middle-income settings, where access to essential medicines depends heavily on the availability of off-patent alternatives once innovator exclusivity lapses.

The pharmaceutical markets of the BRICS and MIST blocs occupy a pivotal position in this picture. These nine countries roughly doubled their combined pharmaceutical revenues over five years, capturing approximately 20% of worldwide sales, with multiple analyses projecting that figure will surpass 30% before 2030.[5,14] Hundreds of generic manufacturers operate across these markets, serving billions of patients whose medicine access is shaped by the regulatory environments those manufacturers must navigate.

Two categories of requirement control whether a generic drug is approved: Good Manufacturing Practice, which defines the conditions under which a product must be produced to guarantee consistent quality, purity, and potency; and Good Clinical Practice, which governs the bioequivalence and bioavailability studies required to establish pharmaceutical equivalence with the reference innovator. Both originate in internationally harmonized frameworks — principally ICH Q7 for active pharmaceutical ingredient GMP, ICH E6(R2) for GCP, the WHO GMP standards, and the PIC/S Guide to GMP for Medicinal Products.[10,17] Nevertheless, the degree to which BRICS and MIST countries have adopted, adapted, or departed from these frameworks varies widely.[14,17]

Practical consequences follow directly. A company seeking simultaneous generic registration in Brazil, India, South Korea, and Indonesia must engage four separate regulatory authorities, potentially in four different dossier formats, with differing bioequivalence data requirements and GMP inspection processes that may not recognize one another's certificates.[14] Such fragmentation raises development costs, defers patient access, and injects regulatory unpredictability into investment decisions. A structured, country-level mapping of GMP and GCP requirements across these markets therefore carries both scholarly and practical value.

1.1 Scope and Objectives

- Compare GMP frameworks for generic drug manufacturing across all nine BRICS and MIST countries against the consolidated ICH-member standard.
- Map GCP and bioequivalence study requirements — including study design, reference product rules, and ethics committee obligations — across the same jurisdictions.
- Identify specific points of convergence and divergence, supported by quantitative data where available.
- Propose targeted, evidence-grounded recommendations for improving GMP/GCP alignment to accelerate generic drug regulatory efficiency across these markets.

2. METHODOLOGY

This is a structured literature-based comparative review; no primary clinical, manufacturing, or survey data was collected. The search covered PubMed/MEDLINE, ScienceDirect, Google Scholar, the International Journal of Drug Regulatory Affairs (IJDRA), and the International Journal of Pharmaceutical Investigation (IJPI), alongside official regulatory agency websites for all nine countries reviewed: CDSCO (cdsco.gov.in), ANVISA (anvisa.gov.br), NMPA (nmpa.gov.cn), the Russian Ministry of Health (roszdravnadzor.gov.ru), SAHPRA (sahpra.org.za), COFEPRIS (gob.mx/cofepris), BPOM (pom.go.id), MFDS (mfds.go.kr), and TITCK (titck.gov.tr). ICH and PIC/S primary guideline texts were obtained directly from ich.org and picscheme.org. Search terms included combinations of 'GMP,' 'GCP,' 'generic drug,' 'bioequivalence,' 'BRICS,' 'MIST,' 'ICH,' 'PIC/S,' and the agency abbreviations for each country covered. Peer-reviewed publications from 2016 onward were prioritized; primary regulatory texts and guidelines were cited regardless of date where they remain in force. A source was included if it directly addressed GMP, GCP, or generic drug registration requirements in at least one of the nine focal jurisdictions.

3. Pharmaceutical Market Landscape of BRICS and MIST Countries

The combined pharmaceutical markets of BRICS and MIST nations are among the fastest-growing in global healthcare. As Figure 1 illustrates, these nine countries held approximately 20% of worldwide pharmaceutical sales as of 2019, a share projected to exceed 30% by 2025, driven by demographic growth, rising insurance coverage, expanding domestic manufacturing, and the patent expiration of major originator products.[5,14]

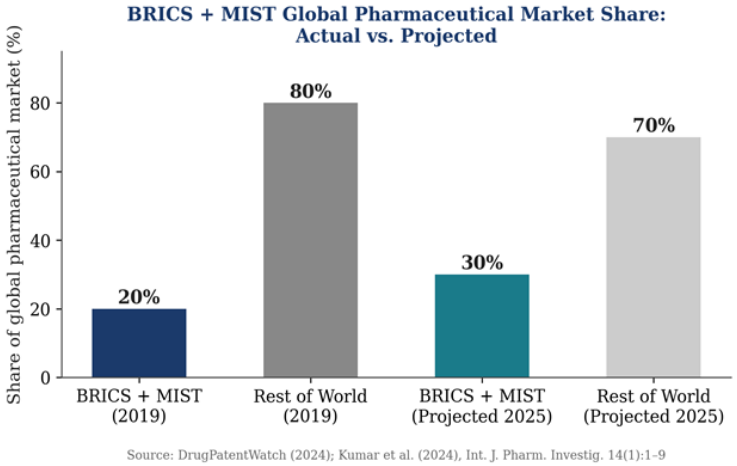

Figure 1: Estimated share of global pharmaceutical market held by BRICS and MIST countries, 2019 actual vs. projected 2025. Source: DrugPatentWatch;[5] Kumar et al.[14]

India leads the world in generic medicine exports by volume, supplying approximately 20% of global generic drug demand.[12] China's NMPA completed a sweeping reform of its generic drug review system between 2015 and 2019, clearing a large backlog of unapproved applications and substantially raising the technical threshold for approval toward international benchmarks. Brazil's ANVISA attained full PIC/S membership in 2022, a benchmark that recognises the maturity of its GMP inspection infrastructure.[8] South Africa's SAHPRA has aligned its processes with WHO prequalification standards, with generics accounting for roughly 40% of the domestic market and expected to outpace originator sales by 2027.[5]

Within MIST, South Korea's MFDS is a full ICH and PIC/S member, operating GMP and GCP oversight systems comparable in rigor to the US FDA or EMA.[16] Turkey's TITCK joined PIC/S in 2010 and has progressively converged toward EU GMP norms, though procedural inconsistencies in implementation were noted in a 2018 cross-agency comparison.[1] Mexico's COFEPRIS achieved PIC/S membership in 2018 and updated its GMP guidelines through a 2025 strategic agenda.[19] Indonesia's BPOM and Russia's Ministry of Health represent the most significant remaining gaps from international norms within their respective blocs, the former still outside PIC/S and the latter maintaining language and procedural requirements that fragment its regulatory process from those of major trading partners.[14]

4. Key GMP Requirements for Generic Drug Manufacturing

4.1 International GMP Framework: ICH Q7 and PIC/S

Two international frameworks anchor GMP requirements for generic drug manufacturing. ICH Q7, the Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, defines the production standards applicable across all ICH member and observer countries, covering quality management systems, personnel, facilities and equipment, documentation, material controls, production processes, packaging, laboratory testing, validation, and change control.[10] A November 2024 interpretive update issued by the Active Pharmaceutical Ingredients Committee (APIC) revised chapters on quality management, process equipment, and change control to incorporate ICH Q9(R1) risk-based principles into manufacturing oversight.[10]

For finished dosage form manufacturers, the PIC/S Guide to GMP for Medicinal Products serves as the primary international benchmark.[17] PIC/S membership signals that a country's national GMP standards and inspection systems have met independently verified international criteria. Among BRICS and MIST nations, Brazil (ANVISA), Mexico (COFEPRIS), South Korea (MFDS), and Turkey (TITCK) currently hold PIC/S membership, giving these four the most externally validated inspection systems in the group.[5,14] India's CDSCO and South Africa's SAHPRA are in active accession processes, while China and Indonesia have not yet joined; Russia maintains select bilateral recognition agreements but is not a PIC/S member.[5,17]

4.2 BRICS Country-Specific GMP Requirements

India (CDSCO/DCGI): India's GMP framework for pharmaceutical manufacturing is governed by Schedule M of the Drugs and Cosmetics Act, 1940, which was comprehensively overhauled in 2023 to better reflect current international standards.[9] Generic drug manufacturers must hold a valid manufacturing licence under Schedule M-I and face periodic inspections by State Licensing Authorities (SLAs), with CDSCO directly overseeing export-oriented units. A comparative analysis of GMP containment requirements across major regulatory agencies found that CDSCO mandates segregated, rather than fully dedicated, areas for highly active APIs, a distinction that sets it apart from the FDA, EMA, and COFEPRIS, all of which require completely dedicated facilities for such substances.[20]

Brazil (ANVISA): ANVISA issues its own GMP certificate for any manufacturing site seeking Brazilian market authorization; initial certification requires a direct on-site ANVISA inspection, while re-certifications proceed through a risk-based assessment process.[8] Since achieving PIC/S accession in 2022, ANVISA's inspection procedures are now benchmarked against internationally agreed criteria, consolidating its position as one of the most technically rigorous GMP authorities in Latin America.[8] Bioequivalence studies for generic drugs must be conducted using Brazilian-approved reference products at ANVISA-accredited study centers.[7]

China (NMPA): China's GMP requirements were fundamentally reformed from 2010 onward through the Chinese GMP Standard of 2010, which drew substantially on both WHO and EU GMP frameworks.[13]

Between 2016 and 2019, NMPA implemented a consistency evaluation program requiring that previously approved generics demonstrate quality and efficacy equivalence with the originator, a reform that materially raised domestic GMP and bioequivalence standards.[13] Manufacturing sites supplying the Chinese market are inspected by NMPA directly; unlike most ICH-member jurisdictions, domestic submissions must be documented in Mandarin, and mutual recognition of GMP inspection outcomes with non-PIC/S countries is currently limited.[13]

Russia (Ministry of Health): Russia's GMP requirements are established through GOST R 52249, the national standard modeled primarily on EU GMP, and generic drug registrations are processed under Federal Law No. 61-FZ.[14] Full dossier submissions must be prepared in Russian, and while Russia nominally adopts the ICH

CTD format, its Module 1 national requirements differ substantially from those of other ICH-aligned jurisdictions. GMP inspections are conducted by Roszdravnadzor, which has neither PIC/S membership nor broad bilateral inspection recognition with major Western agencies, creating a structural barrier to concurrent multi-market registration.[14]

South Africa (SAHPRA): SAHPRA applies GMP requirements aligned with WHO standards and has made demonstrable progress toward PIC/S and ICH alignment through risk-based application prioritization measures that have reduced approval timelines to approximately 12 months for well-prepared submissions.[5] A UNIDO and Italian Government-funded project specifically targeted the development of GMP-compliant biologics and vaccine manufacturing capacity within South Africa, reflecting the ongoing need for infrastructure investment alongside regulatory advancement.[18]

4.3 MIST Country-Specific GMP Requirements

Mexico (COFEPRIS): Mexico entered PIC/S in January 2018, a formal acknowledgment of the maturity of its GMP inspection systems.[19] Manufacturers seeking Mexican marketing authorization must request a COFEPRIS GMP inspection before dossier submission, though holders of GMP certificates from COFEPRIS-designated reference agencies may qualify for inspection waivers. Foreign GMP certificates must be apostilled or legalized and are subject to independent COFEPRIS verification.[11] Generic dossiers in Mexico use a three-module format with BA/BE data in Module 3, and approval timelines typically run 12 to 24 months.[11,19]

Indonesia (BPOM): BPOM governs generic drug registration and GMP compliance in Indonesia; the agency has made incremental progress toward international alignment but is not yet a PIC/S member, and its inspection framework is regarded as partially aligned with WHO GMP standards.[14] Dossier submissions follow a modified CTD format that includes Bahasa Indonesia sections and country-specific Module 1 documentation; bioequivalence studies must be carried out at accredited domestic centers, and approval timelines are among the longest in the MIST group at 18 to 24 months.[14]

South Korea (MFDS): As both a full ICH member and PIC/S member, South Korea's MFDS maintains one of the most internationally harmonized regulatory frameworks among BRICS and MIST nations.[16] The MFDS GMP Guideline No. 2021-87 specifies enforcement procedures, GMP certificate validity periods, and documentation expectations for medicinal product manufacturers.[16] Generic approvals require bioequivalence data and quality documentation in lieu of full clinical safety and efficacy data, consistent with the ICH abbreviated new drug application model; South Korea also participates in international joint GMP inspection programs that facilitate mutual recognition with recognized authorities.[15,16]

Turkey (TITCK): TITCK joined PIC/S in 2010 and has progressively aligned its regulatory framework with EU GMP and ICH standards.[1] A cross-agency comparison of TITCK against TGA (Australia), Health Canada, SFDA (Saudi Arabia), and HSA (Singapore) found that TITCK's review timelines exceeded its own internal targets and recommended that TITCK formalize the sharing of GMP inspection outcomes and certificates with peer recognized authorities — a practice not fully in place at the time of that study.[1] Generic drug registration requires evidence of approval in another jurisdiction, though a Certificate of Pharmaceutical Product from the country of manufacture is not mandatory.[1]

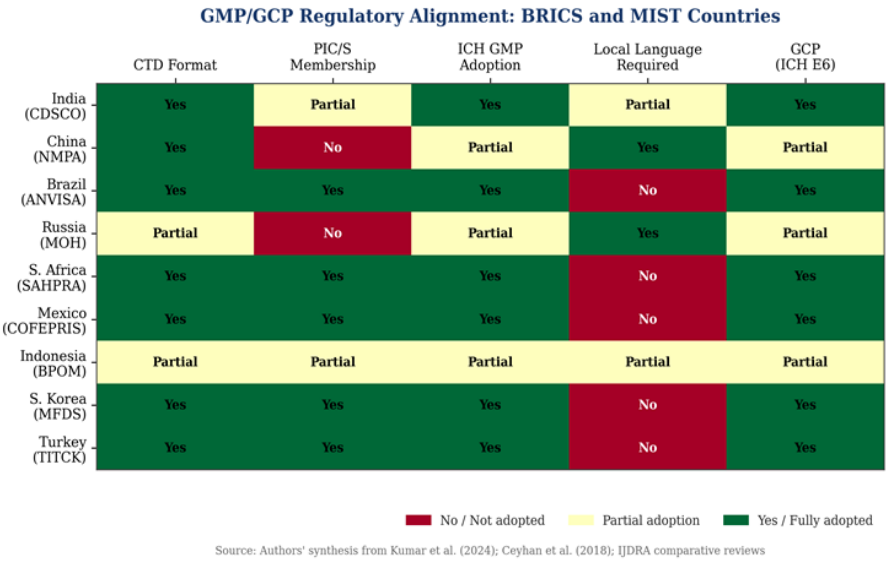

Figure 2: GMP/GCP regulatory alignment matrix across nine BRICS and MIST countries and five key regulatory domains. Author-constructed synthesis from Kumar et al.,[14] Ceyhan et al.,[1] Patil et al.,[17] and primary agency sources.

5. Key GCP Requirements for Generic Drug Clinical Studies

5.1 International GCP Framework: ICH E6(R2) and Bioequivalence Principles

For generic drugs, Good Clinical Practice requirements centre on bioequivalence studies — the experimental confirmation that a generic formulation releases its active ingredient into systemic circulation at the same rate and to the same extent as the innovator reference product under equivalent conditions. ICH E6(R2) sets the international standard for all interventional clinical research governance, including BA/BE studies, and its adoption entails independent ethics committee approval, written informed consent from study subjects, strict protocol adherence, and systematic adverse event reporting.[9] The Declaration of Helsinki supplies the overarching ethical foundation recognised across all of the jurisdictions reviewed here.

5.2 GCP and Bioequivalence Requirements: BRICS Countries

India (CDSCO): Bioequivalence studies in India are governed by the New Drugs and Clinical Trials Rules (NDCT), 2019, which require all BA/BE studies to be registered with the Clinical Trial Registry of India (CTRI) before the first subject is enrolled, conducted at CDSCO-accredited centres, and overseen by an ethics committee registered under the NDCT framework.[9] The NDCT further mandates a defined compensation structure for study-related injury or death, with payment quantum calculated according to a formula specified in the Seventh Schedule.[9] In May 2024, CDSCO issued revised guidance on clinical trial submissions for biological products, further aligning Indian requirements with ICH E6(R2) and WHO GCP principles, and requiring that serious adverse events be reported to DCGI and the overseeing ethics committee within 14 days.[4]

Brazil (ANVISA): Brazilian BE studies must be conducted exclusively against domestic reference products at ANVISA-approved study sites, a requirement that effectively mandates study duplication for manufacturers who have already completed studies against another jurisdiction's reference product.[7] ANVISA applies Resolution RDC guidelines for BE conduct; these broadly follow ICH E6(R2) but impose additional country-specific requirements around ethics committee composition and study report structure.[7] ANVISA and COFEPRIS have jointly outlined strategic plans through 2027 to further deepen GCP alignment, including digital submission of clinical data and enhanced integration with pharmacovigilance systems.[7]

China (NMPA): Following its landmark 2016 reform, NMPA requires all previously approved generics to pass a consistency evaluation demonstrating equivalence with the innovator.[13] BE studies must comply with NMPA's Technical Guidelines for Bioequivalence Studies. A published bioequivalence evaluation of metformin hydrochloride sustained-release tablets (trial registration CTR20171306) in healthy Chinese volunteers illustrates the operational application of NMPA's requirements: a randomized, open-label, two-period crossover design enrolling 48 subjects with a seven-day washout period, conducted under Chinese GCP standards aligned with ICH principles.[2]

Russia and South Africa: Russia nominally follows ICH E6 for its BE study governance but requires Russian-language protocol documentation and mandates the use of Russian-approved reference products.[14] South Africa requires BE studies conducted in compliance with SAHPRA's guidelines, which are broadly consistent with WHO and ICH standards, making them among the more internationally portable in the BRICS group.[5]

5.3 GCP and Bioequivalence Requirements: MIST Countries

Mexico (COFEPRIS): COFEPRIS oversees the authorization and monitoring of all clinical studies conducted in Mexico, operating under the General Health Law, Health Research Regulations, and NOM-012-SSA3-2012.[3] BE data for generic drugs are submitted as part of the three-module dossier in Module 3 and must be generated using the Mexican reference product. COFEPRIS monitors approved studies through periodic site visits and requires clinical trial authorization from the agency before any human subjects study commences.[3]

South Korea (MFDS): MFDS bioequivalence requirements align closely with ICH standards, accepting pharmacokinetic BE studies designed according to internationally recognized principles.[16] Summary documents must be prepared in Korean, though originals in other languages are acceptable if accompanied by certified translations for safety and efficacy sections. Adverse event tracking is managed through KIDS (Korea Institute of Drug Safety) and the KAERS pharmacovigilance database, providing a structured post-study safety monitoring environment.[15]

Turkey (TITCK): TITCK accepts BE data from both domestic and certain internationally recognized study centres for generic drug registration purposes, a degree of data portability not available in Brazil, China, or Indonesia.[1] The 2018 Ceyhan et al. cross-agency comparison recommended that TITCK develop and implement formal Good Review Practice procedures to standardize its internal review processes, noting that such procedures were not yet fully formalized at the time of the study.[1]

Indonesia (BPOM): Indonesian GCP requirements for BE studies are formally aligned with WHO GCP standards, and all studies require ethics committee approval from a BPOM-recognized committee.[14] Studies must be conducted at BPOM-accredited domestic centres, and all documentation must include

sections in Bahasa Indonesia. BPOM does not currently accept BE data generated abroad, making re-conduct of studies mandatory for manufacturers entering from other markets.[14]

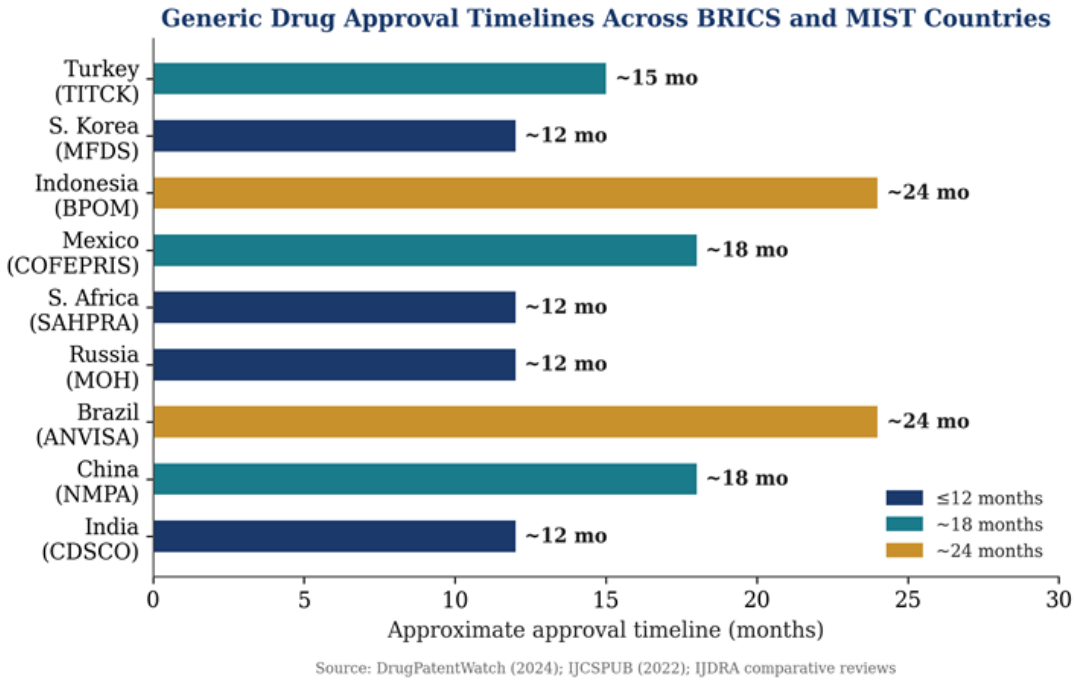

Figure 3: Approximate generic drug approval timelines across BRICS and MIST countries. Source: DrugPatentWatch;[5] IJCSPUB;[11] Kumar et al.[14]

6. Comparative Analysis: BRICS, MIST, and ICH Requirements

Table 1 and Figure 4 bring together the country-level findings of Sections 4 and 5 into a side-by-side matrix across nine regulatory parameters. The ICH-member column represents the consolidated standard applicable to the US FDA, EMA, Health Canada, TGA, and PMDA — the reference framework against which BRICS and MIST alignment is measured.[14,17]

Table 1: Comparative summary of key GMP and GCP requirements for generic drug registration across BRICS and MIST countries. Reference numbers in each cell indicate the source supporting that data point. Compiled from Ceyhan et al.,[1] Chen et al,[2] ClinRegs,[3] DrugPatentWatch,[5] GaBI Online,[7,8] Government of India,[9] IJCSPUB,[11] Kalra et al.,[13] Kumar et al.,[14] Lee et al.,[15] MFDS,[16] Patil et al.,[17] RAPS,[19]

Parameter	India	China	Brazil	Russia	S.Afr.	Mexico	Indon.	S.Kor.	Turkey
Regulatory Body	CDSCO[9]	NMPA[13]	ANVISA[8]	MOH[14]	SAHPRA[5]	COFEPRIS[19]	BPOM[14]	MFDS[16]	TITCK[1]
CTD Format	Yes (M2-M5)[9]	Yes[13]	Yes[8]	Partial[14]	Yes[5]	3-Module[11]	Modified CTD[14]	Yes[16]	Yes (EU-based)[1]
PIC/S Member	No (accession)[17]	No[13]	Yes (2022)[8]	No[14]	Progressing[5]	Yes (2018)[19]	No[14]	Yes[16]	Yes (2010)[1]
ICH GCP E6 Adopted	Yes-NDCT 2019[9]	Partial[13]	Yes[7]	Partial[14]	Yes[5]	Yes[3]	WHO GCP[14]	Yes[16]	Yes[1]
BE Study Required	Yes[9]	Yes (2016)[13]	Domestic[7]	Yes[14]	Yes[5]	Yes[3]	Domestic[14]	Yes[16]	Yes[1]
Local Language Mandatory	No[9]	Yes-Mandarin[13]	No[8]	Yes-Russian[14]	No[5]	Partial-Spanish[11]	Yes-Bahasa[14]	Partial-Korean[16]	No[1]
Foreign Site GMP Inspection	Yes[9]	Yes-own[13]	Yes-own[8]	Yes[14]	WHO-based[5]	Waiver avail.[19]	Yes[14]	Yes[16]	Yes/CPP[1]
Approx. Approval Time	~12 mo[5]	~18 mo[14]	~24 mo[11]	~12 mo[14]	~12 mo[5]	12-24 mo[11]	~24 mo[14]	~12 mo[15]	~15 mo[1]

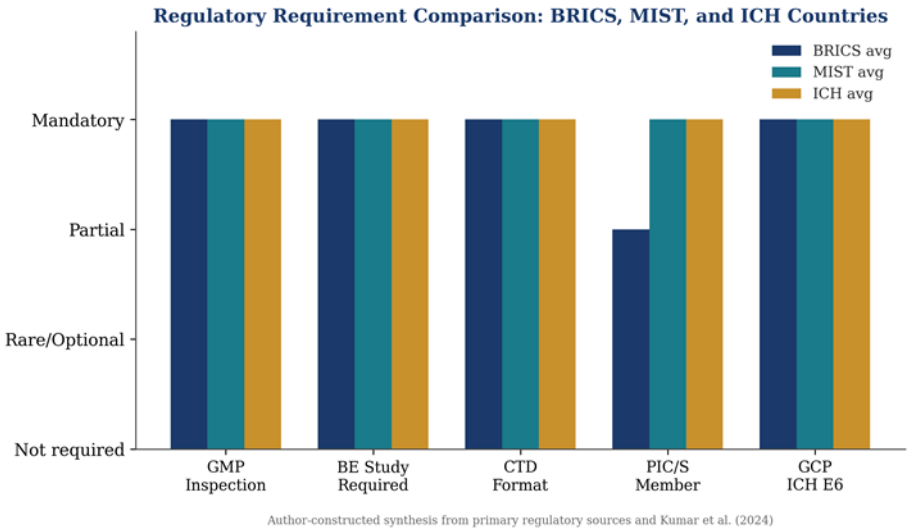

Figure 4: Comparative assessment of key regulatory requirement domains across BRICS, MIST, and ICH country groupings. Author-constructed synthesis from primary regulatory sources, Kumar et al. [14], Patil et al. [17], and Ceyhan et al.[1]

Three patterns emerge clearly from Table 1 and Figure 4. First, the four countries in this group with PIC/S membership — Brazil, Mexico, South Korea, and Turkey — consistently show the highest alignment with ICH GMP and GCP standards, which supports treating PIC/S accession as a reliable proxy for GMP inspection maturity, given that membership requires independently verified evidence that national standards and inspection systems meet agreed international criteria.[17]

Second, mandatory local-language documentation requirements in China and Russia create regulatory silos that meaningfully raise the cost and complexity of concurrent multi-market registration. A manufacturer aiming at simultaneous approval in China or Russia alongside ICH-standard markets must produce complete parallel documentation sets, a burden that falls disproportionately on smaller companies and academic-origin candidates without large regulatory affairs teams.[1,14]

Third, the requirement to conduct bioequivalence studies domestically — accepting no data from foreign accredited sites — is a major cost and timeline driver in Brazil, China, and Indonesia, where studies must be re-run locally regardless of existing internationally conducted data.[7,13,14] South Korea and Turkey, by contrast, accept internationally generated BE data subject to bridging requirements, a position more consistent with ICH principles and one that materially reduces development cost for multi-market programs.[1,16]

7. Challenges in GMP and GCP Harmonization

7.1 Regulatory Capacity and Infrastructure

The nine countries reviewed do not operate regulatory agencies of comparable technical capability. Indonesia's BPOM, committed to improvement but managing a high application volume relative to its current review capacity, consistently records the longest generic approval timelines in the MIST group at approximately 24 months.[14] Russia's Roszdravnadzor conducts domestic re-inspection of all foreign manufacturing sites regardless of existing WHO-prequalification or PIC/S certifications, because it holds no mutual recognition agreements with those bodies.[14] Meaningful harmonization progress in these jurisdictions requires foundational investment in laboratory infrastructure, inspection workforce training, and digital submission capacity, not merely regulatory text revision.[17]

7.2 Reference Product Availability and BE Data Portability

Country-specific reference product mandates in Brazil, Russia, and Indonesia create a structural problem for multi-market registration. Where the same innovator drug is marketed under different formulations or from different manufacturing sites in different countries, pharmacokinetic data generated against one jurisdiction's reference may not reliably predict equivalence against another's, requiring fresh studies for each market.[12] This multiplies costs and timelines without generating proportionate new scientific information about the product's safety or effectiveness.

7.3 API Quality Standards and Supply Chain Oversight

GMP compliance at the finished dose level depends on the standards applied to the active ingredients used in manufacturing. A comparative analysis found that CDSCO, NMPA, and ANVISA require only segregated rather than fully dedicated manufacturing areas for highly active APIs, while the FDA, EMA, and COFEPRIS require complete facility dedication for such substances.[20] This divergence partly reflects genuine differences in manufacturing infrastructure across markets — multi-product API facilities are commercially prevalent in India and China — but it also means that risk controls for highly potent substances are not

equivalent across jurisdictions, which has direct patient safety implications.

7.4 Language and Documentation Barriers

China's mandatory Mandarin submission requirement and Russia's Russian-only dossier obligation each effectively insulate those regulatory systems from international data-sharing and impose substantial duplication costs on any manufacturer seeking concurrent registration elsewhere. A 2018 comparative agency review identified language accessibility as one of the most practically actionable near-term improvements available to regulators seeking to reduce multi-market registration barriers, noting that Turkey successfully maintains a broadly harmonized regulatory framework without requiring Turkish-language submissions for the main dossier.[1]

8. Recommendations for Strengthening GMP/GCP Alignment

- Accelerate PIC/S accession for India (CDSCO) and South Africa (SAHPRA) [17]: Both agencies are actively pursuing PIC/S membership; formal accession would internationally validate their GMP inspection systems and reduce redundant foreign-site re-inspections by importing countries.
- Formalize GMP inspection-sharing agreements across BRICS and MIST:[19] Following the COFEPRIS model — which permits inspection waivers for sites already certified by recognized reference agencies — all nine countries should establish mutual recognition of inspection outcomes from PIC/S-member and WHO-prequalified agencies to eliminate unnecessary duplication.
- Adopt BE data portability for Brazil, China, and Indonesia:[7,13,14] These three countries should consider accepting well-designed BE studies conducted at accredited international centres against recognized reference products, subject to pharmacokinetic bridging, rather than mandating domestic re-conduct — a change aligned with ICH BE principles that would reduce development costs without compromising scientific validity.
- Introduce English-language submission options in China and Russia:[1,14] Permitting dual-language submissions — full English text with local-language Module 1 only — would remove one of the most practically significant barriers to concurrent multi-market registration and is consistent with the global trend toward electronic regulatory submissions.
- Strengthen ethics committee and GCP inspection infrastructure:[9] For GCP governance, the most impactful near-term investment is in ethics committee registration, structured training, and periodic reaccreditation, building on the model established by the NDCT Rules 2019 in India, which introduced mandatory EC registration and training to reduce procedural inconsistency in study oversight.
- Support Indonesia and Russia through structured ICH and PIC/S engagement:[14,17] Technical assistance programs — potentially coordinated through WHO, the ICH secretariat, or BRICS pharmaceutical working groups — could provide both countries with a defined roadmap and implementation support for aligning their GMP and GCP frameworks with international standards.

9. CONCLUSION

This review has mapped, on a country-by-country and parameter-by-parameter basis, the principal GMP and GCP requirements that govern generic drug registration across the nine BRICS and MIST nations, benchmarked against the harmonized ICH framework maintained by the United States, European Union, Japan, Canada, and Australia. The picture that emerges is one of meaningful but uneven progress. Brazil's PIC/S accession in 2022, South Korea's and Turkey's full ICH and PIC/S membership, Mexico's PIC/S entry in 2018, India's NDCT 2019 and Schedule M revision, and China's 2016–2019 generic drug consistency evaluation reforms collectively represent a substantial and measurable elevation of GMP and GCP standards within this country group.[1,5,8,9,14,19]

At the same time, important structural divergences remain. Russia and Indonesia have not joined PIC/S, maintain mandatory local-language documentation requirements, and require domestic BE study re-conduct that cannot be satisfied by internationally generated data.[14] GMP containment standards for highly active APIs differ across the nine countries in ways that reflect both infrastructure realities and, in some cases, genuinely different regulatory risk assessments.[20] These residual gaps matter in practical terms: they fragment multi-market registration strategies, raise development costs, and delay patient access to affordable medicines.

The combined BRICS and MIST pharmaceutical market will very likely exceed 30% of global value within the next decade.[5,14] Getting GMP and GCP right in these markets is not a narrow regulatory housekeeping exercise — it directly determines the quality and safety of the generic medicines that hundreds of millions of people rely upon. Targeted harmonization measures, particularly PIC/S expansion, formal inspection-sharing arrangements, BE data portability, and language access reforms, represent concrete and achievable steps toward a global generic drug regulatory environment that is both more coherent and more effective at protecting patients.

Declarations

Conflict of Interest: The authors declare no conflict of interest.

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Ethical Approval: Not applicable; this is a literature-based review involving no primary data collection from human or animal subjects.

REFERENCES

1. Ceyhan, E. M., Gürsöz, H., Alkan, A., Coşkun, H., Koyuncu, O., & Walker, S., The Turkish Medicines and Medical Devices Agency: Comparison of its registration process with Australia, Canada, Saudi Arabia, and Singapore. Frontiers in Pharmacology, 2018; 9: Article 9. https://doi.org/10.3389/fphar.2018.00009
2. Chen, X., Zhong, D., Li, Y., Zhou, H., Zhao, L., Zhang, Y., & Wang, Y., Bioequivalence and safety evaluation of two preparations of metformin hydrochloride sustained-release tablets (Boke® and Glucophage®-XR) in healthy Chinese volunteers. Frontiers in Pharmacology, 2022. https://doi.org/10.3389/fphar.2022.1003618
3. ClinRegs, NIAID. (n.d.). Clinical research regulation: Brazil and Mexico. U.S. National Institutes of Health. https://clinregs.niaid.nih.gov/country/brazil/mexico
4. DIA Global Forum., The evolving regulatory framework in India: Impact on the pharmaceutical industry, 2024. https://globalforum.diaglobal.org/issue/december-2024/the-evolving-regulatory-framework-in-india-impact-on-the-pharmaceutical-industry/
5. DrugPatentWatch, Finding generic drug entry opportunities in emerging markets, 2024. https://www.drugpatentwatch.com/blog/generic-drug-entry-emerging-markets/
6. DrugPatentWatch, GMP in generic drug manufacturing: The complete strategic guide, 2024. https://www.drugpatentwatch.com/blog/the-role-of-good-manufacturing-practice-gmp-in-generic-drug-manufacturing-ensuring-quality-and-safety/
7. GaBI Online, Strategic plans of ANVISA and COFEPRIS to advance health regulation, 2024. https://gabionline.net/policies-legislation/strategic-plans-of-anvisa-and-cofepris-to-advance-health-regulation
8. GaBI Online., GMP certification requirements in Argentina, Brazil and Mexico, 2024. https://gabionline.net/reports/gmp-certification-requirements-in-argentina-brazil-and-mexico
9. Government of India, Ministry of Health and Family Welfare. (2019). New Drugs and Clinical Trials Rules, 2019. Gazette of India Extraordinary, G.S.R. 227(E). https://cdsco.gov.in
10. IntuitionLabs., ICH Q7 GMP guidelines for pharma: A complete guide, 2024. https://intuitionlabs.ai/articles/ich-q7-gmp-api-compliance-guide
11. IJCSPUB, Regulatory requirements for drugs in Latin American countries. International Journal of Creative and Systematic Research, 2022; 12(4). https://rjpn.org/ijcspub/papers/IJCSP22D1225.pdf
12. Jayachandran, P., Advances in quantitative methods and modeling for complex generic drugs. CPT: Pharmacometrics & Systems Pharmacology, 2023; 12(7). https://doi.org/10.1002/psp4.12968
13. Kalra, G., Ahuja, H., & Lala, M., Regulatory requirements for registration of generic drugs in BRICS countries, 2016. Available from: https://www.academia.edu/33793069
14. Kumar, J., Ramkishan, A., & Venkatesh, M. P., Navigating global regulatory requirements for generic drugs: A comparative study of MIST, BRICS, and ICH countries. International Journal of Pharmaceutical Investigation, 2024; 14(1): 1–9. https://doi.org/10.5530/ijpi.14.1.1
15. Lee, D. H., Kim, J. A., Lim, K. M., Jung, J. W., Park, S. M., Jang, Y. A., & Lee, J. H., International comparison of generic competition, prices, and usage trends: South Korea and G20 countries. Frontiers in Public Health, 2025; 13: Article 1559823. https://doi.org/10.3389/fpubh.2025.1559823
16. MFDS., Good Manufacturing Practices (GMP) for Medicinal Products. Ministry of Food and Drug Safety, South Korea. Notification No., 2021; 2021-87.
17. Patil, A., Kuchal, M. D., & Prasanthi, D., Comparison of GMP for drugs in EU, US, Canada, WHO and Australia. International Journal of Drug Regulatory Affairs, 2024; 12(4): 82–91. https://doi.org/10.22270/ijdra.v12i4.724
18. PMC/PubMed Central., Essential drugs production in Brazil, Russia, India, China and South Africa (BRICS): Opportunities and challenges, 2014. https://pmc.ncbi.nlm.nih.gov/articles/PMC4258887/
19. RAPS., Latin America roundup: COFEPRIS updates GMP guidelines. Regulatory Affairs Professionals Society, 2025. https://www.raps.org/resource/latin-america-roundup-cofepris-updates-gmp-guideli.html
20. ResearchGate., Bridging the gap: Aligning GMP requirements for generic manufacturing across the US, EU and Japan, 2023. https://doi.org/10.13140/RG.2.2.26476.64640