International Journal of Science and Research (IJSR)
ISSN: 2319-7064
Impact Factor 2025: 7.089

When Regulatory Framework Ensures Sameness between Branded Generics and Generics: A Review of Evidence and Policy Implications

Dr. Shilpa B. Mendon

Ph.D., Independent Medical and Regulatory Expert

Abstract: ***The distinction between branded generics and plain generics has long been debated in pharmaceutical markets, particularly in India. Globally, generics are marketed under International Non-proprietary Names (INN), but India sustains a dual system: branded generics marketed under trade names, and plain generics marketed under INN. Despite this commercial differentiation, both categories are subject to identical regulatory requirements under DCGI and the Indian Pharmacopoeia (IP). This review provides a descriptive analysis of the scientific and regulatory framework that ensures therapeutic equivalence, including bioequivalence studies, dissolution testing, impurity profiling, stability evaluation, and pharmacovigilance. It also explores biowaivers, excipient considerations, and empirical evidence from India. By contextualizing industry narratives and policy responses, the article highlights how regulatory science dismantles misconceptions about branded superiority. Findings confirm no significant difference in quality between branded and plain generics, reinforcing that the distinction is commercial rather than scientific. Policy implications emphasize recognizing regulatory equivalence to promote rational prescribing, patient confidence, and access to affordable medicines.***

Keywords: generic medicines, bioequivalence testing, drug quality standards, regulatory compliance India, affordable healthcare

1. Introduction

Generic medicines are indispensable to modern healthcare systems, offering cost-effective alternatives to innovator drugs once patents expire. Their role in ensuring treatment continuity and expanding access to essential medicines is universally acknowledged. In most countries, generics are marketed under their INN, with no distinction between branded and plain versions. India, however, sustains a unique dual system:

- Branded generics: marketed under trade names by pharmaceutical companies, often supported by promotional strategies and physician engagement.
- Plain generics: marketed under INN without branding, typically distributed through government schemes such as Jan Aushadhi.

This distinction has generated debate among physicians, regulators, and patients. While branded generics dominate prescriptions due to perception and marketing, plain generics are promoted as affordable alternatives. Scientifically and regulatorily, however, both categories are identical.

2. Regulatory Equivalence

Bioequivalence Studies

Bioequivalence (BE) studies are the cornerstone of generic approval. They confirm that the generic drug has the same rate and extent of absorption as the innovator. Pharmacokinetic parameters such as *Cmax* and Area Under Curve (AUC) are measured in healthy volunteers. Regulatory authorities mandate that the 90% confidence interval for the ratio of generic to innovator values must fall within 80–125%. [1, 2]

Dissolution Testing

Dissolution testing ensures that the drug dissolves at the same rate and extent as the innovator, which is critical for absorption. A similarity factor $f_2 \geq 50$ is required. [2]

Impurity Profiling

Impurity profiling identifies and quantifies impurities, degradation products, and residual solvents. Techniques such as HPLC, GC, and MS are employed. ICH guidelines mandate strict impurity thresholds. [3]

Pharmacovigilance

Pharmacovigilance involves post-marketing surveillance to monitor adverse drug reactions (ADRs). Mandatory ADR reporting and risk management plans are required. Continuous safety monitoring applies equally to all generics, regardless of branding. [4]

DCGI/IP Requirements for Formulations

In India, the DCGI mandates compliance with the IP. [4-5] To ensure quality, safety, and therapeutic equivalence, the following compliance tests are mandated for all pharmaceutical formulations, aligned with international standards: [1-7]

- Identity & Assay - Confirms correct active ingredient and potency.
- Purity & Impurity Profiling - Detects and limits impurities to ensure safety.
- Dissolution & Disintegration - Ensures drug releases appropriately for therapeutic effect.
- Uniformity of Dosage Units - Guarantees consistent dose delivery across batches.
- Microbial Limit & Sterility Tests - Prevents contamination and ensures product safety.
- Stability Studies - Establishes shelf life and storage conditions.
- Bioequivalence/Bioavailability Studies - Confirms therapeutic equivalence with reference product.
- Pharmacovigilance - Monitors post-marketing safety and adverse events.

Table 1: Pharmaceutical Quality Assurance: Core Regulatory Tests

Test/Requirement	India (DCGI/IP)	Global (USFDA/EMA/WHO)
Identity & Assay	Mandatory (IP)	Mandatory
Dissolution	$f_2 \geq 50$	$f_2 \geq 50$
Purity & Impurity Profiling	ICH Q3A/Q3B	ICH Q3A/Q3B
Stability	ICH Q1A	ICH Q1A
BE/BA	Mandatory	Mandatory
Pharmacovigilance	PSURs, ADRs	PSURs, ADRs

Note: In India, disintegration testing is included alongside dissolution, though not separately highlighted in global guidelines.

Biowaivers and *In Vitro* Equivalence

DCGI/CDSCO follows a risk-based framework consistent with World Health Organization (WHO), United States Food and Drug Administration (USFDA), and European Medicines Agency (EMA).[5-8]

- Mandatory BE: oral solids, modified-release formulations, narrow therapeutic index drugs.
- Biowaivers: BCS Class I drugs (e.g., Atenolol), BCS Class III drugs (e.g., Metformin).
- In vitro tests: dissolution, impurity profiling, stability studies, In vitro release testing (IVRT) for topical products.

Excipients and Therapeutic Equivalence

Excipients may influence dissolution, stability, or tolerability. For example, Metformin formulations may differ in gastrointestinal tolerability, and Atenolol tablets may vary in disintegration time.[8-10] Regulatory frameworks address this by requiring demonstration that excipients do not alter therapeutic equivalence. BE studies and dissolution testing capture excipient effects, and biowaivers are granted only when excipients are shown not to affect absorption.[11]

Stability and Storage Conditions

Drug efficacy depends on stability and storage. Regulators mandate accelerated and long-term stability studies, packaging validation, and explicit storage instructions. Shelf life and storage conditions are approved only after review of detailed data.[6]

Industry Narratives vs Regulatory Responses

- *Claim*: Branded generics are produced in superior GMP-compliant facilities.
  Response: All manufacturers must comply with Schedule M and WHO GMP.[12]
- *Claim*: Branded generics companies track adverse events more rigorously.
  Response: Pharmacovigilance obligations apply equally to all authorization holders.[7]
- *Claim*: Branding and packaging improve adherence.
  Response: Compliance is behavioural, not pharmacological.

Empirical Evidence from India

The Citizens' Generic vs Branded Drugs Quality Project, spearheaded by hepatologist Dr. Cyriac Abby Philips ("The LiverDoc"), evaluated 22 commonly prescribed medicines across therapeutic categories. The study demonstrated that:[13]

- There was no significant difference in quality or efficacy between branded generics and plain generics.
- Both categories consistently met regulatory standards for dissolution, impurity limits, and therapeutic effect.
- Higher prices of branded generics did not translate into superior quality.
- Jan Aushadhi outlets offered the lowest prices for 82% of medicines tested.

Despite such evidence and policymakers' encouragement, the widespread acceptance of generic medicines in India remains limited. Their use is largely confined to government facilities, while prescribing and dispensing in private practice continue to favour branded generics. This reluctance stems from entrenched perceptions, limited awareness, and inadequate education among both healthcare professionals and patients.

Studies highlight that consumer opinions are shaped primarily by physician recommendations and prior experiences, with cost savings recognized as the main advantage of generics. However, retailers are often influenced by doctors' preferences and pharmaceutical company incentives, further reinforcing the dominance of branded generics.[14-15]

Global Context

India's uniqueness lies in sustaining branded generics as a formal market category, while globally generics are generics- branding is not a regulatory distinction but a commercial choice.[15]

Table 2 summarizes how generics are marketed and regulated across regions, highlighting India's distinctive position

Table 2: Global Practices in Generic Medicines: India vs. Other Regions

Region	Generics Practice	Branded Generics Concept	Key Drivers
India	Generics marketed both under INN and trade names.	Formal, widespread category.	Physician incentives, patient perception, market fragmentation, branding.
US & Europe	Generics marketed only under INN; pharmacists dispense approved equivalents.	No regulatory category.	Strong regulatory communication, physician prescribing by INN.
Emerging Markets (Latin America, Africa, SE Asia)	Generics marketed under INN; occasional informal branding.	Informal, not regulatory.	Marketing strategy only; not recognized by regulators.
China & Japan	Generics marketed under INN; branding minimal.	Absent.	Regulatory-driven uniformity; physician prescribing by INN.

Table 2 illustrates that while India sustains branded generics as a formal category, other regions treat generics uniformly under INN, with branding absent or informal. This underscores that branding is a commercial, not regulatory, distinction.

3. Policy Implications

Recognizing regulatory equivalence is essential to:

- Promote rational prescribing practices.
- Strengthen patient confidence in generics.
- Reduce unnecessary healthcare costs.
- Enhance access to affordable medicines globally.

4. Conclusion

The distinction between branded generics and plain generics is scientifically unfounded. Regulatory frameworks ensure sameness, rendering both categories therapeutically identical.

India's persistence in sustaining branded generics reflects market dynamics and perception rather than scientific difference. Empirical evidence from Indian studies, including those led by Dr. Cyriac Abby Philips, further validates this equivalence.

Globally, generics are recognized solely by their INN, with branding absent as a regulatory category. Acknowledging this equivalence is essential for rational prescribing, patient confidence, and equitable policymaking. Policymakers must prioritize regulatory science over perception to strengthen trust, reduce costs, and advance fair pharmaceutical access.

References

[1] US Food and Drug Administration. *Guidance for Industry: Bioavailability and Bioequivalence Studies.* Silver Spring, MD: USFDA; 2003.

[2] European Medicines Agency. *Guideline on the Investigation of Bioequivalence.* EMA/CHMP/EWP/1401/98 Rev. 1/Corr. London: EMA; 2010. Available at: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-investigation-bioequivalence-rev1_en.pdf. Accessed 25 Mar 2026.

[3] International Council for Harmonisation. *ICH Q3A(R2): Impurities in New Drug Substances.* Geneva: ICH; 2006. Available at: https://www.ich.org/page/quality-guidelines. Accessed 25 Mar 2026.

[4] Indian Pharmacopoeia Commission. *Indian Pharmacopoeia.* Ghaziabad: IPC; 2022. Available at: https://ipc.gov.in/mandates/indian-pharmacopoeia/indian-pharmacopoeia-2022.html. Accessed 25 Mar 2026.

[5] Central Drugs Standard Control Organization (CDSCO). *Guidance for Industry: Requirements for Bioequivalence Studies.* New Delhi: CDSCO; 2005. Available at: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/BA_BE/guidance_doc_BABE_NOC1_1Jan2018.pdf. Accessed 25 Mar 2026.

[6] International Council for Harmonisation. *ICH Q1A(R2): Stability Testing of New Drug Substances and Products.* Geneva: ICH; 2003. Available at: https://database.ich.org/sites/default/files/Q1A%28R2%29%20Guideline.pdf. Accessed 25 Mar 2026.

[7] World Health Organization. *The Importance of Pharmacovigilance.* Geneva: WHO; 2002. Available at: https://www.who.int/publications/i/item/10665-42493. Accessed 25 Mar 2026.

[8] International Council for Harmonisation. *ICH M9: Biopharmaceutics Classification System-Based Biowaivers.* Geneva: ICH; 2020. Available at: https://database.ich.org/sites/default/files/M9_Guideline_Step4_2019_1116.pdf. Accessed 25 Mar 2026.

[9] Iswariya VT, Swarnalatha KM, Keerthi U, Tejaswini P, Ashok B. Formulation and evaluation of oral disintegrating tablets: Metformin. *CMR College of Pharmacy, Hyderabad*; 2019.

[10] Bhosale A, Shinde P. Formulation and evaluation of Metformin HCl gastroretentive floating sustained release tablet. *Int J Sci Res Tech.* 2025;2(6):6–16.

[11] Metry M, Polli JE. Evaluation of excipient risk in BCS Class I and III biowaivers. *AAPS J.* 2022; 24: 20.

[12] Central Drugs Standard Control Organization (CDSCO). *Schedule M: Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.* New Delhi: CDSCO; 2005.

[13] Philips CA, Thomas TL, Bhattacharya S, et al. Citizens' Generic vs. Branded Drugs Quality Project. *MedBound Times.* 2026 Jan 5. Available at: https://meshindia.org/citizens-generic-vs-branded-drugs-project/. Accessed 25 Mar 2026.

[14] Ranjith RJP, Ghosh T, Nikhil G, Shadan S, Prajwal M, Anil KR, Shashanka KS, Prem F, Basavaraj BV. Consumer preference towards drugs – generic vs branded drugs: A cross-sectional study. *Proceedings of the 2nd Indian International Conference on Industrial Engineering and Operations Management*; 2022 Aug 16–18; Warangal, Telangana, India. p.531–6.

[15] Rana P, Gupta R. Generics versus branded generics: A case of confusion. *Indian J Community Fam Med.* 2025 Jun;11(1):4–7.