

An Empirical Study on Generic Medicine and Branded Medicine

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Abstract: *In a person's mind, there are certain myths and misconceptions regarding generic medicines and their uses, safety, and potency, due to the information prevailing in the community. But the actual facts are totally different from that, and this is based on scientific evidence. The purpose of this review is to create awareness and increase knowledge about generic medicine as well as prescribe generic medicine in India. Generic medicine is the same as branded medicine, and it has the same quality, safety, and efficiency as branded medicine. Both medicines undergo rigorous regulatory testing, and after compliance with regulatory requirements, they get approval for marketing. Generic medicines are less costly as compared to branded ones because they do not undergo drug discovery, preclinical studies, advertisements, and so on. Due to this reduction in all processes, billions of dollars are saved, and manufacturing costs are low. Instead, all processes for generic medicine Bioequivalence and bioavailability studies prove that medicines are safe, effective, and as similar as branded products in terms of therapeutic effects and any side effects. To increase generic prescribing and acceptance in India, healthcare professionals have created an awareness program, given knowledge, and promoted generic prescriptions. The prescribing of drugs by a registered medical practitioner with the best utilization of practice and experience according to the disease condition of patients.*

Keywords: Bioequivalence, Regulatory Authority, NDA, ANDA, Drug Development, Generic Medicine, Drug Discovery

REFERENCES

- [1]. Kuchekar BS. Pharmaceutical jurisprudence. Pragati Books Pvt. Ltd.; 2008 Jan 8. Gundersen L. The complex process of naming drugs.
- [2]. Pasupula SK, Sanjay Y, Raviteja C. Attitude towards generic drugs: A comparative Study among clinicians and pharmacy professionals. *Telangana Journal of Psychiatry*. 2018 Jul 1;4(2):72.
- [3]. Mogolian, E., & Mrydral, P. (2004). What's the difference between brand-name and Generic prescription drugs. *Sci Am*, 12-13.
- [4]. Lipsky MS, Sharp LK. From idea to market: the drug approval process. *The Journal of The American Board of Family Practice*. 2001 Sep 1;14(5):362-7.
- [5]. Lipsky MS, Sharp LK. From idea to market: the drug approval process. *The Journal of The American Board of Family Practice*. 2001 Sep 1;14(5):362-7
- [6]. Robles Vázquez W. Preparation of New Drug Application (NDA)/Abbreviated New Drug Application (ANDA) Major and Moderate Post-Approval Changes for Parental Drug Products Site Transfer. *Revista Politechne*; 2010.
- [7]. Alfonso-Cristancho R, Andia T, Barbosa T, Watanabe JH. Definition and Classification of generic drugs across the world. *Applied health economics and health Policy*. 2015 Aug;13:5- 11.
- [8]. Hornecker JR. Generic drugs: history, approval process, and current challenges. *US Pharm*. 2009;34(6):26-30.
- [9]. Lee CY, Chen X, Romanelli RJ, Segal JB. Forces influencing generic drug Development in the United States: a narrative review. *Journal of Pharmaceutical Policy And practice*. 2016 Dec;9(1):1-6

- [10]. Handoo S, Arora V, Khera D, Nandi PK, Sahu SK. A comprehensive study on Regulatory requirements for development and filing of generic drugs globally. *International journal of pharmaceutical investigation*. 2012 Jul;2(3):99.
- [11]. Dunne S, Shannon B, Dunne C, Cullen W. A review of the differences and Similarities between generic drugs and their originator counterparts, including economic benefits associated with usage of generic medicines, using Ireland as a case study. *BMC Pharmacology and Toxicology*. 2013 Dec;14:1-9.
- [12]. Dunne SS, Dunne CP. What do people really think of generic medicines? A Systematic review and critical appraisal of literature on stakeholder perceptions of generic Drugs. *BMC medicine*. 2015 Dec;13(1):1-27.
- [13]. Badjatya JK. Generic drugs market: brand versus generic. *Journal of Drug Delivery And Therapeutics*. 2013 Mar 15;3(2).
- [14]. Schwartz LM, Woloshin S. The Drug Facts Box: Improving the communication of Prescription drug information. *Proceedings of the National Academy of Sciences*. 2013 Aug 20;110(supplement_3):14069-74
- [15]. Mohs RC, Greig NH. Drug discovery and development: Role of basic biological Research. *Alzheimer's & Dementia: Translational Research & Clinical Interventions*. 2017 Nov 1;3(4):651-7.
- [16]. Pandey S, Pandey P, Tiwari G, Tiwari R. Bioanalysis in drug discovery and Development. *Pharmaceutical methods*. 2010 Oct 1;1(1):14-24.
- [17]. Ng R. *Drugs: from discovery to approval*. John Wiley & Sons; 2015 Jun 22.
- [18]. Brent MB. Abaloparatide: A review of preclinical and clinical studies. *European Journal of Pharmacology*. 2021 Oct 15;909:174409.
- [19]. KambleTD, Khatmode MB. Review on Preclinical And Clinical Studies: Indryani Institute of pharmaceutical education and areserch Talegaon Dabh
- [20]. Data from International Conference on Harmonization 1996, Guideline for Good Clinical Practice (GCP), viewed 2014 March 3
- [21]. Holbain, M. B. [2009]. Understanding FDA regulatory requirement for investigational new drug application for Sponsor -investigator. *Journal of Investigative medicine* ,57[6],688-694.
- [22]. Gupta NV, ohan Reddy CM, Reddy KP, Kulkarni RA, Shivakumar HG. PROCESS OF APPROVAL OF NEW DRUG IN INDIA WITH EM PHASIS ON CLINICAL TRIALS. *Marketing*. 2012 Mar;6:8.
- [23]. Rick NG, Wiley-Blackwell A, von Arzneimitteln DN. *Drugs-From Discovery to Approval*.
- [24]. Jawahar N, Lakshmi VT. Regulatory requirements for the drug approval process in US, Europe and India. *Journal of Pharmaceutical Sciences and Research*. 2017 Oct 1;9(10):1943- 52.
- [25]. Zareen SR, Ahmed O, Reshma MS, Rasheed A. PHARAMACEUTICAL REGULATORY AGENCIES OF INDIA. *European Journal of Biomedical*. 2023;10(2):113-5.
- [26]. Sutar M, Gawhane D, Tenpe CR. Study of Drug Regulatory Approval Process an Comparative Requirement of Common Technical Documents (CTD) in Europe, USA and India in Coordination with Drug Developmental Process. *International Journal of Pharmaceutical Sciences Review and Research*. 2013;20(2):68-79.
- [27]. Joshi SS, Shetty YC, Karande S. Generic drugs-the Indian scenario. *Journal of Postgraduate medicine*. 2019 Apr;65(2):67.
- [28]. Kumar SA, Sanjita D. A review article on bioavailability and bioequivalence studies. *International Journal of PharmTech Research*. 2013;5(4):1711-21.
- [29]. Pichholiya M, Basu A, Yadav AK, Kothari N, Tahashildar J. An observational Comparative study of cost between branded medicines and generic medicines. *Int J Basic Clin Pharmacol*. 2015 Mar;4(2):269-72.
- [30]. Arora K, Singh S, Singh PK. A Review on Generic and Branded Drugs- Competence Of Generic Drugs in Comparison to Branded Drugs. *Current Research in Pharmaceutical Sciences*. 2019:63-6.
- [31]. Kumar SA, Sanjita D. A review article on bioavailability and bioequivalence studies. *International Journal of PharmTech Research*. 2013;5(4):1711-21.
- [32]. Roth, D. Binz, H. & Watty, r. [2010]. Generic structure of knowledge within the product development process. In DS 60: Proceeding of DESIGN 2010 OF 11TH International design conference Croatia

- [33]. PARSRAMPURIA,S,SETRTKAYAMA,LORD,A,& BERGER ,C [2021].COST OF GENERIC DRUG DEVELOPMENT AND APPROVAL FINAL.
- [34]. Dharani T, Kumar PP, Phanindra DS, Nagabhushanam MV, Bonthagarala B, RamakrishnaG, Sindhu YR, Ch SK. A REVIEW ON ABBREVIATED NEW DRUG APPLICATION (ANDA).
- [35]. Rafi N, DS S, Narayanan A. Regulatory requirements and registration procedure for Generic drugs in USA. Indian journal of pharmaceutical education and Research,2018,Oct,1;52:544- 9
- [36]. .Davit ,B.M, P.E Buehler, G,J,Conner ,D,P., Haider Compering Generic andInnovator Drugs:Arevie of 12 years bioequivalence data FDA ,Annal of pharmacotherphy 43 [10],1583-1579.