

# Comparative efficacy between Branded and Generic antibiotics against common pathogenic bacteria.

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**Abstract:** The concept of generic prescription is prevalent in various parts of the world but it had failed to gain popularity in India due to non-availability and incredulity on product's standard. The consumption of generic drugs compared to branded counterparts has the prospective to significantly cut-down the out-of-pocket expenditure of patients. In our study, the objective was to assess the efficacy between different branded and generic drugs against four different microorganisms. Using agar cup-plate method the antibiotic efficacy studies were observed. Dilutions of different drugs were made at concentration of 1mg/ml. After 24 hours of incubation, the zone of inhibition for each of the drug used, were measured and represented in graphical form to compare the results obtained. In the experiments were performed, four groups of drugs were taken and the zone of inhibition were measured with respect to four different organisms, that are *Streptococcus sp.*, *Pseudomonas sp.*, *Bacillus megaterium* and *Salmonella abony*. It was observed that all the four groups of drug had shown maximum inhibition against the organism *Salmonella abony* whereas, minimum inhibition was showed by *Streptococcus sp* and *Pseudomonas* and *Bacillus megaterium* showed lowest inhibition. It was observed that difference between antibiotic efficacy of branded and generic drug was not statistically significant. Therefore, it can be said that brand names are only for mental satisfaction for consumers and doctors who prescribe, trustworthy are those generic drugs which are available at a suitable cost.

**Keywords:** Generic, branded, antimicrobial potential, zone of inhibition.

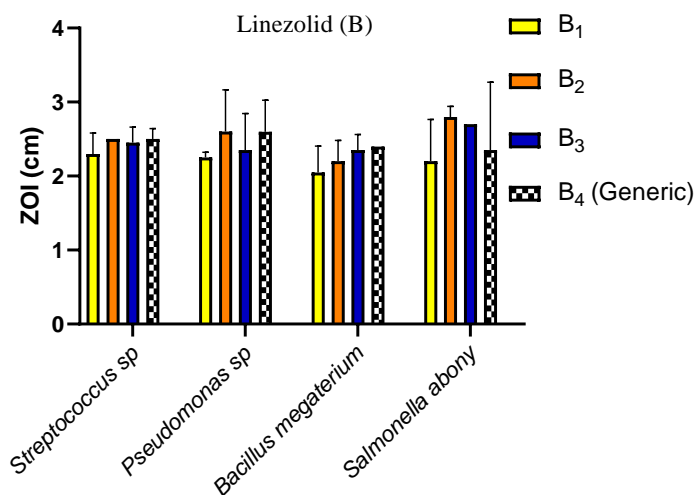
**Introduction:** In the recent years, due to booming pharmaceutical costs, generic medicines are now in heightened use worldwide<sup>[1, 2]</sup>. Generic medicines are identical, or bioequivalent, to a brand name drug in dosage form, safety, strength, route of administration, quality, and intended use<sup>[2]</sup>. The soaring prices of branded medicines owes to the extensive clinical trials conducted and the faulty drug policies of governments<sup>[3]</sup>. There has been constant discrepancy in the marketing and distribution of generic drugs due to illicit selling of branded medicines in the pharmacies<sup>[2]</sup>. Developing countries especially India, require generic medicines to provide affordable medical care to patients at low costs<sup>[4]</sup>. To promote the usage of generic medicines, the Indian Government has adopted several acts and initiatives. The Patents Act (1970) in India, amended in 2005, has allowed the Indian pharmaceutical giants to reverse engineer the drugs and produce low cost generic medicines, also embarking upon fall in the prices of the medicines and the introduction of a large number of generic versions of patented products<sup>[5]</sup>. Schedule M compliance is implemented from July 1, 2005, based on WHO-GMP guidelines, which classifies the various statutory requirements mandatory to be followed by pharmaceutical units in India<sup>[6]</sup>. Also, in 2008, the Indian government launched the 'Jan Aushadhi' scheme, so as to furnish low-cost and effective generics through exclusive outlets in different Indian districts.

The objective of our investigation was to juxtapose the antimicrobial efficacy of generic drugs and their branded counterparts and comprehend the relevance of generic drugs to emerge as a future medicament. To address this particular evaluation, generic and branded medications of four classes of antibiotics were considered- a) Amoxicilin and Potassium clavulanate, b) Linezolid, c) Cefuroxime Axetil and d) Cefpodoxime Proxetil and their antimicrobial efficacies were tested against the following test microorganisms: *Streptococcus sp.*, *Pseudomonas sp.*, *Bacillus megaterium* and *Salmonella abony* by comparing their zones of inhibition using cup-plate assay and through statistical analysis. Amoxicilin inhibits bacterial cell wall synthesis by binding to Penicillin-binding proteins and Potassium Clavulanate augments its potential by blocking beta-lactamase activity. Linezolid blocks protein synthesis by preventing the formation of 70S ribosomal complex. Cefuroxime Axetil and Cefuroxime Proxetil both belong to the class of Cephalosporins, which are bacterial cell wall synthesis inhibitors. Thus, the experiment focuses on the potency of generic drugs against branded drugs to combat microorganisms and pave the way for a cheaper alternative remedy.

**Material and Methods:** Four Drugs, Cefpodoxime Proxetil, Linezolid, Cefuroxime Axetil and Amoxicillin and Potassium Cluvunate (Sample A, B, C, D) respectively [under these groups, sub-groups are present which represent branded and generic drugs], formulations were taken for anti-microbial assay. LA media plates were prepared and bacterial strains of *Bacillus megatarium*, *Streptococcus sp.*, *Pseudomonas sp.* and *Salmonella abony* were plated on four different plates using spread plate technique. Anti microbial assay was performed using cup-plate method.<sup>[7]</sup>

Antibiotic mother stock solutions were prepared by grinding the tablet and dissolving in sterile water to prepare a concentration of 50mg/mL, from which stock solutions of 1mg/mL were prepared by dilution of the mother stock (0.2 mL of mother stock solution diluted in 9.8mL of sterile water). 20µL of the antibiotic solutions were pipetted into the wells and zone of inhibition (ZOI) was measured after overnight incubation. Statistical analysis was carried out with the ZOI values using GraphPad Prism software.

**Results and Discussion:** Our major findings suggest that our four group of drugs i.e. Cefpodoxime Proxetil, Linezolid, Cefuroxime Axetil and Amoxicillin along with Potassium Clavulanate had shown maximum inhibition against the organism *Salmonella abony* when compared to a database of zone of standards to determine whether the bacteria is susceptible, moderately susceptible or resistant to the antibiotic in question whether generic or branded. Moderate inhibition was observed against *Streptococcus sp.* and *Pseudomonas sp.*, while minimum inhibition was observed against *Bacillus megatarium*. In the first case the four types bacteria tested against Cefpodoxime Proxetil where two types of brand A1 (quality branded) and A2 (generic drug). The A2 drug showed similar results at par with branded A1 maximally inhibiting the *Streptococcus sp.* In the second case of our study using Linezolid group if drug we found that the generic brand B4 clearly had similar efficacy with respect to B1, B2, B3 group of branded drugs. Here *B. megatarium* showed greater susceptibility than other bacterial types. In the third case, the efficacy of C1 (generic) and the branded ones C2 and C3 were determined. Here C1 company drug showed high efficacy results against *Streptococcus sp.*, *Pseudomonas sp.* and *B. megatarium*; however *S. abony* had greater susceptibility with C3 drug type. In the last case, we took Amoxicillin along with potassium clavulanate drug type where the branded drug company D1 and D2 showed equivalent results with D1 generic company drug.



In this study we observed that generic drugs were as effective as branded drugs, even in some results where it was found to be better over a huge percentage. In India there is wrong perception that generic drugs are not real medicines and are suitable for minor treatments only. It is also believed that the medicine might also be adulterated and patients might suffer with a great deal of side effects from the drug. In our study the branded drugs from four different types of drug variety showed more or less similar results ( $p < 0.05$ ) comparing the zone of inhibitions using the antibiotic cup assay technique. This study is basically to hinder stereotypical side of people regarding the selection of generic drug over branded ones.

Das et. al. conducted a survey regarding the patients suffering from chronic diseases in public hospital outpatient department were treated them with generic and branded drug of various kind. Many people were reluctant to be treated under the generic drugs but those who did 95% of them were satisfied to the instructions given to them.<sup>[8]</sup> The government of West Bengal, India has initiated exclusive generic drug outlets called 'Fair price medicine shop' (FPMS) inside the government hospital premises in a 'Public Private Partnership' (PPP) model since 2012. Thus people have to believe that generic drug is not harmful. The effectiveness and safety regarding the generic drug should be highlighted by the policy makers. Such attempts should be made in every other state in all over India.

Even after the law made by FSSAI or the State government there is alternative to the policy when it comes to business. People has to understand that the generic drugs are available at a cheaper rate because the manufacturers did not have the expenses of developing and marketing a new drug, because it is the same composition drug with cheaper rates. When a company brings a new drug in the market, the company has already spent substantial money on research, development, marketing and promotion of the drug. Hence a patient is handed the real drug at only the production cost. The competition in the market also makes the price much cheaper with respect to other branded ones of their own company products. Therefore people think that generic drugs are poor in quality and inferior to the branded ones, as nobody compromises on one's health issues. Also, the trademark law does not allow the generic drugs to be exact resemblance to the branded drugs in respect to colour and flavour, even though its ingredients, preparation and medicinal effects remain the same. So people are in constant doubt in purchasing them.

The primary limitations of our study were the non-availability of the generic drug. Not all stores contain the exact required medicine; this is also one of the main cause for not using the generic drugs in our country. Retailer should always keep the medicine in- stock. Another, limitation in our study is that we directly applied the drug on the microorganisms to check its potentiality, but using in-vivo technique such as mice model would have given an appropriate interpretation to our main motive of the research.

However, in our study the results were encouraging so prescribing the generic drugs in the state and nation is a worthwhile implementation. Further research with other genera of drugs can further be used in these cases of studies. Also using the generic drugs against the MDR microorganisms are the real challenge. Wide term awareness should be spread; the pharmacists and doctors should be well documented and updated of the drugs in the market. Government organizations and agencies must undertake the initiative of generic medicines as potential futuristic therapy, so that it becomes a subsequent guardian of humanity from different ailments despite complications.

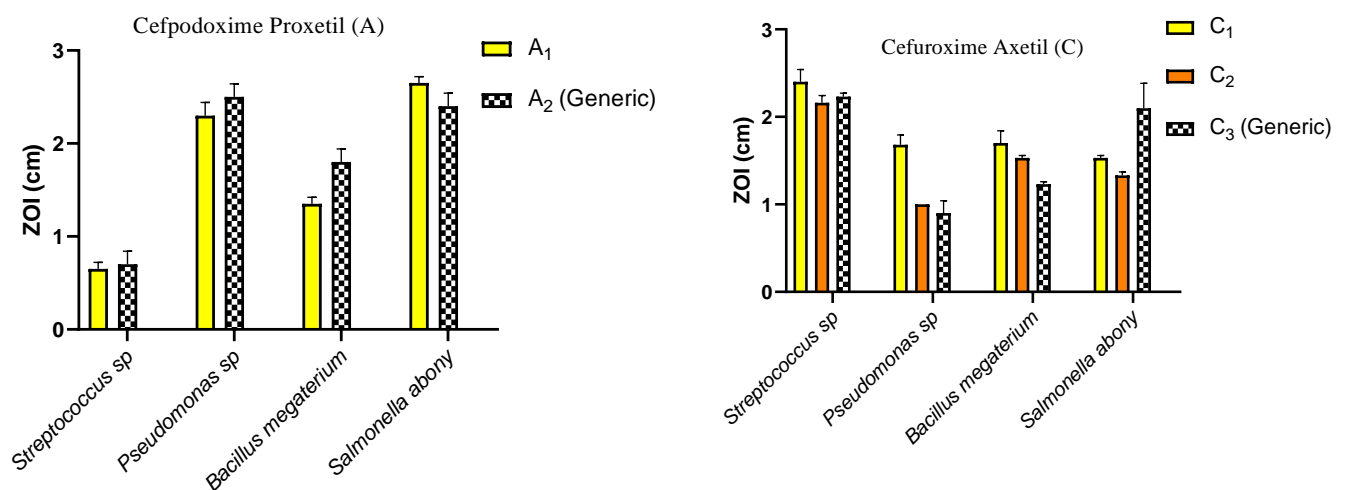


Fig. 1: Graphical representation of the results from anti-microbial activity of Cefpodoxime Proxetil (A), Linezolid (B), Cefuroxime Axetil (C) and Amoxicillin and Potassium Cluvunate (D), [checked shade represents generic drug of that group], all the test were performed in duplicate and data represent the mean value. Graph, Mean and Standard Deviation were performed by using GraphPad Prism 8 Software.

**Conclusion:** In our experiment, four groups of drugs were taken and the zones of inhibition were measured with respect to four different organisms, namely, *Streptococcus sp.*, *Pseudomonas sp.*, *Bacillus megaterium* and *Salmonella abony*. It was observed that there was no significant difference between the antibiotic efficacy of generic drugs and branded drugs ( $p < 0.05$ ) when compared according to their zones of inhibition. Therefore we can conclude that as generic drugs are bioequivalent of brand-name drugs that have exactly the same dosage, intended use, effects, side effects, route of administration, risks and safety, their pharmacological effects are exactly the same as those of their brand-name counterparts.

#### Reference:

1. Badalkumar.P.et al. Formulation development & evaluation of Cefpodoxime Proxetil Dispersible Tablets. *Int. J. Drug Dev. & Res.* (April-June 2012); 4 (2): 124-131
2. Kanavos P, King RD. Encouraging the Use of Generic Medicines: Implications for Transition Economies. *Croatian Medical Journal* (2002); 43(4):462-469.
3. Toverud El, Hartman K, Hakonsen H. A Systematic Review of Physicians' and Pharmacists' Perspectives on Generic Drug Use: What are the Global Challenges? *Appl Health Econ Health Policy* (2015); 13 (Suppl 1):S35-S45
4. Aivalli PK, Elias MA, Pati MK, Bhanuprakash S, Munegowda C, Shroff ZC, Srinivas PN. Perceptions of the quality of generic medicines: implications for trust in public services within the local health system in Tumkur, India. *BMJ Glob Health*. 2018 Jan 13;2(Suppl 3):e000644.
5. Gupta N, Khurana K, Arora Sethi V. Revised Schedule M & its Impact on SSI's. *Asian Journal of Biochemical and Pharmaceutical Research*. Issue 3(Vol. 7) 2017.
6. Roy V, Rana P. Prescribing generics: All in a name. *Indian J Med Res.* 2018 May; 147(5): 442-444.
7. W F J Cuthbertson. Recent development in microbiological methods. *Analyticachimica ACTA*. Vol3 761 (1948).
8. Das M, Choudhury S, Maity S, Hazra A, Pradhan T, Pal A, et al. Generic versus branded medicines: An observational study among patients with chronic diseases attending a public hospital outpatient department. *J Nat Sc Biol Med* 2017;8:26-31.