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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

I. INTRODUCTION

Any pharmaceutical for the inner or outer utilization of people or creatures" is the definition of a sedate. As an elective, recommend "Substances other than those recorded over" or "Any substance aiming for utilization within the conclusion, treatment, moderation, or anticipation of any malady or clutter in humans or creatures." Rather than nourishment, things that modify the structure of the human body or offer assistance kill disease-transmitting creepy crawlies or rodents, or "substances implied to be utilized as medicate components, such as purge gelatin capsules." [1] The names of the medications are as follows: the World Wellbeing Organization gives bland or non-proprietary names; the Universal Union of Pure and Applied Chemistry (IUPAC) gives chemical names; and the World Health Organization gives either restrictive or branded names. Any pharmaceutical for the inner or outer utilization of people or creatures" is the definition of a sedate. As an elective, recommend "Substances other than those recorded over" or "Any substance aiming for utilization within the conclusion, treatment, moderation, or anticipation of any malady or clutter in humans or creatures." Rather than nourishment, things that modify the structure of the human body or offer assistance kill disease-transmitting creepy crawlies or rodents, or "substances implied to be utilized as medicate components, such as purge gelatin capsules." [1] The names of the medications are as follows: the World Health Organization gives bland or non-proprietary names; the Universal Union of Pure and Applied Chemistry (IUPAC) gives chemical names; and the World Exchange Organization gives either restrictive or branded names. [2]

Branded drugs are defined as pharmaceuticals marketed under a particular trade name by the company that first introduced them to the market, whether or not they have a patent on them. Has passed away. [3] Any new pharmaceutical's development is a costly and intricate undertaking. Pharmaceutical corporations' research departments frequently dedicate years to examining various facets of the disease's biology and biochemistry. Medicinal chemists start preparing possible chemical inhibitors after the biology of the disease is known and an assay or animal model is in

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place. Based on preliminary findings in the biological system, chemists proceed to synthesize novel and potentially enhanced lead compounds.

It frequently takes years for chemists and biologists to collaborate in this way before a final set of lead compounds is prepared for further research. Important assessment. At this stage, a potential medication is assessed in an animal model (such as rats or dogs) for toxicity, effectiveness, and other characteristics. This review procedure could take several years. Assuming that the medication candidate passes these examinations, Following the accomplishment of preclinical research with success An investigational new drug (IND) must be submitted by the drug developer or sponsor in an application to the appropriate regulatory body, such as the CDSCO in India, the FDA in the US, etc., in order to begin clinical research. The official procedure via which a sponsor gets authorization for a drug's testing in human participants. Following the submission of the IND, the relevant regulatory body examined all the information and, if satisfied, allowed the sponsor to start the clinical trial. The FDA will take 30 to 60 days to approve a clinical trial following an IND submission. [4]

Following approval, start Phase 1, Phase 2, and, at last, Phase 3 human clinical trials. Based on standards specific to the disease being treated, the FDA determines the minimum number of individuals needed for each stage of the clinical studies. At the conclusion of the clinical trials, the FDA receives the data from the firm and determines whether to authorize the medicine for general distribution or not. [5] Following the successful completion of clinical research, the drug sponsor can submit a New Drug Application (NDA) to the appropriate regulatory authority in order to obtain a marketing license and begin commercial production, provided the drug candidate has demonstrated sufficient safety and efficacy for its intended use.To file an NDA (New Drug Application) filing, the drug sponsor is expected to submit all necessary documentation and research data gathered from preclinical to Phase 3 clinical trials. Nowadays, the average cost of creating a new medication is far higher than $1. billion and takes over a decade. A firm creating a new medication typically has 10 years of patent protection (at the most, with the exception of rare cases of "orphan diseases") during which the treatment is on the market. This is because patents are normally issued during the early research phase of exploration. Therefore, the reason why brand-name prescription pharmaceuticals cost more is that the firms need to recover their investment over the course of the patent's term, which is usually seven to ten years, in addition to profiting from the sale. Because brand-name medications are typically marketed at a premium price to offset the costs associated with drug research and development, the price of branded medications is higher than that of generic medications. Medical [6] Although the word "generic medicine" has diverse meanings in different markets, the World Health Organization (WHO) defines it as a pharmaceutical product that "is usually intended to be interchangeable with an innovator product" or "is produced without the innovator company's license" and "is sold after the patent or other exclusive rights expire. [7]

Must include the exact same active substances as those used in the original recipe. The US Food and Drug Administration (FDA) states that generic medications are either exactly the same as their brand-name equivalents or fall into an acceptable bioequivalent range in terms of pharmacokinetics and pharmacodynamics. Therefore, the FDA believes that generics are equivalent in terms of dosage, potency, mode of administration, and safety. Effectiveness and purpose. Generic products are typically accessible after the original developer's patent protections have lapsed. When generic products are made available, market competition frequently results in insignificantly reduced costs for both the generic versions and the original brand-name product. The duration of time it takes for a generic medication to be released. [8] Other pharmaceutical companies may apply to the FDA for approval to produce and market a generic version of the original substance once the patent expires.

The FDA requires medication companies to file a shortened new drug application (ANDA) for authorization to sell a generic medication that is bioequivalent to or identical to the brand-name medicine. The FDA examines the application to make sure the pharmaceutical companies have proven that the generic medication can be used in place of the name-brand medication that it mimics. The generic medication's equivalent to the brand must be demonstrated by an ANDA. [9] The precise definition of a generic medication varies depending on the legal needs of the various jurisdictions. Nonetheless, the idea of bioequivalence serves as a fundamental tenet for the safe and efficient use of generic medications. Equivalency in biological terms is as follows: two pharmaceutical products are considered bioequivalent if they are both pharmaceutically equivalent and share a similar level of bioavailability (rate and extent of availability) following administration at the same molar dose, meaning that one can reasonably expect that their effects will be

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nearly identical in terms of both efficacy and safety. The same amount of the same active ingredient(s) in the same dose form for the same route is implied by pharmaceutical equivalency. [10]

Because generic drug businesses do not need to spend as much time and money on research and development as branded drug companies do due to FDA testing and brand approval, generic medications can be up to 85% less expensive than their branded counterparts. The ingredients for the medication are already complete. This implies that generics can be offered for a lot less than brand-name medications and reach the market more quickly. [11]

Rationale of Study:

Preparing these reviews had as its primary goal raising awareness of and totally dispelling myths and misconceptions around generic medications. Because of misconceptions and a lack of knowledge about the distinction between brand and generic products, it's critical to inform patients of this information. These studies' data on generic versus brand-name medications may enhance generic prescribing practices and, in the end, contribute to the creation of reasonably priced healthcare.

II. MYTHS AND FACTS ABOUT GENERIC DRUG IN PEOPLE MIND

MYTS	FACTS
Generic medications are weaker, and their effects on the body take longer to manifest.	The active components in generic medications are identical to those in name-brand medications in terms of strength, quality, purity, and stability. The same amount of the active component is delivered by the generic medication over the same period of time [12].
Generic medications are not produced in the same facilities as brand-name medications.	The FDA forbids the use of poor facilities and inspects establishments to make sure that safe procedures are followed. [13]
More side effects are caused by generic medications.	The FDA keeps an eye out for adverse drug reactions (ADRs) before a generic version is put on the market, and it has found that the levels of ADRs in brand-name and generic medications are the same. [14]
Although generic pharmaceuticals are inferior to name-brand medications, they are less expensive.	Because generic manufacturers typically do not participate in costly marketing and promotion, research and development, or advertising, they are able to sell their products for less money, not because the products are of worse quality. [15]

BRANDED MEDICINE

A medicine that is marketed by its designer under a particular trade name that was first introduced to the market, irrespective of the drug's patent expiration date. Any new pharmaceutical's development is a difficult and costly undertaking that involves a number of steps, including drug discovery, drug development, preclinical research, clinical research, regulatory requirements, and the introduction of the medication into the community's market.Medicate Revelation: Novel viewpoints into the ailment handle motivate researchers to make inventive drugs that stop or turn around the side effects of infection. Numerous molecular-compound ponders have been conducted to discover conceivable medicines for a wide range of maladies. Analysts have already looked at compounds found in plants, fungi, or marine life forms to supply the establishment for these potential drugs. Nowadays, scientists use their understanding of hereditary qualities and protein structure to make modern compounds through computer innovation. From a list of 10,000 chemicals, 10 to 20 compounds that will possibly interfere with the illness preparation will be chosen.[16]

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STEPS IN DRUG DISCOVERY:

1. Target distinguishing proof: Through target distinguishing proof, a quality or protein that plays a major part in a malady is found. To date, 120 targets have been detailed from differing perspectives; genomic, proteomics, and biomolecular approaches have all been utilized for target drug-inverse science. Docking is applicable.
2. Verification of the target: Targets are confirmed by the utilization of modern methods and disobedient methods, such as utilitarian quality examination, cell-based protein interaction signaling circuit investigation, and disease
3. Assay improvement and confirmation: It is a basic stage in sedate revelation. Measures are test setups that are utilized to foresee the cellular, atomic, and organic behavior of conceivable novel medications.
4. High-throughput screening: By utilizing mechanical forms, control programs, fluid handling devices, touchy finders, and automated forms, millions of robotized pharmaceutical, chemical, and hereditary tests are sparing hours of difficult testing by researchers. HTS finds substances, qualities, and antibodies that have a critical effect on humans.
5. Hit to lead: Utilizing the warm to lead method, little atom hits from HTS are looked into and optimized into a lead.
6. Lead optimization: a strategy to boost an effect's quality and reduce its negative impacts Optimization of leads creates a restorative candidate and utilizes a creature demonstration of ADMET in preclinical testing. The sedate advancement handle starts once a single lead particle has been found and optimized for a potential helpful [17]

DRUG DEVLOPMENT

Pharmaceutical medication development is the method of presenting a newly synthesized helpful atom into the showcase in a helpful dose frame that's straightforward to manage for patients. The two steps within the sedate improvement handle are preclinical inquiry and clinical research.

III. PRECLNICAL OR NON-CLINICAL STUDY

Preclinical Studies Preclinical considers are planning to supply data on the security and viability of medical candidates before testing them on people. Also, they can provide evidence of a compound's organic impacts and ordinarily incorporate both in vitro and in vivo considerations. Preclinical thinkers must follow great research facility rules to guarantee dependable outcomes and are required by administrative organizations such as the FDA, which recently applied for IND endorsement. Understanding compound dose and harmfulness is basic to deciding whether it is justified and sensibly secure to continue with clinical trials and is given through pharmacokinetic and pharmacodynamic data.

	PRECLINICAL STUDY // NON CLINICAL STUDY	
1	**PHARMACOLOGICAL STUDY**	**Pharmacokinetic studyPharmacokinetic Study: In general, ADME studies are conducted in both rodents and non-rodents to determine the optimal dose level in male and female species and to provide dose-relationship information. In vitro: Physical and chemical properties, metabolic study, hepatic clearance, tissue binding and permeability. In vivo: Pharmacokinetic profile [disadvantages vs. time], AUC, C Max and T Max Half-life, bioavailability and elimination rate.**
		Pharmacodynamic safety studies: Addresses therapeutic response and mechanism of action. In a primary pharmacodynamic study: Study the physiological effects of drugs. In a secondary pharmacological study → study Mechanism of action and effect of relevant compounds unrelated to the desired therapeutic effect A pharmacological safety study was conducted to identify a possible adverse pharmacodynamic effect of the compound on selected physiological functions that may have an impact on human safety.
2	**TOXICOLOGY STUDY**	**Acute and chronic toxicity:** drugs with acute toxicity are studied for two weeks up to the lethality threshold (LD 50) with a 95% confidence interval. Animals used in a chronic toxicology study were given multiple doses at substantial doses over six to nine months, seven days a week. The highest dose produced specific observable toxicity, while the lowest dose produced no observable toxicity.

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		Reproductive Toxicity: The study assesses the drug candidate's potential teratogenicity, care for young children during nursing, and effects on both male and female fertility.
		Genotoxicity study: It establishes whether a suggested medication has the ability to modify DNA by influencing alterations in chromosomal structure or nucleotide sequence. conducted both in vivo and in vitro.
		Carcinogenicity Toxicity: The specific medication administered for a duration longer than six months in this kind of research animal was watched for the growth of tumors.
		Immunotoxicitity study: It does not cause any allergic reaction or swelling toward the drug administered [18], [19].

INVESTIGATIONAL NEW DRUG APPLICATION (IND)

When satisfactory results from the pre-clinical study are obtained,the sponsor applies for an investigational new drug application to the FDA in order to receive approval for human clinical trials. authoris The preclinical study report needs to be filed with and reviewed by the FDA,a regulatory body.

Once the authority has reviewed the satisfactory results, the clinical trial can be authorized. Upon receiving authorization to perform a clinical study, It was divided into four main stages, which are as follows: Microdosing is in phase 0. Phase I: profile of a safe dosage. Phase II: research on negative effects at different dosages; Phase III .Investigation of Adverse Reactions Following phase III of a clinical study, the sponsor must file an NDA application with the FDA by submitting all preclinical data in addition to phase I, II, and III data. [20]

CLINICAL RESEARCH:

PHASES	NAME	TYPE OF STUDY	No. OF SUBJECTS	TIME REQUIRED FOR STUDY	PURPOSE OF TRIAL
0	Microdosing	Open lable	10 – 15 (Healthy)	15 day to one month	To study PK, PD, And toxicology data.
I	Safety and Phrmacology trial	No Blinding and Control	20 – 80 (Healthy)	Study period upto Months.	To study PK, PD, BE, and maximum tolerability dose of drugs.
II	Therapeutic Exploratory Trial	Single Blindingwith Control	300 - 500 (VTM)	1 to 2 year	To study Drug Drug interaction, Drug disease interaction, ADR, and effectiveness of drug on increase dose level.
III	Therapeutic Confirmatory trial	Double Blindedwith Control	1000 - 3000 [VTM]	SeveralYears	Evaluation of Overall Risk and Benifits, Dosage interval study, Efficacy and Safety of subgroups.
IV	Post Marketing Surveince	-	More than1000 depending on end point of study	Severalyears	Monitor the Ongoing Safety and efficacy in large population, To studylong-term adverse effects and effect on special groups like children, Pregnant ladies, elderly [21], [23]

New Drug Application (NDA): A New Drug Application could be a formal proposition made by a medicate support to the FDA for the deal or promoting of a medication that has been affirmed for commercialization. Taking after receipt by a administrative body, an NDA is subject to a specialized audit prepare. This evaluation affirms that there have been sufficient provided information and data. Taking after an NDA review, there are three conceivable results that may well

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be sent to support. Not Approvable: It records the lacks and gives an clarification for the dismissal. Satisfactory minor changes such as showcasing application ought to be altered. Approved Approved pharmaceutical for checking The clinical trial post-marketing reconnaissance stage IV :- In this arrange taking after the commercialization of a item within the advertise, security is evaluated and checked, and ADR in coordinate concept or people who patients or people treated by a specialist and given a yellow or blue card stamped Supports report detailed antagonistic medicate responses (ADRs) to the FDA and get endorsement to alter or remove the item from the advertise. [22]

REGULATORY AUTHORITIES

Improving the quality, safety, and adequacy of pharmaceutical items could be the best need for administrative undertakings since sedate improvement may be a complicated, costly,and unsafe handle. Laws relating to pharmaceutical are required to ensure the viability, security, and quality of Drugs since to their basic part in keeping up human wellbeing. The administrative undertakings specialists are the sole association with total responsibility for keeping up all information and keeping up items in compliance. In arrange to protect open wellbeing, directions include a comprehensive assessment of a specific pharmaceutical item, in expansion to item publicizing, pharmaceutical enlistment, showcasing authorization, consequence and conveyance, and pharmacovigilance. [24]

Nation Name	Regulatory Authority
India	Central Medicate Standard Control Organization (CDSCO).
USA	Food and Sedate Organization (FDA)
UK	Medicines and Health care Items Administrative Agency.
Europe	European Medications Organization (EMA)
Australia	Therapeutic Merchandise Organization (TGA)
China	State Nourishment and Sedate Organization (SFDA)
New Zealand	Medicines and Medical Gadgets Security Authority (Medsafe)
Switzerland	Swiss Organization for Therapeutic Products..
Japan	Ministry of Well Being Work & Welfare (MHLW)
Canada	Health Canada [25]

GENERIC MEDICINE:

The time period “regular drug” or “generic medicinal drug” should talk over with various things in specific markets, despite the fact that the world fitness business enterprise describes it as a term that is broadly understood. Pharmaceutical product that: 1) generally designed to be interchangeable with an inventor’s product; Produced with out the company’s authorization; and 3) disbursed after the patent or other one-of-a-kind rights expire .A ordinary drug is any medication this is offered through its chemical call alternatively than by way of selling its emblem call or composition[27].The “Drug charge competition & Patent term recovery Act surpassed” (additionally called the Hatch-Waxman Act) was surpassed by means of the us Congress on September 24, 1984. The purpose of this rules is to create a cutting-edge system of government law of familiar tablets in the u.s.a. by the pharmaceutical quarter. medications targeted as generics are those which can be analogous to logo-name tablets that have already been accepted via regulators in terms of their energetic ingredients, dose, approach of administration, efficiency, safety, and pleasant. they might have extraordinary elements and a one-of-a-kind appearance from their branded opposite numbers. It is not vital for producers of popular capsules to contribute more money to preclinical and medical research or drug improvement. because they are much less pricey, generics provide a country with the possibility to decrease its standard medicinal drug spending. Pharmaceutical organizations ought to put up a shortened new drug software (ANDA) in order for the regulatory bodies to permit the commercialization of a usual drug.

Because the branded equivalents have undergone prior evaluation and approval for their efficacy and safety, the ANDA process spares the manufacturer from having to again conduct time-consuming, animal testing on generics. They can be created after the inventor's patent and other unique rights have expired[28].The main benefit of generic medications is that they are substantially less expensive than their branded counterparts without sacrificing quality or efficacy. this is

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usually because they are no longer in need of funding for the creation and study of the medicine. Since it's not required to duplicate theexpensive clinical trials, these tablets are unquestionably a better deal. All the procedures required to place a generic drug on the market are involved in the process of producing a generic pharmaceutical product. Goods The procedures used in the creation of generic pharmaceutical goods varied significantly. No set of rules or regulations exists that are applicable to all industries. A genetic product was created as a result of their literature analysis.

Choosing potential drugs: The organization puts together a team of experts and selects from a number of options to address the problem that the market research identified. A comprehensive selection is made in order to identify a possible Doug candidate. The group selects the applicant who advances to the following round of the preliminary

Candidate Drug Screening: Candidates for drugs who have been chosen in a previous stage are screened to obtain a general idea of possible candidates; this is done to accept the best candidates and weed out the idea development. A product concept, which is a more thorough version of a product idea, is created from the screening of candidate medications.

Identification of the target market, generation and evaluation of different product concepts,and selection of one development for additional work are all System-level design includes defining the product's composition, dividing it into subsystems, and defining the final formulation plan for the production system. A draft diagram of the manufacturing process flow. Specifications: comprehensive material and limit specifications, all components in product identification of all likely suppliers. A process plan was created.

Specifications: comprehensive material and limit specifications; all components in product identification of all likely process plans created within the system; this phase's output controls the product's documentation.

Concept testing: This part of the generic product development process begins with an accelerated study of stability and experimental creation based on scientific measurements. The pipeline for developing new products is longer than the phase

Analysing business: It's a crucial stage in any organization. The time needed to complete the product development process and its benchmarks should be set in stone. The impact of delays and the timing of product launches on this phase have also been thoroughly

Development of the prototype: this phase comprises the creation of the prototype, testing, adjustments, and pilot production. Increase business output prior to a predicted increase in product demand. Technology development includes the transfer of an industrial process and the registration of paperwork. One of its constituents is clinical research. Thorough stability analysis, bioequivalent investigation, and toxicological investigation Registrations: At this point, you must finish a dossier at the authority that regulates. It ends when a product is registered.

Acquiring the required documentation and marking for registration.

In the end, present a product to a targeted market. (31)

REQUIREMENTS FOR ANDA

An ANDA, or abbreviated new drug application, is the application used to request approval for generic pharmaceuticals. There is no requirement for the sponsor to replicate the clinical trials carried out for the initial, name-brand product. Instead, manufacturers of generic drugs must confirm that their product is a bioequivalent version of a brand-name drug that has previously been approved. Information is submitted with an accelerated new drug application (ANDA) to the FDA in order to have a generic drug product reviewed and potentially approved. An ANDA, or abbreviated new drug application, contains data and is submitted to the FDA for review and potential approval of a generic pharmaceutical product. Once approved, the applicant can move forward with the manufacturing and marketing of the generic drug product, providing a more affordable, secure, and useful alternative to the brand-name drug it references. Since preclinical (animal) and clinical (human) data required to demonstrate safety and efficacy are frequently missing, applications for generic pharmaceuticals are referred to as "abbreviated." Rather, applications for generic medicines must present scientific proof that their product performs comparably to the novel drug.

One way that applicants demonstrate that a generic drug performs comparably to the innovator drug is by timing the time it takes for the drug to enter the bloodstreams of healthy volunteers. This "bioequivalency" demonstration provides information about the generic medication's rate of absorption, or bioavailability, which may be compared to the innovator drug's rate. To receive FDA approval, a generic drug must deliver the same amount of active ingredients into

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a patient's bloodstream in the same period of time as the innovator drug. In order to assess and approve generic versions, the FDA developed the ANDA in 1970. Until 1978, candidates for generic drugs had to submit evidence from clinical trials attesting to their complete safety and effectiveness. Post-1978 public reports of these trials were required of applicants. recording safety and efficacy. All of the necessary information is provided by Section 505(j)(2) of the FD&C Act and is found in ANDA (A). 505(j) application: The same active ingredient, dosage form, strength, route of administration, labeling, quality, and performance are all present in the suggested product, according to information in the new drug application.

FDA's Application for a New Drug Market under 21 CFR Part 314 Subpart C of 21 CFR Part 314: Abbreviated Application e.Drug products for which a shortened application may be filed are listed in items 92 and 94, respectively.

97: Additions and other modifications to an approved ANDA; • 96: Modifications to a disapproved ANDA

99: The applicant's additional duties as an ANDA FDA response to application (SUBPART D).

100: Application review and shortened application deadline

101: submitting an ANDA and getting an NDA

105: the NDA and ANDA are approved

107: the 505(j)(b)(2) application or ANDA [32]

date of acceptance Before a patent expires, marketing a generic medication requires certification: The generic verifies one of four things for each patent:

Paragraph (I): No patent information about that name-brand drug has been sent to the FDA. Paragraph II: The patent has reached its expiration date. Paragraph (III): The generic version won't be accessible after a certain date, when the patent expires. Paragraph IV: The manufacture, use, or distribution of the innovative medicine for which the ANDA was submitted will not breach the patent or render it null and void. Once the generic has received paragraph I or II certification, the FDA can swiftly approve the ANDAThe FDA has the authority to accept a paragraph III certification at any time after the patent expires. The implications of a paragraph IV certification are significantly more intricate. A generic manufacturer is certified under paragraph IV when it chooses to introduce its own generic version of a drug without first waiting for the patent rights of the pioneer to expire. Instead, it argues that the pioneer's patent is invalid or that its medication does not infringe upon it, which supports its early market entry [33].

RECORDS NEEDED FOR INDIA'S Generic DRUG PRODUCTS REGISTRATION REQUIREMENTS:

Form 44 must be submitted for approval of generic pharmaceuticals in

In India, a Treasury Challan of INR 15,000 is needed for all active chemicals for longer than a year, while INR 50,000 is approved for less than a

The applicant possesses a manufacturing license for the manufacturing of pharmaceuticals and raw materials in bulk. For medications purchased in bulk, a copy of the same must be Information about active substances is included in the chemical and pharmacological information.

The master manufacturing recipe; the formulation's specifics, including information on inactive substances; and the finished product specification

Quality control check during the

COA, which includes assay, identification, pH, homogeneity of content, and

Comparative dissolution data when using an oral dose form

Stability study evaluation in accordance with timetable requirements The drug's regulatory status, including the names of the companies that market it in the

Bioavailability and bioequivalence study reports (for oral dosage forms)

Sub-acute toxicity data collected with the applicant's product in the case of injectable formulation Prescribing information Draft labels and cartons and a copy of the license in Form [34]

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COMPARISON BETWEEN GENERIC MEDICINE AND BRANDED MEDICINES:

GENERIC MEDICINE	BRANDED MEDICINE
1. A medication's generic form may have different excipients, such as color or flavor. 2. Low prices are accessible to underprivileged patients. 3. Preclinical and clinical research are not necessary. 4. by manufacturing a generic version by an inventor other than the innovator itself. 5. Studies of bioequivalence are carried out. 6. The FDA must grant permission in an ANDA application in order to market a medicine. 7. The 2-4-year product development process is quick. 8. Short approval times	1. Branded medicines have the same excipient in the brand, which is the is the right of patent. 2. High price of drugs due to drug discovery, preclinical study, and marketing 3. Preclinical research and clinical research are necessary. 4. Only innovators have the authority to manufacture a drug until the patent expiration. 5. A study of bioavailability and bioequivalence was carried out. 6. The FDA must grant permission in an NDA application in order to market a medicine. 7. It requires several years for product development and marketing. **8.** longer approval period [35]

IV. CONCLUSION

The empirical study suggests that generic medicines are generally as effective and safe as their branded counterparts, often at a lower cost. However, individual responses may vary, and certain factors like patient preferences and regulatory standards can influence outcomes. Overall, it underscores the importance of informed decision-making by patients and healthcare professionals based on specific circumstances and needs. The Prescribing of drugs by registered medical practitioner with best utilization of Practice and experience according to disease condition of patients. Further study and Awareness Programme required to educate and eliminate misconception and myths about Generic drugs.

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