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A REVIEW: NEW DRUG DISCOVERY AND DEVELOPMENT

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ABSTRACT
Drug discovery is a systematic endeavor aimed at identifying compounds that possess therapeutic potential for the treatment and management of diseases. The journey from a conceptual idea to the market introduction of a drug is intricate and can span approximately 5 to 10 years, incurring costs around $1.7 billion. To define the pharmacological properties and toxicity profile of a new drug molecule, both pre-clinical and clinical studies are integral components of the research and development process. The development of a new drug must progress through multiple phases to ensure the creation of a safe and effective medicine that meets all regulatory standards. The drug discovery and development process initiates with the identification and validation of targets, followed by optimization, lead compound discovery, and preclinical animal testing. These stages are essential precursors to clinical trials and the evaluation of drug candidates in human subjects. Preclinical studies are crucial for assessing the efficacy of therapeutic drugs or strategies before advancing to clinical trials. The pharmaceutical industry's development of generic drug products represents a scientific and technical approach within the drug discovery and development framework. Currently, pharmaceutical companies are increasingly focusing on the development of generic products, as this pathway typically requires less time and financial investment compared to that of innovator companies. This review aims to provide a comprehensive discussion of the drug design methodologies for newly discovered drugs from 2020 to 2024, emphasizing their pharmacokinetic and pharmacodynamic profiles, as well as in vitro and in vivo evaluations. Additionally, this article offers a concise overview of the new drug discovery and development processes, along with a brief explanation of the distinctions between innovator and generic drugs, including the steps involved in the generic drug development process.

KEYWORDS: Drug discovery & development, Pre-clinical study, Clinical study, Innovator & Generic drug.

INTRODUCTION
The process of developing new pharmaceuticals is highly intricate, expensive, and fraught with risks.[1] In the domains of medicine, biotechnology, and pharmacology, drug discovery refers to the methodology through which new potential medications are identified. Traditionally, the discovery of drugs involved isolating the active components from conventional remedies or through chance occurrences, exemplified by the discovery of penicillin.[5] Researchers are primarily focused on creating new molecular entities (NMEs) and innovative dosage forms during the new drug discovery (R&D) process in various pharmaceutical companies. Since the 1990s, the FDA has approved fewer novel drugs (Mullard, 2015), most likely as a result of lower R&D spending on NME manufacture (Munos, 2009).[2] Research and development expenses for each effective medication are expected to range from $900 million to $2 billion on average.[7] A wide range of interests and expertise are combined in the drug discovery process. From a straight forward method of determining the active ingredient. Finding a novel chemical compound that alters a cell or tissue's function is just the beginning of the medication development process. Before a chemical can be deemed a medicinal entity, it must be completely non-toxic, have a good bioavailability, and be commercially viable after it has been shown to be efficacious and selective.[8] Periods in Drug Discovery and Development Process: It is estimated that the entire drug discovery and development process, including its introduction into the commercial market, takes five to ten years, and that the process costs approximately $1.7 billion to complete successfully.[5]

Objectives of Drug Discovery & Development
-Discovery/Screening: 5000-10,000
-Enter Preclinical Testing: 250
-Enter Clinical Testing: 5
-Approved by Regulatory Bodies: 1.[5]

Drug discovery history

1) Early drug discovery

The history of drug discovery extends back to the earliest periods of human civilization. Drugs known as "lullabies" were utilized in those days for both bodily and spiritual healing, as well as for religious purposes. The primary sources of the early medications were minerals, plants, and animals. In the latter part of the 18th century, drug discouragers began to employ scientific methods. The use of castor oil as a laxative and funnel plants to relieve gas and intestinal colic are two examples from Greek drug innovation.

2) Middle Age Drug Discovery

The middle age, Many portions of Europe were plagued by plagues between 400 and 1500 AD. Such diseases as scabies, leprosy, smallpox, tuberculosis, and bubonic plague were uncontrollable, and many people died from them. The Bible makes very few mentions of using herbs to treat illnesses. The transcriptions of Greek medical treatises and manuscripts are preserved by numerous churches.

3) Current drug Discovery

The foundation for systematic research and the development of drugs was Laid in the past 100 years. Pharmacist, Scientist, Clinicians And Statisticians, Marketing personals, Medical practitioner, economist And legal attorney are working in teams The process of drug discovery. On average, a drug takes 10 to 15 years from Initial research to reach the commercialization Stage. The cost of this process is estimated to be more than US$ 800 million. Developing a new drug is a tedious and expensive task. The primary compound undergoes a series of laboratory and animal tests to evaluate its impact on biological systems. In contemporary drug discovery, numerous modifications are implemented to enhance the compound's interaction with targets, minimize toxicity, or improve pharmacokinetic properties.[15]

➢ **STAGES OF DRUG DISCOVERY**

- Drug discovery is an expensive process involving high R & D cost and extensive clinical testing.
- A typical development time is estimated to be 10-15 years.

Fig 1: Stages of Drug Discovery.

1) Target Identification

Target identification represents the initial and crucial phase in the drug discovery process. A drug target refers to the precise binding site within a living organism where a drug exerts its effects.[15] The process of target identification initiates with the delineation of the function of a prospective therapeutic target, which may include a gene, nucleic acid, or protein, along with its involvement in disease pathology. This identification can be grounded in the foundational principles of various scientific fields, including molecular biology, biochemistry, genetics, biophysics, and others.[8] The process of identifying a target is succeeded by an analysis of the molecular mechanism associated with that target. An optimal target must demonstrate efficacy, safety, compliance with clinical and commercial standards, and possess 'druggability'.[7]

Approaches

- Identification, selection, and prioritization of potential disease targets.
- Genetic polymorphisms and their association with diseases.
- Alterations in mRNA and protein expression levels.
- In vitro investigation of cellular mechanisms.
- Application of knockdown, knockout, or target-specific tools.[8]

2) Target Validation

Target validation refers to the procedure through which the anticipated molecular target, such as a gene, protein, or nucleic acid associated with a small molecule, is confirmed.[21] Target validation involves establishing the functional significance of a designated target in relation to the disease phenotype. Although assessing a drug's efficacy and toxicity across various disease-relevant

cellular and animal models is highly beneficial, the definitive evaluation lies in the drug's performance within a clinical environment.[7] Validation may be achieved through a variety of techniques. Examples of these methods and tools include the antisense approach utilizing RNA-like compounds, the use of transgenic animals to assess drug effects, tissue restriction and knockout techniques, monoclonal antibodies, and more recently, chemical genomics.[8]

The process of target validation encompasses the following steps.
-Identification of the biomolecule of interest.
-Assessment of each candidate's viability as a target.
-Development of a bioassay to assess its biological activity.
-Establishment of a high-throughput screening methodology.
-Execution of screening to identify potential hits.
-Analysis of the identified hits.[15]

3) Lead Identification

A chemical lead is characterized as a chemically stable, viable, and drug-like compound that demonstrates activity in both primary and secondary assays, exhibiting acceptable specificity, correlation, and selectivity for the target receptor.[4] This necessitates the establishment of the structure-activity relationship, along with the assessment of synthetic feasibility and initial evidence of in vivo efficacy and target engagement. This process is also referred to as the developmental candidate.[21]

The attributes of a chemical lead include the following.

a. Defined Structure-Activity Relationship (SAR)
b. Assessment of drugability, including preliminary toxicity and hERG channel interactions
c. Feasibility of synthesis
d. Selection of specific mechanistic assays
e. In vitro evaluation of drug resistance and efflux potential
f. Demonstrated in vivo efficacy of the chemical class
g. Knowledge of pharmacokinetics and toxicity of the chemical class derived from preliminary toxicity studies or in silico analyses.[7]

To minimize the incidence of compounds that do not succeed in the drug development process, the assessment of drug potency is frequently conducted. This assessment plays a crucial role in the progression of a compound from a lead molecule to an approved drug. For a compound to qualify as a drug, it must demonstrate the ability to bind to a designated target; nonetheless, factors such as distribution, metabolism, and excretion are equally significant. Additional evaluations will assess the potential toxicity of the candidate compound, including tests like the Ames test and the cytotoxicity test.[8]

4) Lead Optimization

At this stage, the objective is to preserve the essential characteristics of lead compounds while addressing any structural deficiencies to develop a preclinical drug candidate.[5] The procedure consists of a repetitive sequence of synthesis and characterization of a prospective drug, aimed at developing an understanding of how the chemical structure correlates with its activity, particularly regarding interactions with its targets and its metabolic processes.[21] The objective of lead optimization is to maintain the advantageous characteristics of lead compounds while addressing their structural shortcomings. To develop a preclinical drug candidate, it is essential to modify the chemical structures of the lead compounds, whether they are small molecules or biologics, to enhance their specificity and selectivity towards the target. Additionally, pharmacodynamic and pharmacokinetic parameters, along with toxicological properties, are assessed. Laboratories are required to gather data regarding the toxicity, potency, stability, and bioavailability of the lead compound to effectively characterize it and determine a suitable optimization strategy.[8]

5) Pre-clinical Phase

Prior to administering a drug to human subjects, it is essential for researchers to assess its potential to inflict significant harm. Preclinical studies are conducted using animal models under controlled laboratory settings. There are two primary categories of preclinical research:
• In Vitro: These experiments take place outside of living organisms in a regulated laboratory environment.
• In Vivo: These experiments are conducted within living organisms.
Typically, preclinical studies are not overly extensive; however, they must yield comprehensive data regarding dosage and toxicity levels. Following the completion of preclinical testing, researchers evaluate their results to determine the feasibility of progressing to human trials. Various experiments carried out during these studies encompass:
• Single dose toxicity assessments
• Repeated dose evaluations.[8]

6) Clinical Trials

Clinical trials involve the participation of volunteers and are designed to address particular inquiries regarding the safety and effectiveness of medications, vaccines, alternative therapies, or innovative approaches to utilizing existing treatments.[21] Clinical trials adhere to a defined study protocol that is developed by the researcher, investigator, or manufacturer.[7]

Subsequently, they determine the following aspects.
- Criteria for participant selection.
-Total number of individuals involved in the study.
-Length of the study period.
-Dosage amount and method of administration.
-Evaluation of parameters.
-Collection and analysis of data.[4],[7]

Fig 2: Phases of Clinical Trials.

Phase 0: Clinical Trial

Phase 0 refers to investigational studies involving first-in-human (FIH) trials that are carried out in accordance with FDA regulations. These studies, distinct from those known as human microdose studies, involve the administration of individual subtherapeutic doses to a group of 10 to 15 volunteers. The primary purpose of Phase 0 studies is to gather pharmacokinetic data or to aid in the imaging of specific targets without eliciting any pharmacological effects. The pharmaceutical industry undertakes Phase 0 studies to identify which drug candidates exhibit the most favorable pharmacokinetic characteristics in human subjects.[8]

Phase 1: safety and dosage

Phase I trials represent the initial stage of testing a drug, involving a limited number of healthy human participants. Typically, these trials include between 20 to 80 healthy individuals who may have the specific disease or condition under investigation. Generally, patients are only included if the drug's mechanism of action suggests it may not be safe for healthy subjects. For instance, if a new medication is intended for diabetes patients, Phase I trials will be conducted with individuals diagnosed with that particular type of diabetes. These studies are rigorously monitored to gather data on pharmacodynamics within the human body. Researchers utilize dosage regimens informed by prior animal studies to determine the tolerable dose and identify any acute side effects. As the Phase I trial progresses, researchers gain insights into the drug's mechanism of action, the side effects associated with increasing dosages, and its overall effectiveness. This information is crucial for the subsequent design of Phase II studies. Approximately 70% of drugs advance to the next phase.[21]

Phase 2: Efficacy and side effects

Phase II trials involve a larger cohort of patients, typically numbering in the hundreds, and are designed to assess the drug's efficacy while reaffirming the safety findings from Phase I. However, these trials alone do not provide sufficient evidence to determine the drug's therapeutic potential. They yield additional safety data that researchers utilize to refine their research questions, enhance research methodologies, and formulate new protocols for Phase III studies. Approximately one-third of drugs progress to the subsequent phase. Notably, Phase II clinical studies are crucial for establishing therapeutic dosages for the extensive Phase III trials.[8]

Phase 3: Efficacy and adverse drug reactions monitoring

Researchers are preparing to conduct Phase 3 studies to determine whether a product provides a beneficial effect for a specific population. Often referred to as pivotal studies, these investigations typically involve between 300 and 3,000 participants. Phase 3 studies are crucial for gathering extensive safety data, as earlier studies may not identify less common side effects. Due to the larger number of participants and the extended duration of Phase 3 studies, they are more likely to uncover long-term or rare side effects. Approximately 25-30% of drugs progress to the subsequent phase of clinical research.

If a drug developer possesses data from prior preclinical and clinical trials demonstrating that a drug is safe and effective for its intended use, they may submit an application to market the medication. The FDA review team thoroughly evaluates all submitted data regarding the drug and ultimately decides whether to grant approval.[21]

New Drug Application (NDA)

provides a comprehensive overview of a drug molecule. Its primary aim is to confirm that a drug is safe and effective for its intended use in the studied population. The drug developer is required to include all relevant information, from preclinical data to Phase 3 trial results, in the NDA. This submission must encompass reports on all studies, data, and analyses. In addition to clinical trial outcomes, developers must also provide.

- Proposed labeling
- Safety updates
- Information on potential for drug abuse
- Patent information
- Compliance information from the institutional review board
- Directions for use.[21]

FDA review & approval

Upon receipt of the New Drug Application (NDA), the review team at the FDA assesses its completeness. Should the application be found lacking, the review team has the authority to reject the NDA submission.

Conversely, if the application is deemed complete, the review team is allotted a timeframe of 6 to 10 months to reach a decision regarding the approval of the drug.

In situations where the FDA concludes that a drug has demonstrated safety and efficacy for its intended use, it is then required to collaborate with the applicant to formulate and finalize the prescribing information. This process is referred to as "marking." The labeling provides corrections and objectives that outline the rationale for approval and the optimal usage of the drug. Nevertheless, there are often outstanding issues that must be addressed prior to the drug receiving marketing approval. At times, the FDA may ask the developer to respond to inquiries based on the available data. In other instances, the FDA may mandate additional studies. At this juncture, the developer must decide whether to proceed with further development. Should the developer disagree with the FDA's determination, there are established formal appeal processes available.

➢ INNOVATOR AND GENERICS

Innovator

The innovator product is typically defined as the first product to receive marketing authorization, usually under patent protection. In cases where a substance has been on the market for an extended period, it may become challenging to pinpoint a specific innovator pharmaceutical product.[21] An innovative drug refers to the initial tablets developed with a specific active ingredient that has gained recognition for its application. This product is typically characterized by established efficacy, safety, and quality standards. When a new drug is initially developed, the originating company often secures a patent for it.[22] The majority of drug patents are safeguarded for a duration of up to 20 years. During this patent term, other companies are prohibited from manufacturing or marketing the identical drug until the patent reaches its expiration.[4]

Generic

Generic pharmaceutical products are essential to the healthcare system in the United States.[16] The aim of this legislation was to promote the production of generic medications by pharmaceutical companies and to create a contemporary framework for the regulation of generic drugs by the government in the United States.[15] The landscape of generic drug development is in a state of continuous evolution, influenced by regulatory changes, technological innovations, and market dynamics. Despite the challenges that must be addressed, the ongoing expansion of the generic drug market is anticipated to offer patients greater access to affordable healthcare solutions and support the overall sustainability of healthcare systems globally.[20] Instances of brand name and generic medications can be illustrated with the following examples related to diabetes and hypertension. Metformin serves as the generic name for a diabetes medication, while its brand name is Glucophage. In a similar vein, Metoprolol is recognized as a generic drug for hypertension, with Lopressor being its brand name. Although these medications may be referred to by various names in different countries, the generic names remain unchanged.[22]

Difference[22]

INNOVATOR DRUG	GENERIC DRUG
1.Same active ingredient.	1.Same active ingredient.
2.High price compared to generic.	2.Low price compared to innovator.
3.No difference in strength & dosage.	3.No difference in strength & dosage.
4.Marketed under brand name of company	4.Produce by Generic companies.
5. Protected by a Patent	5.After Patent rights they produce low cost.

➢ GENERIC DRUG PRODUCT DEVELOPMENT

Generic products are the pharmaceutical equivalent of innovator product where active ingredients are present in same proportion, in the same dosage form and given in the same route of administration. When active components are present in the same amount, in the same dosage form, and administered via the same route, generic drugs are the pharmaceutical equal of innovator products.[22]

1) Generic products are the pharmaceutical equivalent of innovator product where active ingredients are present in same proportion, in the same dosage form and given in the same route of administration.[18]
2) When possible bio-involution issues are absent, the biological activity of a generic product is the same.[22]
3) They have enough labeling and are deemed safe and effective.[18]
4) According to the FDA's good manufacturing practice guidelines, they are produced to the same demanding standards as innovator goods.[22]

Generic Product Development in the Pharmaceutical Industry: A great deal of study and scientific evaluation are needed to produce generic products in the pharmaceutical industry. Appropriate strategic planning is necessary to meet the desired launching time.

1) STRATEGIES FOR DEVELOPMENT

Conversely, manufacturers of generic drugs are required to demonstrate that their formulation is bioequivalent to the name-brand equivalent in terms of both quality and performance.[18] Manufacturers of generic drugs, however, are required to demonstrate that their formulation is bioequivalent to the name-brand equivalent in terms of performance and quality.[22]

2) REFER THE PATENT

The industries should definitely take market share and patent status into account when deciding which generic product to produce.[22] However, manufacturers of generic drugs must demonstrate that their formulation is bioequivalent to the brand-name equivalent in terms of both performance and quality.[18]

3) SELECTION AND CHARACTERIZATION OF REFRENCE PRODUCTS

As previously stated, one of the main requirements for developing a generic product is that it be bio-equivalent to the reference listed drug (RLD).[18] The lab performs all in-vitro tests following the RLD in the pharmaceutical industry, including assay and dissolution of related substance.[22]

4) CHOOSING A TARGET MARKET

The company's approach to developing the generic product, analyzing the reference and generic products, conducting stability tests, choosing the batch size, and many other factors are all influenced by the target market selection.[18] The choice of target market influences a number of factors, including how the business will design the generic product, study the reference and generic products, conduct stability tests, choose the batch size, and many more.[22]

5) FACILITY FOR MANUFACTURING

The manufacturer must have a facility licensed by the MHRA or GMP to manufacture the drug, conduct stability testing, and manufacture in quantity in order to register a generic product for the US, EU, or other countries. Next, before shipment and before submitting the dossier and other papers, the auditor will also tour the factory.[22] The manufacturer must have a facility licensed by the MHRA or GMP to manufacture the drug, conduct stability testing, and manufacture in quantity in order to register a generic product for the US, EU, or other countries. Next, before shipment and before submitting the dossier and other papers, the auditor will also visit the factory.[18]

6) DEVELOPING FORMULATIONS

According to studies, the pharmaceutical industry must pay between 14 and 18 percent of its yearly sales. Therefore, given the strict regulatory constraints, the industry makes the crucial decision to produce generic products when profit is unclear.[18]

7) PREFORMULATION EXAMINATION

Drug-excipient compatibility must be established in preformulation studies since it influences the drug's stability and final dose form and can alter its pharmacological action. To gather as much information as possible on the drug substance and reference product, "pre-formulation" work must be examined before creating actual trial formulations.[22] Drug-excipient compatibility must be established in preformulation studies since it influences the drug's stability and final dose form and can alter its pharmacological action. To gather as much information as possible on the drug substance and reference product, "pre-formulation" work must be examined before creating actual trial formulations.[18]

8) EXCIPIENT SELECTION

Pharmaceutical excipients must meet a few fundamental requirements: Chemically inert; accessible and reasonably priced They are used to express the desired reaction.[22] The nature of the API and the excipient used in the reference product aid in the design of the formulation and the choice of the appropriate excipient from the perspective of development. Instead of using lactose monohydrate as a filler and maize starch as a disintegrating agent, anhydrous lactose and cross povidone would be a better choice if any API is moisture sensitive. Formulation scientists must evaluate these crucial factors while choosing the best excipient for formulation development.[18]

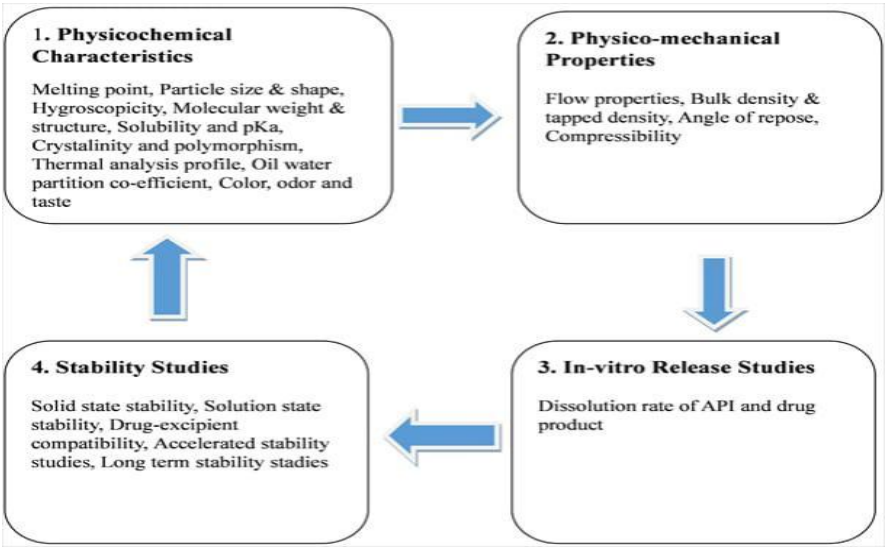

Fig 3. Parameters To Be Considered During A Preformulation Study.

9) CHOSSING A MANUFACTURING PROCESS

The most important choice in formulation creation is the production method; for example, direct compression or granulation might be used for solid dosage forms. Once more, granulation may be dry or wet. Numerous factors influence the approach to be taken, such as the properties of the API; if the API is sensitive to heat or moisture, wet granulation is not feasible; likewise, if the API particle size is greater, the distribution of the API may not be uniform in the finished goods.[18] Wet granulation The process of compression. The process of extrusion Drying Blending dry Compaction of rollers Coating for Encapsulation.[22]

10) LEAD FORMULA IDENTIFICATION

Trials are scheduled to be carried out after pre-formulation, excipient selection, and manufacturing technique have been designed. Given the industry's costs, the batch size should be as minimal as feasible. Aligning the dissolution profile with the reference is the main goal. Therefore, formulation scientists take the excipient fraction into account while designing a unit formula composition. The formulation scientist will determine the goal weight that permits manufacture by taking an appropriate percentage of each excipient.[18]

11) ANALYTICAL METHOD DEVELOPMENT

One of the most important steps in the process of choosing an API for the development of generic drugs is the development and validation of analytical methods. Other important steps include proper API characterization, sensitivity, precision, accuracy for drug quantification in a dosage form, linearity, and assurance of inactive ingredient compatibility.[18] The procedure's quality, including its accuracy, precision, specificity, limit of detection, quantitative limit, and robustness.[22]

12) SUBMISSION BATCHES OR SITE TRANSFER BATCHES

The generic company intended to carry out their site transfer or submission batches after the formulation was developed and the analytical process was moved to the production site. These batches will be submitted along with the dossier. Occasionally, two successive validation or submission batches are taken after an optimization batch. Until a successful optimization batch is completed, it may occasionally be necessary to run several optimization batches. Sometimes depending upon the capacity of RMG batch size can be adjusted. If the product the coated, then size of the coating pan is a limiting factor to determine the batch size. This happens especially for low dose drug with low average weight. Batch size, stability protocol of the developed product depends on the market being targeted.[18] Batch manufacturing record, Batch size, Process validation batches, Validation master plan will be the key for manufacturing process.

•The following should be included in a validation master plan

- Sampling plan
-Critical process steps
-The study purposes
-Responsibilities of personnel
-Critical parameters of process and product
-Testing plan
-Criteria of acceptance.[22]

•The following items should be included in the validation report

-Critical process steps studied
-Aim of the validation study
-List of manufacturing equipment
-Recommendations by the validation department
-Statistical analysis of results
-Attachments of copies of the executed batch records
-List of raw materials used in the manufacturing process
-Product and process acceptance criteria evaluation.[18]

13) PROTOCOL FOR STABILITY

Based on the target market, the QC and QA department at the business site should carefully develop the stability process. These data will be submitted to the relevant regulatory bodies for dossier approval. A stability study design such as the one below should be part of the protocol: Package dimensions, sampling intervals, strengths, and bracketing.[18]

14) BIOEQUIVALENCE AND BIOAVAILABILITY

As previously stated, a generic medication must be bioequivalent to the original medicine or reference product. Bioequivalence studies can be conducted under fed or fasting conditions. Depending on the regulatory agencies, both investigations may occasionally be necessary. Guidelines for bioavailability and bioequivalence have been established by the FDA and the European Medicines Agency (EMA). In a book known as the "Orange Book," the FDA lists approved products along with their equivalents.[18]

15) ANDA

First, the applicant sends an ANDA to the "Centre for Drug Evaluation and Research" or "Office Generic Drugs." The ANDA is next processed by the document room personnel, who assigns it an ANDA number and stamps the ANDA's cover letter with the date of receipt. A consumer safety technician is then tasked with examining the ANDA checklist's preliminary portions when it has been given to them.[22] The drug's labeling, microbiology, chemistry, and bioequivalence are all considered when filing an ANDA. The review of the filing is finished in sixty days. ANDA is approved when the proposal inspection is examined and further documents are examined and determined to be satisfactory.[18]

16) The process of the BIOEQUIVALANCE REVIEW

When evaluated under the same conditions, the innovator and generic drugs should have the same pharmacological characteristics, such as the same strength, dosage form, and administration method.[18]

17) LABELLING REVIEW PROCESS

The review procedure guarantees that the labeling of both generic and innovator Drugs is consistent. After the final level administrative review and individual disciplines have resolved their shortcomings, and if there are any unexpired patents Or exclusivities given to the RLD, the application will either get a complete approval or a preliminary approval letter.[18]

➢ CONCLUSION

The procedure can highlight the significance of reporting adverse drug events, encourage innovation, assist doctors in evaluating new drugs, and provide them the knowledge they need to tell patients about taking part in clinical trials. Pre-clinical research is a crucial step in the creation of new drugs. Instead of focusing on innovation, a successful pre-clinical trial yields a wealth of knowledge for improving drug research and ic drug products. later experiment in humans. Instead of focusing on innovation, the majority of nations concentrate on creating generic drug items. The increasing success rate of drug discovery procedures gives optimism that the pharmaceutical industry will be able to handle present and upcoming difficulties and will keep creating new medications and making them available to those in need.

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