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Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Chapter 14 : New Drug Development

Chapter 14
New Drug Development

Introduction to BCS system of classification

→ The Bio pharmaceutics Classification System (BCS) is a scientific framework developed to predict the behavior of a drug product in the human body based on its physicochemical properties.

The BCS classifies drugs into four categories (BCS Class I to IV) based on their solubility and permeability.

1. BCS Class I drugs are highly soluble and highly permeable, meaning they dissolve readily in the gastrointestinal tract and are easily absorbed into the bloodstream.
    - Examples of BCS Class I drugs include caffeine and ibuprofen.
2. BCS Class II drugs are poorly soluble but highly permeable, These drugs may have difficulty dissolving in the gastrointestinal tract, but once absorbed, they can pass through cell membranes easily.
    - Examples of BCS Class II drugs include ketoconazole and danazol.
3. BCS Class III drugs are highly soluble but poorly permeable, meaning they dissolve easily in the gastrointestinal tract but may have difficulty passing through cell membranes.
    - Examples of BCS Class III drugs include atenolol and cimetidine.
4. BCS Class IV drugs are poorly soluble and poorly permeable, meaning they have difficulty dissolving in the gastrointestinal tract and passing through cell membranes.
    - Examples of BCS Class IV drugs include griseofulvin and diazepam

Simple method

1. BCS Class I (High solubility , High permeability drugs)
2. BCS Class II (Low solubility , High permeability drugs)
3. BCS Class III (High solubility , Low permeability drugs)
4. BCS Class IV (Low solubility , Low permeability drugs)

Basic Concepts of clinical trials

- → Clinical trials are research and studies performed with volunteer people,
- → Clinical trial is done to test safety and efficacy of new drugs or new surgery procedure.

Types of clinical trial

- **Treatment trial :** This is performed for experimental treatments , test of new combination of drugs, or for new surgery procedure.
- **Preventions trial :** This is performed test a drugs foe prevention of disease , like vaccines , vitamins etc.
- **Screening trails (early detections) :** This trail is performed for detection of certain disease or health condition.
- **Diagonstic trail :** This is performed for diagnosing a particular disease or condition, of people have sign and symptoms.
- **Quality of life trail :** This performed to explore the ways which can improve comfort and quality of life in chronic illness.

Phases of Clinical Trials

1) Phase I trials test the safety and tolerability of a new intervention in a small group of healthy volunteers.
2) Phase II trials test the effectiveness and safety of the intervention in a larger group of patients.
3) Phase III trials test the effectiveness and safety of the intervention in an even larger group of patients, and compare the intervention to standard treatment or placebo.
4) Phase IV trials are conducted after the intervention has been approved for use, and evaluate its long-term safety and effectiveness

Abbreviated New Drug Application (ANDA)

- ANDA is an application submitted to FDA for the review and approval of a generic drug for production , this application contains necessary data of related drugs.
- Once FDA approved the application , the applicant can manufacture and market that generic drug, to offer a safe , effective and lower cost alternative drug to the brand name drug.
- Generic drug application are not required to provide pre clinical(on animal) and clinical (on human) data to prove safety and effectiveness of drugs , that is why they are called ”abbreviated applications ".

New Drug Application (NDA)

→ NDA is an application submitted to U.S. FDA to get permission for marketing a new drug product in United States . If FDA satisfied with provided data (safety , effectiveness , strength , quality etc) , approved for marketing.

NDA required following document to provide the information about the drug

- Procedure of clinical test
- Ingredients of the drug
- Result of animal studies
- Pharmacokinetics
- Manufacturing , processing and packaging of drug

New Drug development:

→ New drug development is the process of discovering, designing, and testing new medications for treating specific diseases or health conditions.

→ It involves a long and complex process of research and development, which begins with identifying potential drug targets and compounds that can modify those targets.

→ The process includes various stages, such as pre-clinical testing, clinical trials, regulatory approval, and post-marketing surveillance.

→ New drug development is a complex and time-consuming process, often taking several years or even decades to bring a new drug to market.

→ However, it is a critical component of modern medicine, as it allows researchers to identify new treatments for previously untreatable diseases, and improve existing treatments to better meet the needs of patients

New drug and clinical trial rules 2019

➢ The ministry of Health and family welfare has released the latest drug and clinical trial rules in 2019

➢ The new rules promote the Clinical research and provide easy explanation of difficult subjects like orphan drugs , Post trial access, pre and post submission meeting.

➢ The new drug and clinical trials rules 2019 are organised in 13 chapters and every chapter has many of rules . (107)

Generic Drugs vs Brand Name Drugs

Features	Generic Drugs	Brand Name Drugs
Definition	A generic drug is an off-patent pharmaceutical product that is manufactured by a pharmaceutical company in the same strength, dosage form, route of administration, safety, quality, performance characteristics, and intended use after expiring the patent of the relevant brand name drug (Innovator drug).	A Brand name drug is a pharmaceutical product that is developed and marketed under a patent or registered trademark by a pharmaceutical company. But it is approved after establishing the drug's safety and effectiveness through animal and clinical (human) studies. Also, brand name drugs known as innovator drugs.
Patents	Off patent.	Patent protected.
Trade Name	Marketed under the Generic name of the drug.	Marketed under a unique proprietary name given by the company.
Application	ANDA required for USFDA approval.	NDA required for USFDA approval.
Manufactured by	Manufactured by several pharmaceutical companies after patents expiration of the relevant brand name drug.	Developed and manufactured by an innovator company.
Animal & Clinical study	Not required to perform.	Essential to perform.
Price	Cheaper.	Costly than generic drugs.
Appearance (Color, Shape, Size)	Look different from relevant brand name drug.	Unique look as design during product development.
Name variation	Same Generic drug name in any country.	Same or different brand names in different countries.
Excipients	May contain the same or altered but acceptable excipients from relevant brand name drug.	Uses acceptable excipients by the innovator company during development.
Availability	After expiration of patents and exclusivities	From product launch after proving the safety and effectiveness.
Examples	Paracetamol tablet	Tylenol, Para, NAPA, Mapap, Nortemp,

Trade name concept

- A trade name is a term used to refer to a company or business entity's name, often used to identify and distinguish it from other similar entities in the market. It is also sometimes referred to as a "business name" or "doing business as" (DBA) name.
- Trade names can be registered with the government to protect the name from being used by other businesses in the same industry, but this is not always necessary.
- A trade name is a name used by a business or company to identify itself and distinguish it from others in the market. It can be registered or unregistered, and is often used interchangeably with the terms "company name" or "business name".
- Trademark, which is a legal protection for a specific symbol, word, or phrase used to identify a particular brand, a trade name is simply the name that a company uses to conduct business.

Introduction to Patent law

→ Patent Law is defined by various provisions of the patent Act 1970 . According to this law , Patent rights are given for inventions , which includes a new process , product or anything used in manufacture , and they should have patent eligibility .

Patent eligibility (Patentability conditions)

- Novelty.
- Non - Obvious (the invention should not be previously recognised , documented , or used in any form).
- Useful and Industrially Applicable.

Intellectual Property

➢ Intellectual properties refers to creation of mind such as invention , literary and artistic works , design, symbols , name and image used in commerce (businesses) examples of intellectual property Patent , trademark, copyrights, and trade secret.

Intellectual property rights

→ It is a legal right given to the inventor or creator to protect his invention or creation for a certain period of time , in this time period no one can use that properties for creating wealth without permission of owner and utilising intellectual property without permission is illegal and punishable.

Type of Intellectual Property rights

- **Patents :** It is used for protecting new inventions, ideas, or processes. Patent holders need to pay periodic government renewal fees. An approved patent is for a limited time period. Know more about Patents Act in India.
- **Copyrights :** It protects the ideas, examples would be written works, music, art, etc.
- **Trademarks :** It is something that protects the symbols, colors, phrases, sounds, design etc.
- **Trade Secrets :** It may be strategies, systems, formulas, or other confidential information of an organization that provides them a competitive advantage in the market.

Emergency use authorisation (EUA)

→ Emergency use authorisation is an authorisation(Permission) issued for use of unregistered drugs and vaccines in a public health emergency by FDA even in the lake of complete information about the safety and efficacy of the product The FDA determine that , it is appropriate to give permission for use of a drug or vaccine in a declared emergency

Conditions for issuing EUA

➢ FDA may determine (confirm) before issuing emergency use authorisation the

- The agent mentioned in the emergency condition may be serious life threatening illness or not ?
- The available scientific evidence indicates that the product may be useful in diagnosing , treating or preventing a serious life threatening illness
- The known and potential (which may be occur) benefits must be more than the known and potential risk of the product . (Risk reward ratio)

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