HERBAL DRUG TECHNOLOGY

UNIT 4 NOTES

EVALUATION OF DRUGS

- WHO & ICH GUIDELINES
- TESTING OF HERBAL DRUGS

PARENTING & REGULATIONS

- DEFINITION OF TERMS
- BIOPIRACY

REGULATORY ISSUES

- REGULATIONS IN INDIA
- MANUFACTURE OF ASU DRUGS
- SCHEDULE Z DRUGS

IMPERFECT PHARMACY

CONNECT WITH US ON :

IMPERFECT PHARMACY APP

@IMPERFECTPHARMACY

Evaluation Of Drugs

WHO Guidelines For Evaluation Of Drugs

- The world Health Organization (WHO) has given specific guidelines to ensure that herbal & crude drugs are safe, effective and of good quality.
- Because herbal drugs come from natural sources, their quality may vary due to climate, soil, collection method, processing & storage.
- Therefore, WHO guidelines help in standardization, quality control, safety & efficacy evaluation of crude drugs.

Objectives Of WHO Guidelines

- To ensure identity, purity & strength of herbal drugs
- To evaluate safety & efficacy
- To promote rational use of herbal medicines
- To support global acceptance of herbal drugs
- To reduce risks of adulteration & contamination

Main Guidelines

According to WHO, evaluation of herbal drugs is broadly devided into four main aspects:

1. Assessment of Quality
2. Assessment of Safety
3. Assessment of Efficacy
4. Intended Use

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

① Assessment Of Quality

- Quality Assessment ensures that the crude drug is pure, genuine & of good standard.
- It involves :
  - Pharmaceutical Assessment
  - Crude Plant Material
  - Plant Preparation
  - Finished product
  - Stability

ⓐ Pharmaceutical Assessment

- It covers all important quality aspects of herbal drugs.
- Pharmacopoeial standards should be followed whenever available.
- If no monograph is available, a proper monograph should be prepared.
- All manufacturing steps should follow Good Manufacturing Practices (GMP).

ⓑ Crude Plant Material

- Correct botanical name of the plant should be mentioned to avoid adulteration.
- Correct part of the plant used should be clearly specified.
- The condition of the drug should be mentioned whether fresh or dried.
- Important chemical contituents should be identified if possible.
- Limits for foreign matter like dust, insects & microbial contamination should be fixed.
- Each batch should have a voucher specimen authenticated by a botanist.

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

- Voucher specimens should be stored for future reference.
- A lot number should be given to each batch for identification.

ⓒ Plant Preparations

- Method of preparation such as powdering or extraction should be clearly described.
- Identification tests should be carried out to confirm quality.
- If the active compound is not known, chromatographic fingerprinting should be used.
- Consistency in quality should be maintained for every batch.

ⓓ Finished Product

- Complete manufacturing formula including excipients should be mentioned.
- Quality specifications of the finished product should be defined.
- Identification of plant material in the final product should be carried out.
- Uniform quality should be maintained in all batches.

ⓔ Stability

- Physical & Chemical stability of the product should be tested.
- Proper storage conditions should be defined.
- Shelf life & expiry date should be fixed.

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

② Assessment Of Safety

- Safety evaluation ensures that herbal drugs do not cause harmful effects.
- It involves :
  - Toxicological Studies
  - Safety Based on Experience

ⓐ Toxicological Studies

- Toxicity studies should be carried out whenever required.
- These studies help in identifying harmful effects of the drug.

ⓑ Safety Based On Experience

- Long history of traditional use can support safety.
- Known toxic effects & risks should be properly documented.
- Safety should be evaluated in relation to dose.
- Possibility of misuse, abuse or dependence should be checked.
- Side effects should be recorded & monitored.

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

③ Assessment Of Efficacy

- Efficacy assessment checks whether the drug actually works.
- It involves :
  - Activity
  - Evidence Supporting Indications
  - Combination Products

ⓐ Activity

- Pharmacological & therapeutic effects of crude drugs should be described.
- Active constituents responsible for therapeutic action should be mentioned if known.

ⓑ Evidence Supporting Indications

- Therapeutic uses of the drug should be clearly stated.
- For minor disease, traditional evidence may be sufficient.
- For serious, diseases, clinical evidence is required.
- Scientific proof necessary if traditional use is not established.

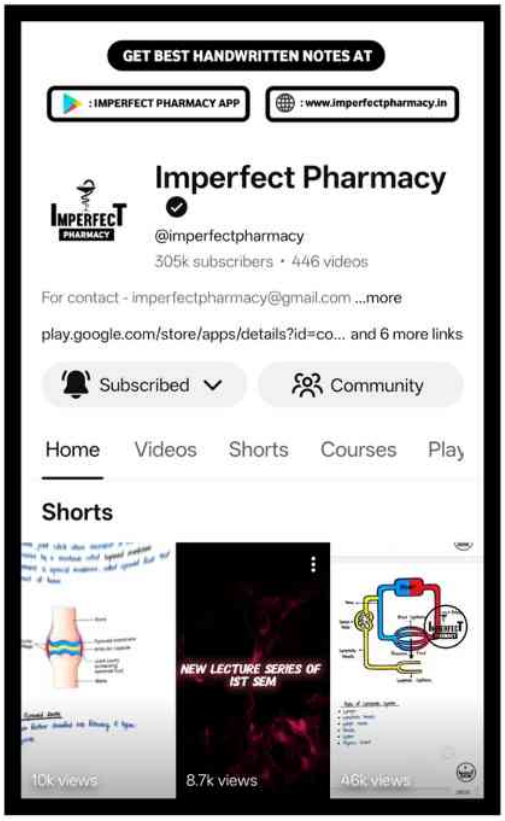
ⓒ Combination Products

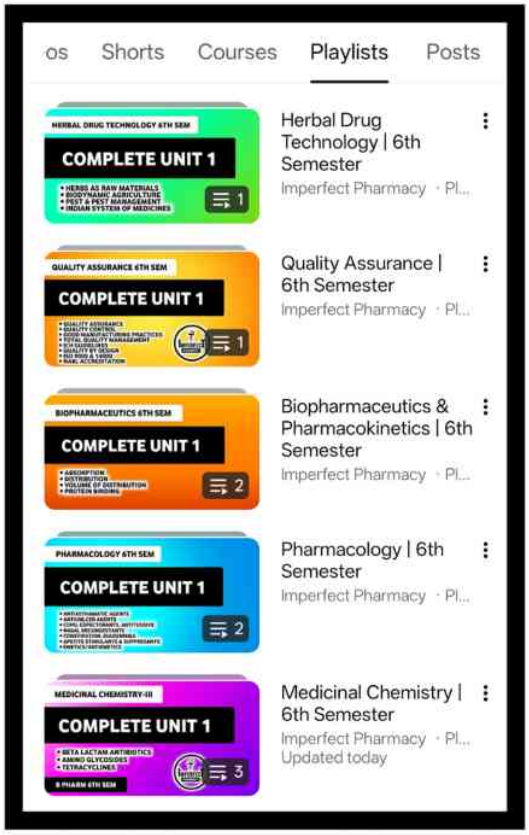
- Many herbal drugs contain more than one ingredient.
- Traditionally used combinations may be accepted based on experience.
- New combinations may require clinical studies.

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

FOR LECTURE VIDEOS VISIT OUR CHANNEL





FOR MORE CONTENT : VISIT OUR APP

④ Intended Use

- This section explains how the product should be used safely.
- It involves :
  - Product information
  - Promotion

ⓐ Product Information

- Name of the product & botanical name should be mentioned.
- Dosage form & dose should be clearly stated.
- Method & duration of use should be given.
- Warnings & precautions should be included.
- Possible side effects & drug interactions should be mentioned.
- Information regarding use in pregnancy & lactation should be mentioned
- Expiry date, lot number & manufacturer details should be included.

ⓑ Promotion

- Advertisements should be truthful & scientific.
- False or misleading claims should be avoided.

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

ICH Guidelines For Evaluation Of Herbal Drugs

- The International Council for Harmonisation (ICH) provides guidelines to ensure herbal drugs are safe, effective & of consistent quality.
- Although ICH guidelines were mainly developed for synthetic drugs, many principles are also applied to herbal & traditional medicines.

Basic Guidelines Of ICH

- Quality guidelines
- Safety guidelines
- Efficacy guidelines
- Multidisciplinary guidelines

① Quality Guidelines

- ICH quality guidelines focus on maintaining consistent quality of herbal drugs.
  - Proper identification of raw herbal material
  - Control of impurities & contaminants
  - Stability testing to ensure shelf life
  - Use of validated analytical methods
  - Good Manufacturing Practices (GMP) during processing
- This ensures that herbal drugs are safe, pure & of standard quality.

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

② Safety Guidelines

- Safety guidelines evaluate the toxic potential of herbal drugs.
  - Toxicity & genotoxicity studies
  - Carcinogenicity testing (if required)
  - Reproductive & long-term toxicity studies

- These studies help confirm that herbal drugs are safe for human use.

③ Efficacy Guidelines

- Efficacy guidelines ensure that herbal drugs produce the claimed therapeutic effect.
  - Clinical trials in human subjects
  - Dose-response studies
  - Good clinical Practices (GCP)
  - Pharmacovigillance (monitoring adverse effects)

- This proves that herbal drugs are effective & scientifically supported.

IMPERFECT PHARMACY

④ Multidisciplinary Guidelines

- These guidelines cover common technical aspects used in drug evaluation.
  - Common Technical Document (CTD)
  - Electronic Data Submission (eCTD)
  - Standard terminology & documentation

- They help in regulatory submission & global harmonization.

VIDEOS : IMPERFECT PHARMACY

Stability Testing Of Herbal Drugs

- Stability testing is used to determine how the quality, safety & efficacy of a herbal drug change with time, under the influence of temperature, humidity, light & storage conditions.
- It helps in deciding the shelf life & storage conditions of herbal products.

Need For Stability Testing

- To ensure consistent quality
- To determine expiry date
- To maintain safety & efficacy
- To study degradation of active constituents

Factors Affecting Stability

- Light
- Temperature
- Moisture
- Hydrolysis
- Oxidation

Method Of Stability Testing

It mainly involves following methods :

1. Real-time Stability Testing
2. Accelerated Stability Testing
3. Intermediate Stability Testing
4. Stress Testing

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

① Real Time Stability Testing

- This method studies the actual behaviour of herbal drugs under normal storage conditions.
- In this product is stored at normal room temperature.
- It is observed for a long period (months or years) Tested at regular intervals
- It shows the actual shelf life & natural degradation pattern of drugs.

Example: Herbal syrup stored at 25°C / 60% RH & tested every 6 months.

② Accelerated Stability Testing

- This method uses higher temperature & humidity to speed up degradation.
- In this drugs is stored at high stress conditions
  - 40°C ± 2°C
  - 75% ± 5% relative humidity
- Tested for short duration (3-6 months)
- Predicts long-term stability
- Helps in early estimation of shelf life
- It saves time & widely used for herbal formulations.

③ Intermediate Stability Testing

- This method is used b/w real-time & accelerated conditions.
- Product is stored at 30°C / 65% RH.
- Used when accelerated results are not satisfactory.

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

④ STRESS TESTING

- This method studies the effect of extreme conditions.
- Conditions applied :
  - Very high temperature
  - High humidity
  - Light exposure
  - Oxidation

- The main pupose is to identify degradation products to understand weak points of formulation.

PARAMETERS CHECKED DURING STABILITY TESTING

- Physical appearance (colour, Odour, Texture)
- Moisture content
- pH value
- Active constituent content
- No of Microbes

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

Patenting And Regulatory Requirements Of Natural Products

① Patent

- A patent is a legal right granted by the government to an inventor for a new investigation
- It gives the inventor the exclusive right to make, use, sell or distribute the invention for a limited period, usually 20 years from the date of filling.

What Can Be Patented

- New products (e.g. - new drug, device)
- New processes or methods
- Improvements in existing products or processes

Conditions For Patent

- Novel (new)
- Inventive (not obvious)
- Industrially applicable

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

What Cannot Be Patented

- Discoveries of natural substances
- Scientific theories
- Traditional knowledge
- Methods of medical treatment

Importance Of Patent

- Protects the invetor's work
- Encourages innovation & research
- Provides commercial benefits
- Prevents others from copying the invention

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

② Intellectual Property Rights

- Intellectual Property Rights (IPR) are legal rights given to a person or organization for their intellectual creations such as inventions, literary works, designs, symbols & artistic works.
- These rights protect the creator to unauthorized use or copying of their work.
- IPR encourages innovation, creativity & research by providing ownership & economic benefits to creator for a specific period.

Classification Of IPR

IPR can be classified the following main types:

ⓐ Patent

- Protect new inventions (products or processes)
- Valid for 20 years
- Example: New drug, New manufacturing process

ⓑ Copyright

- Protects literary, artistic, musical & dramatic works
- Valid for lifetime of author + 60 years
- Example: Books, Music, Films, Softwares

ⓒ Trademark

- Protects brand identity
- Includes logos, symbols, names, slogans
- Valid for 10 years (renewable)
- Example: Company logo, brand name of a medicine

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

ⓓ Industrial Design

- Protects the appearance or shape of a product
- Valid for 10 years (extendable)
- Example: Design of a bottle or tablet strip.

ⓔ Trade Secrets

- Protects confidential business information
- Example: Manufacturing formula, business strategy.

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

③ BREEDER'S RIGHT

- According to PPFVR (Protection Of Plant Varities & Farmer's Rights Act), 2001
- Breeder's right is a legal right given to a plant breeder who develops a new plant variety.
- This right allows the breeder to control the commercial use of that variety & get economic benefit from their research & effort.
- It also known as Plant Variety Rights.

Breeder

- Anyone who breeds, develops, or discovers & improves a plant variety can be a breeder
- A breeder can be:
  - A scientist
  - A farmer who develops a new variety
  - A research institute
  - A seed company

Conditions for Getting Breeder's Right

To get breeder's right, the plant variety must be:

- Novel: not sold earlier
- Distinct: Clearly different from existing varities
- Uniform: Same characteristics in plants
- Stable: Characters remain same after repeated cultivation

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

Rights Granted To The Breeder

① Exclusive Commercial Rights

- The breeder has the exclusive rights to:
  - Produce seed
  - Sell seed
  - Market the variety
  - Distribute the variety
  - Import & export the variety

- No one else can use the variety commercially without the breeder's permission.

② Right to License

- The breeder can:
  - Give the variety to another person or company on license
  - Recieve royalty or payment for its use

This helps breeders earn from their innovation.

③ Right to protect

- Breeder's right protects:
  - Time
  - Money
  - Scientific research

- It prevents unauthorized copying of the plant variety.

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

④ Right to Take Legal Action

- IF someone:
  - Copies the variety
  - Sells it without permission
  - Misuses it commercially

- The breeder can take legal action under PPVFR Act.

Duration Of Breeder's Right

- Breeder's right is granted for a limited period:
- Trees & vines → 18 years
- Other crops → 15 years

- After this period, the variety become public property.

Importance Of Breeder's Right

- Encourages research & innovation
- Promote development of high-yield varities
- Improves agricultural productivity
- Supports seed industry growth

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

④ FARMER'S RIGHT

- The PPVFR Act, 2001 provides legal protection to farmers for their contribution in conversation, development & improvement of plant varities.
- Under this Act, farmers are granted the following nine rights.

RIGHTS OF FARMERS

① Right to Save Seed

- A farmer has right to save seed from his harvest for future use.

② Exemption from Registration fee

- Farmers are exempted from paying registration fees while registering their varieties under the PPVFR Act.

③ Right to get seed at reasonable price

- Farmers have right to get quality seeds at a reasonable & affordable price.
- If seeds are sold at an unfair price, action can be taken under the Act.

④ Right to Exchange Seed

- A farmer can exchange seeds with other farmers.

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

⑤ **Right to Sell Seeds**

- A farmer can sell seeds of his produce.
- However, seeds cannot be sold under a brand name.

⑥ **Right to Register Farmer's Variety**

- A farmer can register his own variety or a traditionally conserved variety under the PPVFR Act.

⑦ **Right to Compensation**

- If a registered plant variety fails to perform as claimed, the farmer has right to claim compensation.

⑧ **Protection from Innocent Infringement**

- If a farmer unknowingly used a registered variety, he will not be punished under the Act.

⑨ **Right to Recognition & Reward**

- Farmers who conserve or improve plant genetic resources are eligible for recognition & rewards from the National Gene fund.

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

BIOPROSPECTING

- Bioprospecting refers to the scientific exploration & systematic study of biological resources such as plants, animals, micro-organisms & marine organisms to identify valuable bioactive compounds for medicinal, agricultural & industrial applications.
- It involves the use of traditional knowledge combined with modern scientific techniques to develop new products like drugs, herbal medicines, enzymes & nutraceuticals.

PURPOSE OF BIOPROSPECTING

- Discovery of new therapeutic agents
- Development of pharmaceutical & herbal products
- Identification of useful enzymes & biomolecules
- Support to biotechnology & drug research

BIOPROSPECTING IN PHARMACY

Many important drugs have originated from bioprospecting such as:

- Artemisinin from Artemisia annua (antimalarial)
- Taxol from Taxus species (Anticancer)

ETHICAL & LEGAL ASPECTS

- Bioprospecting must be done:
  - With permission from local communities or government
  - With fair benefit sharing
  - By respecting biodiversity laws & traditional knowledge
- Unethical bioprospecting is called "Biopiracy."

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

BIOPIRACY

- Biopiracy refers to the unauthorized use, patenting, or commercial exploitation of biological resources & traditional knowledge of a country or local community without giving proper permission or benefit-sharing to the original holders.
- In simple words, Biopiracy means stealing natural resources or traditional knowledge (like medicinal plants, seeds or indigenous remedies) & using them for profit without acknowledging or rewarding the people who originally developed or conserved them.

IT INVOLVES

- Use of medicinal plants, seeds, microorganisms or genetic material.
- Misuse of traditional knowledge of farmers or tribal communities.
- Taking patents in foreign countries without consent.
- No benefit-sharing with the source country or community.

COMMON EXAMPLES OF BIOPIRACY

① Turmeric: A patent was granted in the USA for wound healing properties of turmeric, which was already known in India for centuries.

② Neem: Patents were taken for neem-based pesticides despite its long traditional use in India.

③ Basmati Rice: Attempts were made to patent basmati rice varities grown traditionally in India.

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

TRADITIONAL KNOWLEDGE & NATURAL PRODUCTS

- Traditional Knowledge (TK) is knowledge developed & passed on by local & indigenous communities.
- It includes use of medicinal plants, herbs, seeds & natural remedies.
- Natural Products are substances obtained from plants, animals, or micro-organisms.

PATENTABILITY OF TRADITIONAL KNOWLEDGE

- Traditional knowledge cannot be patented directly.
- It is already known & lacks novelty.
- Publicly available traditional practices do not meet patent requirements.

PATENTABILITY OF NATURAL PRODUCTS

- Natural products in their natural or crude form are not patentable.
- Purified compounds, isolated molecules, or modified forms may be patented.
- New formulations or drug delivery systems from natural products can be patented.

PATENTABLE INNOVATIONS UNDER TK

- New extraction or processing methods.
- New pharmaceutical formulations.
- New therapeutic uses proved scientifically.
- Standardized herbal products with improved efficacy.

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

Case Study Of Neem

- Neem (Azadirachta indica) is a tropical evergreen tree
- It is native to India & found in many South-East Asian countries.
- Neem has been in Indian traditional medicines for more than 2000 years.

Traditional Uses Of Neem

- Used in agriculture as a natural insectible & pest repellant.
- Used in Ayurveda for skin diseases, fever, infections & wounds.
- Neem oil is used in soaps, cosmetics & toiletries.
- Neem seed oil is traditionally used for fungal diseases, malaria & infections.

Medicinal Properties

Neem seeds, bark & leaves show:

- Antiseptic
- Antiviral
- Anti-inflammatory
- Antifungal
- Anti-ulcer properties

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

Patent Issue On Neem

- In 1971, a US timber importer Robert Larson observed neem's usefulness in India.
- He conducted safety & performance tests on neem.
- Later, the invention was sold to W.R. Grace Company & The US Department of Agriculture.
- In 1994, the European Patent Office (EPO) granted a patent for a neem-based fungicides.

Opposition & Biopiracy Claim

- In 1995, Indian famers & NGOs opposed the patent.
- They argued neem fungicidal use was already known in India for centuries.
- This became the First Major Biopiracy Case challenged in Europe.

Final Decision

- Indian scientist provided evidence of traditional use.
- In 2000, EPO revoked the patent due to lack of novelty.
- This case became a landmark victory for protection of traditional knowledge.

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

Case Study Of Curcumin (Turmeric)

- Turmeric is a tropical herb grow mainly in India.
- It has deep yellow colour & bitter taste.
- Turmeric has been used in India for "Thousand of years".

Traditional Uses Of Medicine

- Used as:
  - Medicine
  - Spice & cooking ingredient
  - Cosmetic & dye

- Traditionally used for:
  - Wound healing
  - Skin infections
  - Antiseptic purposes

Patent Granted In The USA

- In 1995, the Univesity of Mississippi Medical Center recieved a US patent.
- The patent was for use of turmeric in wound healing.

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

Objection By India (CSIR)

- In 1997, CSIR (Council of Scientific & Industrial Research) filed an Objection.
- CSIR argued turmeric wound healing is traditional Indian knowledge, not a new invention.
- Evidence included:
  - Ancient Sanskirt texts
  - Urdu & Hindi literature
  - A research paper published in 1953.

Final Judgement

- The USPTO investigated the case.
- Patent was cancelled due to lack of novelty.
- The decision confirmed that turmeric use was prior art.
- This case successfully protected India's traditional knowledge.

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

Regulations Of Herbal Drugs In India

- Regulations are legal rules made to control drugs.
- They define :
  - What should be done
  - How it should be done
  - What should NOT be done
  - Punishment for violations
- Herbal drugs mainly include Ayurvedic, Siddha & Unani (ASU) drugs.

Need For Regulation Of ASU Drugs

- To ensure quality, safety & efficacy of herbal drugs
- To control manufacture, sale, distribution & marketing.
- To protect people from harmful or substandard drugs.
- To make quality ASU medicines available to the public.

IMPERFECT PHARMACY

ASU - DTAB

- ASU - DTAB stands for Ayurvedic, Siddha & Unani Drugs Technical Advisory Board
- ASU - DTAB is a Technical advisory body.
- It is constituted by the Central Government.
- It advises both Central & State Gov. on technical matters related to ASU Drugs.

VIDEOS : IMPERFECT PHARMACY

Functions Of ASU - DTAB

- Advises on matters under Section 33-C & 33-D of D&C Act.
- Help in framing rules & standards for ASU Drugs.
- Ensures uniform technical control across India.

Composition Of ASU - DTAB

① Ex-officio Members

- Director General of Health Services
- Drug Controller of India
- Director of Central Drug Laboratory
- Principal officer dealing with Indian System of Medicine in Ministry of Health.

② Nominated Members by Central Government

- Phytochemist
- Pharmacognosist
- Govermet Analyst
- Members from Pharmacopoeia Commitees:
  - 2 from Ayurvedic Pharmacopoeia committees
  - 1 from Unani Pharmacopoeia committees
  - 1 from Siddha Pharmacopoeia committees
- One representative each from Ayurveda, Siddha & Unani Drug industry
- One practioner each from Ayurveda, Siddha & Unani Systems of Medicine
- Teacher in Dravyaguna & Bhaishajya kalpana
- Teacher in Ilm-ul-Advia & Talkis-wa-Dawa-Sazi
- Teacher in Gunapadam

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

Functioning Of ASU - DTAB

- Chairman is appointed by the Central Government
- Members hold office for 3 years.
- Re-nomination is allowed.
- Secretariat & staff are provided by the Central Gov.

ASU - DCC

- ASU - DCC stands for Ayurvedic, Siddha & Unani Drugs Consultative Committee
- ASU - DCC is a consultative body.
- It is formed under section 33-D of the Drugs & Cosmetics Act.
- It ensures uniform implementation of ASU Drug regulations throughout India.

Functions Of ASU-DCC

- Advises Central & State Governments.
- Advises ASU - DTAB on regulatory matters.
- Help in coordination b/w Central & State authorities.
- Solves practical problems in implementation of ASU Drug laws.

Constitution & Working Of ASU - DCC

- Consists of:
  - Two members from Central Gov.
  - One representative from State Gov.
- Regulate its own working procedure.

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

Regulation Of Manufacture Of ASU Drugs

- Governed under session 33 - EEB
- Manufacture must have :
  - Valid license
  - GMP Compliance
  - Proper infrastructure, staff & equipment
  - Compliance with pharmacopoeial standards
- Manufacturing units must follow "schedule-Z".

Prohibition Of Certain ASU Drugs

- Manufacture & Sale are prohibited if :
- Drug is misbranded, adulterated or spurious
- Drug is manufacture without license
- Ingredients are not mentioned on label
- Drug violates provisions of the Act.

Power Of Central Government

- Central Gov. can ban manufacture or sale of ASU Drugs :
  - If drug is unsafe
  - If it has no therapeutic value
  - If it poses risk to humans or animals

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

SCHEDULE Z

- Schedule Z lays down Good Manufacturing Practices (GMP) for Ayurvedic, Siddha & Unani (ASU) drugs.
- It ensures that ASU drugs are safe, clean & of good quality.

MAIN REQUIREMENTS OF SCHEDULE Z

- Manufacturing premises must be clean, hygienic, & well maintained.
- Factory should be located away from open drains, sewage, dust & pollution.
- Proper facilities for:
  - Washing, cleaning & drying of equipment
  - Waste disposal
  - Drinking water & washrooms.
- Workers should:
  - Be free from contagious diseases
  - Wear protective clothing
  - Maintain personal hygiene
- Use of pure & safe water for manufacturing.
- Proper storage areas for raw materials & finished products.
- Record keeping of manufacturing, testing & distribution.

IMPORTANCE OF SCHEDULE Z

- Prevents contamination & adulteration.
- Maintains uniform quality of ASU Drugs.
- Protects public health.
- Mandatory for obtaining & retaining manufacturing license.

IMPERFECT PHARMACY

VIDEOS : IMPERFECT PHARMACY

THANK YOU

FOR CHOOSING IMPERFECT PHARMACY AS YOUR STUDY PARTNER

IMPERFECT PHARMACY

JOIN US ON :

IMPERFECT PHARMACY

IMPERFECT PHARMACY

@IMPERFECTPHARMA

IMPERFECT PHARMACY

@IMPERFECTPHARMACY

IMPERFECT PHARMACY

IMPERFECTPHARMACY@GMAIL.COM