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PHARMACEUTICAL JURISPRUDENCE

For Competitive Examination

Theory & Practice Book

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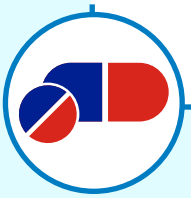

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Practice Book for Pharmaceutical Jurisprudence

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Dedicated to

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All **ASPIRANTS**,

Preparing for PHARMA Examination...

CONTENT

5 DRUGS AND COSMETICS ACT AND RULES

INTRODUCTION

- Drugs and Cosmetics Act was passed on10th April 1940 & Rule in 1945 by the Indian Legislature.
- This Act was amended in1955 by the Indian Parliament and Subsequently amended in 1960, 1962, 1964, 1972, 1982, 1986, 1995, 2000, 2008, 2011 and 2018.

OBJECTIVE

- This is an act to regulate the import, manufacture, distribution and sales of drugs.

TheAct consists of five chapters:

- **Chapter I-** Introductory
- **Chapter II -** Administrative bodies
- **Chapter III-** Import of drugs and cosmetics
- **Chapter IV-** Manufacture, sale and distribution of drugs and cosmetics
- **Chapter IV-**A Provisions relating toAyurvedic, Siddha and Unani drugs
- **ChapterV-** Miscellaneous

CHAPTER I- INTRODUCTORY

- Drug and cosmetic rules have been divided into 18 parts, each dealing with particular subjects.
- There are **2 schedule** to the act and **23 schedule** to the rules,

SCHEDULE TO THE ACT

1. **First Schedule:** It prescribes the list of books specified in Ayurvedic, Siddha or Unani systems of medicine.
2. **Second Schedule:** It prescribes the standards to be complied with by imported drugs and by the drugsmanufactured for sale, sold stocked or exhibited for sale or distributed.

In addition, the following appendix are also prescribed:

Appendix:

I- Data required to be submitted with application for permission to market a new drugs.

II- Format for submission of clinical trial reports.

III- Animal toxicity requirement for clinical trial and marketing of a new drugs.

IV-Number of animals for long term toxicity studied.

V- Patient consent form for participation in a phase I clinical trials.

VI- Four groups of fixed dose combination and their data requirements.

SCHEDULES TO THE RULES

A- Performa for application for the licenses, issues and renewal of licenses, for sending memoranda under the Act.

B -Rates of fee for test or analysisby the Central Drugs Laboratory or the state drug laboratories

B_1- Fee for the test or analysis by the pharmacopeia laboratory for Indian medicine or the govt. analyst.

C - List of biological and other special products whose import, sale, distribution and manufacture are governed by special provision.

C_1- List of other special products whose import, sale, distribution and mfg are governed by special provision.

D- List of **drugs exempted from the provisions to import of drugs.**

E_1- List of poisonous substances under the **Ayurvedic (including Sidha) and Unani systems** of medicine.

F – Requirement for the functioning and operation of **the blood bank and/or for prepration of blood components.**

F_1-

Part I - Provisions applicable to the production of **all bacterial and viral vaccine.**

Part II - Provisions applicable to the production of **all sera from living animal.**

Part III - Provisions applicable to the **manufacture and standardization of diagnostic agent (Bacterial origin)**

F_2- Standards for **surgical dressings.**

F_3- Standards for **sterilized umbilical tapes.**

FF- Standards of **ophthalmic preparations.**

G- List of substances that are required to be used only under **medical supervision**and which are to be labeled accordingly.

H- List of **prescription drugs.**

J- Disease or ailmentswhich a drug may not purport to prevent or cure.

K- Drugs exemptedfrom certain provision relating to manufacture of drugs.

L-Good laboratory practice (GLP)and requirement of premises and equipment.

M - Good manufacturing practice (GMP) requirement of **factory premises, plants and equipment.**

M_1- Requirement of factory premises etc. for **manufacture of homoeopathic preparation.**

M_2- Requirement of factory premises etc. for **manufacture of cosmetics.**

M_3 - Requirements of factory premises for the **manufacture of medical devices.**

N - List of **minimum equipment for efficient running of a pharmacy**.

O - Standard for **disinfectant fluid.**

P- Life **period of drug**.

P_1 - Pack sizes of drugs.

Q - List of coals tar colors permitted to be used in cosmetics.

R - Standard for condoms made of rubber latex and other **mechanical contraceptives.**

R_1 - Standard for **mechanical contraceptive.**

S - Standard for **cosmetics.**

T - Good manufacturing practice for **Ayurvedic Siddha, Unani medicines.**

U - Particulars to be shown in **manufacturing records.**

U_1 - Particulars to be shown in manufacturing, **raw material and analytical records of cosmetic**

V - Standard for **patent or proprietary medicines.**

W - List of drug which is to be marketed under **generic names only.**

X - List of drugs whose import, manufacture and sale, labeling and packaging are governed by **special provision.**

Y - Requirement and guideline for permission to import and manufacture of new drugs for sale or to undertake **clinical trial.**

IMPORTANT AMENDMENTS

1982 : Schedules E, I and L were dropped, Schedules G and H were revised and Schedules X was introduced.

1988 : Schedule M incorporating GMP (Good Manufacturing Practices) was amended and Schedule Y Pertaining to clinical trials of newer drug formulations was incorporated.

2000 : Schedules T of Ayurvedic Siddha and Unani medicines was introduced in 2000.

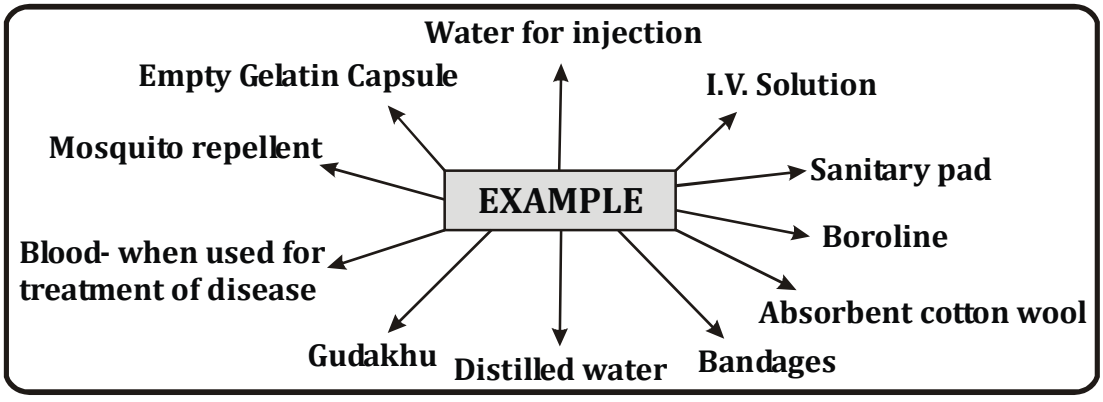
2011 : Schedule H, for curbing the misuse of antibiotics and other drugs.

DEFINITION OF IMPORTANT TERMS

DRUG: [SECTION 3 (B)]

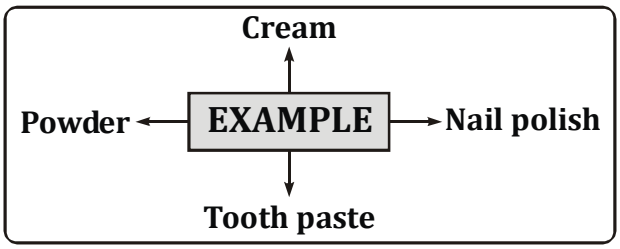
- All medicine for internal or external use of human beings or animals and all substance intended to be used for diagnosis, treatment, mitigation, or prevention of any disease or disorder in human being or animal including preparation applied on human body for the purpose of repelling insect like Mosquito.

Example:



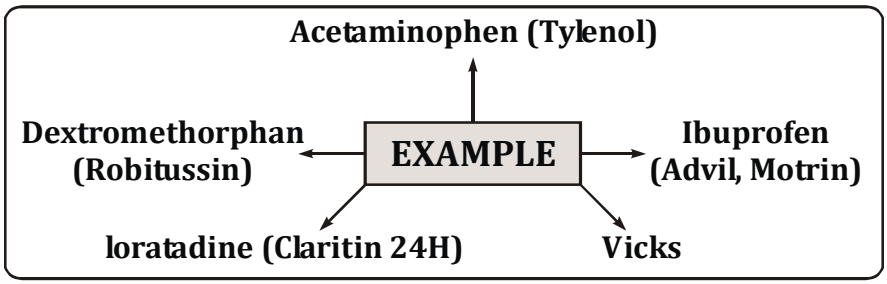
COSMETIC: [SECTION 3 (A)]

It means any article intended to be rubbed, sprayed, poured, sprinkled on or introduced into or otherwise applied to the human body thereof, for cleansing, beautifying or promoting the attractiveness or altering the appearance and also includes any article intended to be used as a component of cosmetic but does not include soap.



OVER-THE-COUNTER (OTC)

Over-the-counter (**OTC**) **drugs** are medicines sold directly to a consumer without a prescription from a healthcare professional, as opposed to prescription **drugs**, which may be sold only to consumers possessing a valid prescription.



MISBRANDED DRUGS	ADULTERATED DRUGS	SPURIOUS DRUGS
• If it is not labeled in the prescribed manner • If it is so coloured, coated, powdered or polished that damage is concealed or if it is made appear of better or greater therapeutic value than it's really. • If it is label or container or anything accompanying the drug bears any statement, design or device which make any false claim for the drug or which is false or misleading in any particular.	• If it is consist in whole or in part, of any filthy, putrid, of decomposed substance • If it has been prepared packed or stored under insanitary conditions whereby have been render injurious to health. • If its container is composed, in whole or in part of any poisonous substance to health. • If it contain harmful or toxic substance injurious to health. • Any substance mixed which reduce the quality.	• If it is imported (manufactured in relation to manufacture, sale and distribution of drugs) under a name which belong to another drugs • If it has been substituted wholly or in part by another drugs or substance • If it purports to be the product of a manufacture of whom it is not truly a product.