D.PHARMA

2 YEAR

Chapter - 3

Drugs and Cosmetics Act- 1940

Chapter - 1

DRUGS AND COSMETICS ACT AND RULES

INTRODUCTION

Drugs and Cosmetics Act was passed on **10th April 1940** & Rule in **1945 by the Indian Legislature.**

औषधि एवं प्रसाधन सामग्री अधिनियम 10 अप्रैल 1940 को पारित किया गया और नियम 1945 में भारतीय विधानमंडल द्वारा पारित किया गया।

DRUGS AND COSMETICS ACT AND RULES

INTRODUCTION

- This Act was **amended in 1955 by the Indian Parliament** and Subsequently amended in 1960 1962, 1964, 1972, 1982, 1986, 1995, 2000, 2008, 2011 and 2018.

इस अधिनियम को 1955 में भारतीय संसद द्वारा संशोधित किया गया था और इसके बाद 1960, 1962, 1964, 1972, 1982, 1986, 1995, 2000, 2008, 2011 और 2018 में संशोधन किया गया।

OBJECTIVE

Chapter I- Introductor

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 to Ayurvedic, Siddha and Unani drugs

Chapter V- Miscellaneous

CHAPTER I- INTRODUCTORY

- Drug and cosmetic rules have been divided into 18 parts, each dealing with particular subjects.

औषधि और कॉस्मेटिक नियमों को 18 भागों में विभाजित किया गया है, प्रत्येक भाग विशेष विषयों से संबंधित है

- **There are 2 schedule to the act and 23 schedule to the rules,**

अधिनियम की 2 अनुसूची और नियमों की 23 अनुसूची हैं,

SCHEDULE TO THE ACT

1. **First Schedule:** It prescribes the list of books specified in Ayurvedic, Siddha or Unani systems of medicine.

पहली अनुसूची: यह आयुर्वेदिक, सिद्ध या यूनानी चिकित्सा प्रणालियों में निर्दिष्ट पुस्तकों की सूची निर्धारित करती है।

2. **Second Schedule:** It prescribes the standards to be complied with by imported drugs and by the drugs manufactured for sale, sold stocked or exhibited for sale or distributed.

दूसरी अनुसूची: यह आयातित दवाओं और बिक्री के लिए निर्मित, स्टॉक में बेची जाने वाली या बिक्री के लिए प्रदर्शित या वितरित की जाने वाली दवाओं द्वारा अनुपालन किए जाने वाले मानकों को निर्धारित करती है।

SCHEDULES TO THE RULES

A- Performa for Application for the licenses, issues and renewal of licenses, for sending

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

B1 - Fee for the test or analysis by the pharmacopeia laboratory for Indian medicine

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

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- List of poisonous substances under the Ayurvedic (including Siddha) and Unani systems of medicine.(Ennie eats poison)

F- Requirement for the functioning and operation of the blood bank and/or for preparation N of blood components.(Fluids)

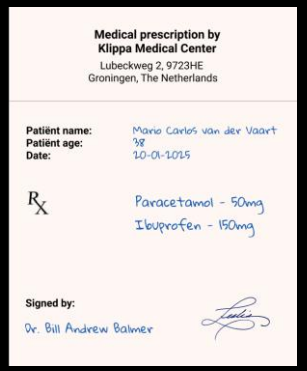
F_1 -

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 of blood components.

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

H - List of prescription drugs.



J - Disease or ailments which a drug may not purport to prevent or cure. (Jaundice)

K - Drugs exempted from certain provision relating to manufacture of drugs.

SET OF 6 MODULES

FOR 2ND YEAR STUDENTS

MASTER NOTES FOR D.PHARMA

2ND YEAR STUDENTS

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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.(Navyug 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.(Sushmita sen)

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(Victory)

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

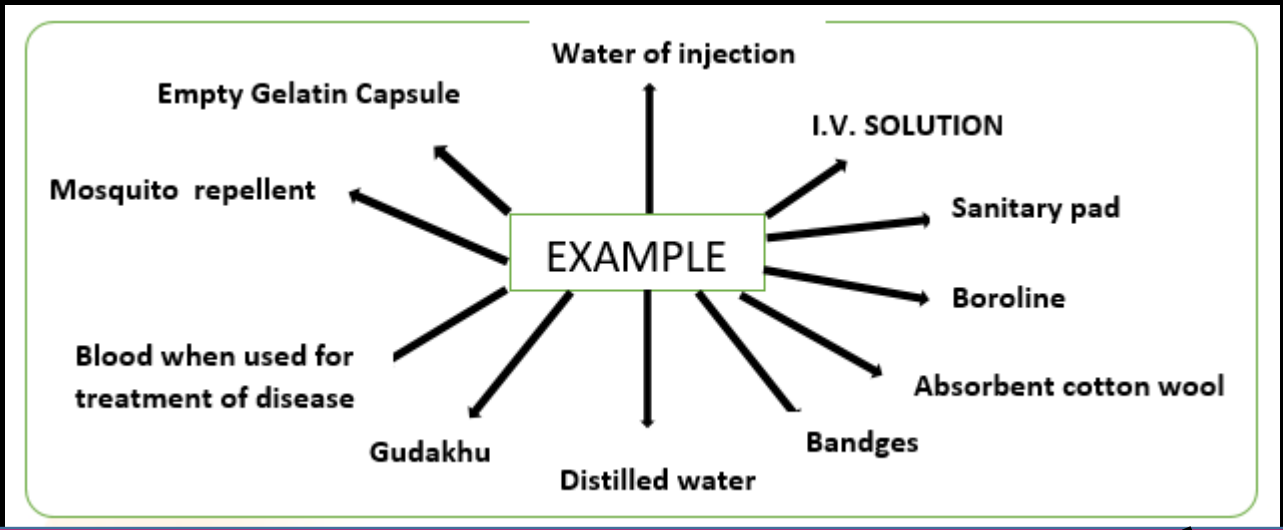
X - List of drugs whose import, manufacture and sale, labeling and packaging are governed by special provision.

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

DEFINITION OF IMPORTANT TERMS

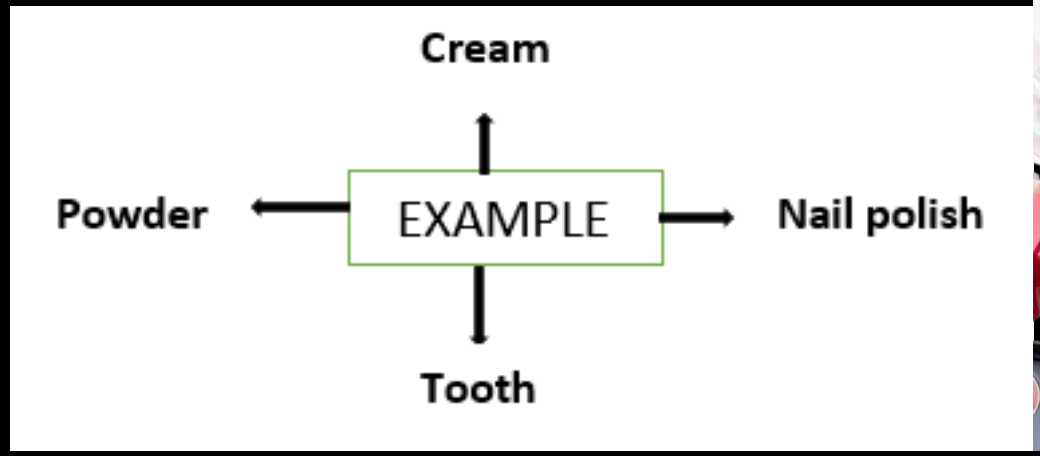
DRUG [SECTION 3 (B)]

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.



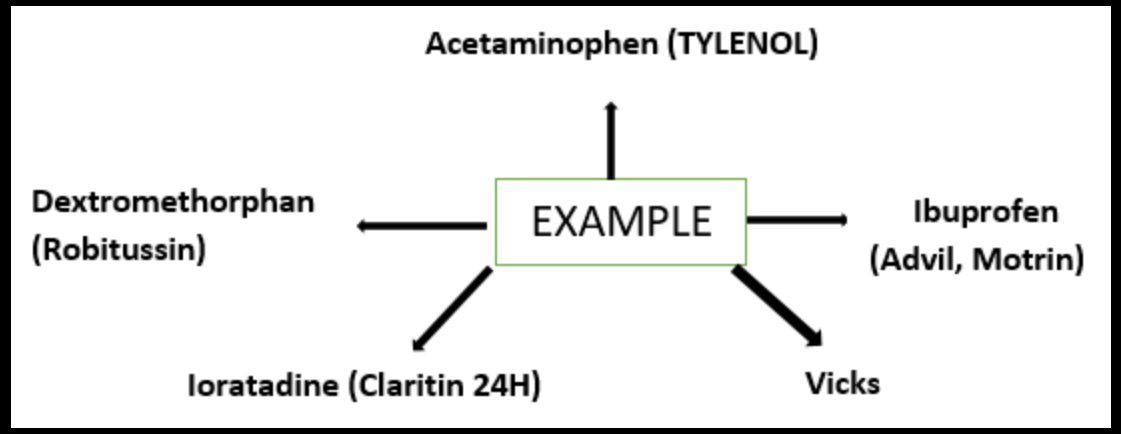
COSMETIC: [SECTION 3 (A)]

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 DRUG	ADULTERATED DRUG	SPURIOUS DRUG

MISBRANDED DRUG

- 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.

ADULTERATED DRUG

SPURIOUS DRUG

MISBRANDED DRUG	ADULTERATED DRUG	SPURIOUS DRUG
• 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. cel • If it contain harmful or toxic substance injurious to health. • Any substance mixed which reduce the quality.	

MISBRANDED DRUG	ADULTERATED DRUG	SPURIOUS DRUG
• 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. cel • 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.

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