
B.PHARMA SEM- 5
UNIT-4
PART-1
PHARMACEUTICAL JURISPRUDENCE
DRUG & MAGIC REMEDIES ACT &ITS IT'S RULES
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JURISPRUDENCE

UNIT-4 PART-1

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Drugs and Magic Remedies Act and Rules

IMPORTANT DATE

Act passed	**1954**
Rule passed and came into force	1st April 1955

Objectives:

- **Prohibition of Misleading Advertisements:** To prevent advertisements that give a false impression about a drug's true nature, make false claims, or are otherwise misleading.
- **Control of Advertisements for Certain Conditions:** To prohibit advertisements for drugs related to the diagnosis, cure, mitigation, treatment, or prevention of specific diseases and disorders listed in the Act's schedule.

- **Regulation of Advertisements for Sexual Matters:** To stop advertisements for drugs used for the enhancement of sexual pleasure, correction of menstrual disorders, or to cause miscarriage or prevent conception.
- **Prohibition of Advertisements for Magic Remedies:** To forbid advertisements for any charm, mantra, or talisman that claims to have miraculous powers to treat diseases in humans or animals.
- **Control over Import and Export of Objectionable Advertisements:** To prohibit the import and export of any documents containing advertisements that are in violation of the Act.

IMPORTANT SECTION

Section 3	**No advertisements for Certain drugs for treatment certain disease and disorder.**
Section 4	Misleading advertisement relating to drugs.
Section 5	Magic remedies for treatment of certain disease and disorder.

DEFINITION:

- **Advertisement:** It include any notice, circular, label, wrapper, or other document and any announcement by light, sound, and orally.
- **Magic remedy:** It include talisman, mantra, kavach, and any other charm of any kind which is alleged to possess miraculous power for or in the diagnosis, cure mitigation, treatment.

Prohibition of Advertisement:

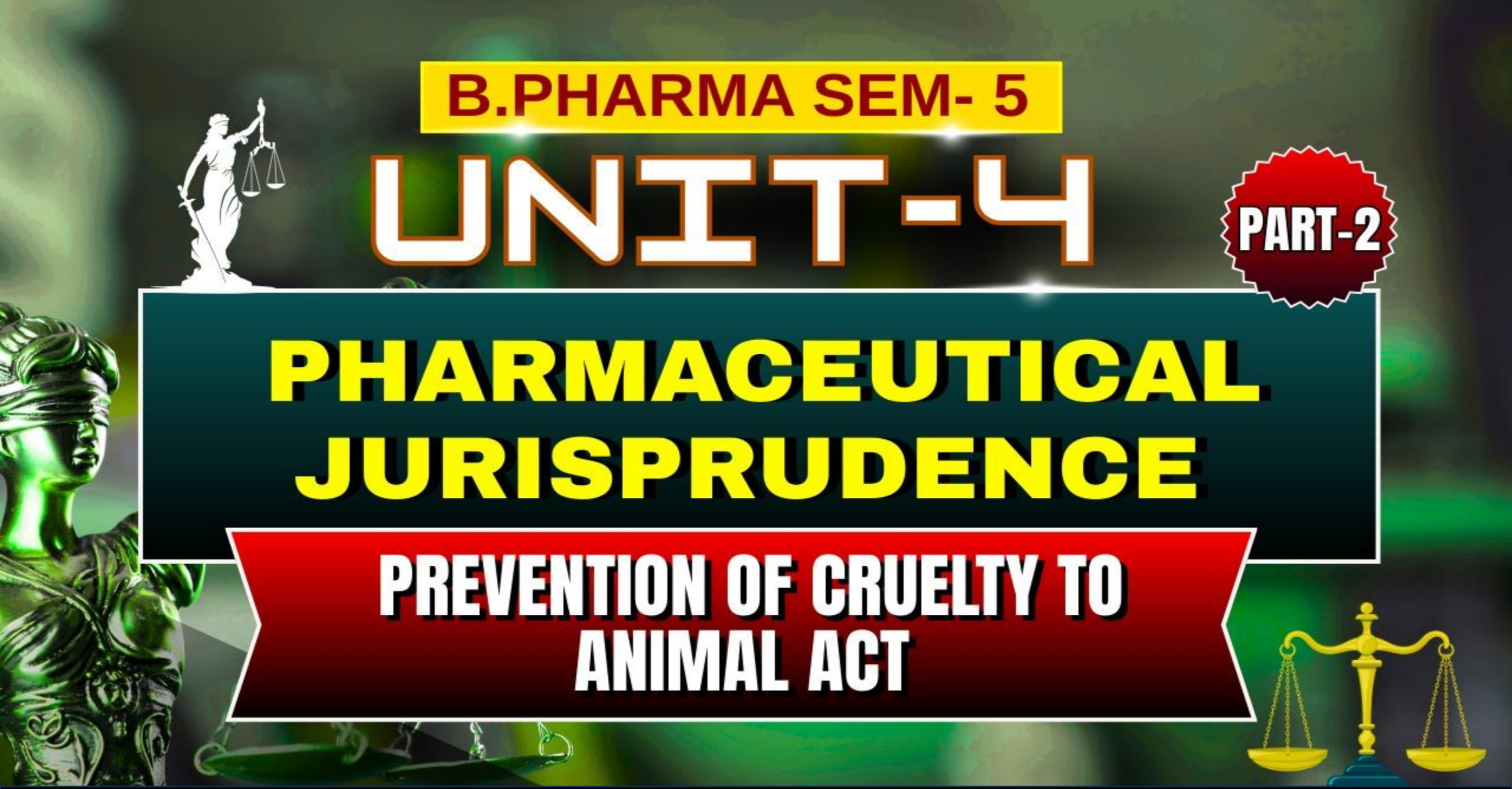
- The maintenance and Improvement of capacity of human for sexual pleasure.
- The correction of menstrual disorder in woman.
- The diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition
- Directly given a false impression regarding the true character of drug
- Make false claim for the doctor.
- The procurement of miscarriage in woman or prevention of conception in woman.

CLASSES OF EXEMPTED ADVERTISEMENT

S.No	Classes of exempted advertisement	Condition
1	Advertisement relating to the drug printed or published by the Govt. or any person with prior permission of the government	If it is needed to spread the awareness
2	Leaflet or literature accompanying packaging of drugs.	Advertisement contain only formulation for RMP following •Therapeutic indication of drugs. • Administration • Dosage • Side effect • Precaution

3	**Advertisement in journals**	**Responsibility to prove the any claim of advertisement in respect to the not false**
4	Price list of manufacturer, distributer, importer of drugs	Advertisement only contain technical information for guidelines for RMP
5	Advertisement of chemical contraceptive for oral	Advertisement to the chemical contraceptive.

S.No	Offence	Penalties
1	First conviction: Whoever contravenes any provision of this act or rules	Imprisonment up to 6 month or with fine or both.
2	Second conviction: Subsequent of the first conviction	Imprisonment up to one year or fine or both any subsequent
3	By company:	• Every person who at the time of commission of the offences was in charge and responsible for the conduct of company business liable for the punishment. •However such person is not liable for the punishment if he proves that offences was committed without his knowledge or that he has taken all the precaution to prevent the commission of such offence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UNIT-4
PART-2
PHARMACEUTICAL JURISPRUDENCE
PREVENTION OF CRUELTY TO ANIMAL ACT
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Prevention to Cruelty to Animals act- 1960

- The Prevention of Cruelty to Animals Act is an Act of the Parliament of India enacted to prevent the infliction of unnecessary pain or suffering on animals and to amend the laws relating to the prevention of cruelty to animals.

OBJECTIVES:

- To consolidate and amend the existing laws related to narcotic drugs.
- To establish more stringent provisions for the control and regulation of operations involving narcotic drugs and psychotropic substances.
- To provide for the forfeiture of property that has been derived from or used in the illicit trafficking of narcotic drugs and psychotropic substances.
- To prohibit, control, and regulate all operations related to narcotic drugs and psychotropic substances.

IMPORTANT DATES

Act passed	**1960**
Rule passed	1998
Rule and regulation	Extend to whole India except Jammu and Kashmir

DEFINITION

- **Board:** It means the animal welfare board establishment under section 4 of the Act.
- **Breeder:** Means a person including an institute which breed animals for the purpose to authorized institution for performing experiment.
- **Committee:** Means the committee constitute under section 15 of the Act for control and supervision on animal.
- **Institute Animal Ethics Committee:** A recognized and registered body, consisting of a group of individuals, is responsible for the control and supervision of animal activities in an establishment, following procedures set by the committee.
- **Contract research:** means any research undertaken by an individual, company, firm, corporation, or institution on behalf of a foreign individual, for any consideration.

CRUELTY TO ANIMAL

- Employing any unfit animals for works or labor.
- Willfully and unreasonably administration any injurious drugs or substance.
- Any animals to unnecessary pains or suffering or treatment.
- Failure to provide any animals with sufficient food, drink or shelter by its owner.
- Needlessly mutilating any animals or killing any animals in unnecessarily cruel manner etc.

INSTITUTIONAL ANIMAL ETHICS COMMITTEE (IAEC)

- A biological scientist.
- Two scientist from different biological disciplines.
- Veterinarian invited in the case of animals.
- The scientist in charge of animal facility of the establishment concerned.
- Scientist from outside the institution.
- Nonscientific socially aware member
- Representative or nominee of the committee.

CPCSEA GUIDELINES

- UNNECESSARY PAIN OR SUFFERING
- UNFIT ANIMAL FOR WORK OR LABOR
- ADMINISTERING ANY INJURIOUS DRUG OR SUBSTANCES (UNREASONABLE)
- CONFINING IN ANY CAGE OR INSUFFICIENT SIZE OR DIFFICULT IN MOVEMENT
- INSUFFICIENT FOOD, DRINK OR SHELTER
- KILLING (CRUEL MANNER) ANY ANIMAL WITHOUT ANY NEED

BREEDING AND STOCKING OF ANIMALS

Only registered establishment can carry on the business of breeding of animal for purpose of experiment

Apply for registration within 60 days from the date of experiment

- Registration is required for establishments/breeders, including universities and colleges, involved in animal experiments.

- The Government of India has established the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA).
- CPCSEA operates under the Ministry of Social Justice and Empowerment.
- CPCSEA is based at Shastri Bhavan, New Delhi.

PERFORMANCE OF EXPERIMENT

- All experiments must be conducted by or supervised by individuals who hold qualifications in-
- various scientific and medical fields,
- including degrees in medicine or veterinary science,
- post-graduate degrees in life or pharmaceutical sciences, pharmacy degrees or diplomas,

RECORDS

Every establishment /institutional animal ethics committee shall maintain a records of the animal under the control and custody and furnish information.

Transfer and acquisition of animals for experiment:

Acquiring animal for conducting any experiment:

- Every breeder has a register and shall apply for experimental activity permission directly to the Secretary or authorized person of Committee Institutional Animal Ethics Committee by stating name of the species and the number of animals acquired.

- The committee shall scrutiny the application, if satisfied, may grant the permission for conducting experiments.
- While granting permission, a condition is applied that animals are not suffering unnecessary pain during or after experiments on them.
- Person carrying on experiments on animals should inform authority about completion of experiment for which the permission has been granted.

Contract animal experiments:

- Contract animal experiment or research shall not permit to any establishments or educational institutional except with prior permission of the committee.
- Collaborative research between two academic institutions may be permitted for such purpose.

Transfer of animals for experiment:

- Transfer of any animal for sale purpose to an unregistered breeder is not permitted.
- A breeder can't acquire any animal by sale except from a registered breeder
- Acquired animal can't be sale except from registered breeder.
- Experiment in production breed improvement programme, animals may be given out by breeder institution for domestic use.
- Genetic experiment on rat and mice not available in India, if such, the breeder shall take the permission from Institutional Animal Ethics Committee (IAEC).

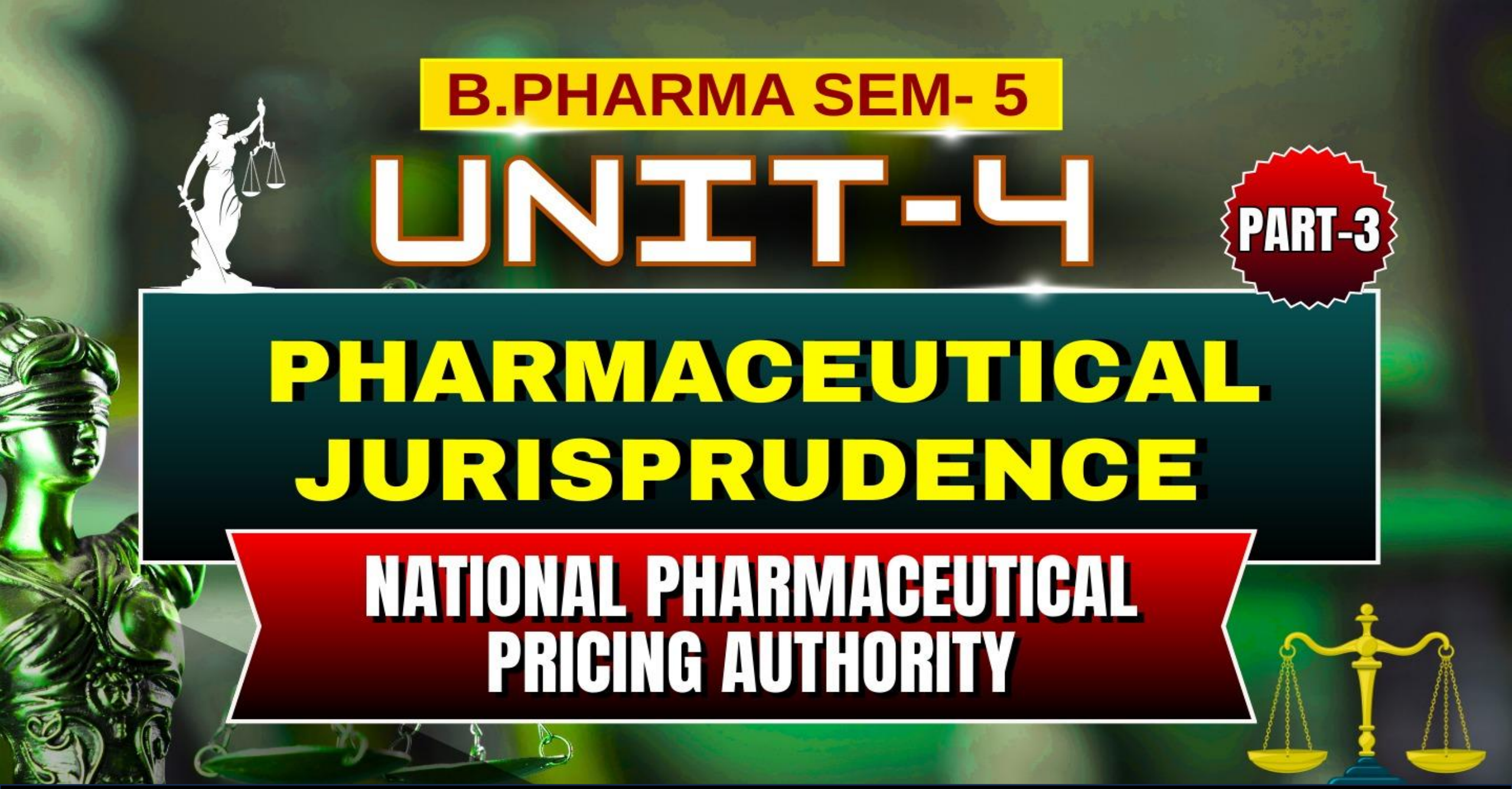
Power to suspend or revoke registration:

Rules made by the committee are not followed or not satisfied by the committee.

- **The Committee giving a reasonable opportunity for rectification, after that the registration may revoke for a specific period or indefinitely or grant the license on a special condition.**
- **Failure of compliance of mule and regulation, the committee may impose pending or suspend the registration.**
- **During suspension period, the breeder shall take care of animals, cease to perform any experiment or acquire or transfer of any animal is prohibited.**

OFFENCE AND PENALTIES

S.NO	OFFENCE	PENALTIES
1.	Treating animals cruelty	Fine up to 50 in the first instance; in case of repeat offence within three years fine may extend to 100 or with imprisonment up to three months or both.
2.	Contravention if any order made by or committing breach of any condition by the committee	Fine extending to 200.
3	Contravention or breach of condition in any institution	Person in charge of the institution shall be guilty of the offence and shall be punishable accordingly.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UNIT-4
PART-3
PHARMACEUTICAL JURISPRUDENCE
NATIONAL PHARMACEUTICAL PRICING AUTHORITY
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National Pharmaceutical Pricing Authority

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National Pharmaceutical Pricing Authority

INTRODUCTION

- The drug (price control) order forms of a part of the new drug policy formed by government of India

1987 → 1995 → 2013

OBJECTIVE

- **Ensure Availability of Essential Medicines: To make sure that essential, life-saving, and prophylactic medicines of good quality are available to the public at reasonable prices.**
- **Promote Rational Drug Use: To encourage the rational use of drugs in the country.**
- **Encourage Cost-Effective Production: To promote cost-effective production of drugs in economic sizes**

DPCO 1995	**Passed on 6th Jan. 1995 by Ministry of Chemical and Fertilizer by virtue of section-3 of essential commodities act.**
DPCO 2013	Passed by ministry of chemical and fertilizer (Department of Pharmaceutics)

IMPORTANT DATE

Essential commodities act	1955
National list of essential medicine	2011
National pharmaceutical pricing policy	2012
DPCO Came into force	15th may, 2013

IMPORTANT POINTS

- DPCO 2013 order does not cover patented drugs.
- Power of govt. under DPCO 2013 - Any gazette officer.
- Power of entry, search, seize - Paragraph 30
- Any new drug patented in India will be exempted from DPCO for 5 year
- Power of review - Paragraph 30.

SCHEDULE OF DPCO

Schedule I	**It contain the national list of medicines 2011 and divided into 27 section.**
Schedule II	It contain the national list of medicines 2011 and divided into 27 section.
Schedule III	Maximum par tax return as sales turnover of manufactured importer of formulation- A, B and C category.

DEFINITION

- Ceiling price: It means a price fixed by govt for scheduled formulation in accordance with p of this order.
- Margin to retailer: It means percentage of price to retailer.
- Maximum retail price (MRP): It means the ceiling price or the retail price plus local taxes and duties as applicable, at which the drug.
- National list of essential medicines: National list of essential medicines 2011 published by ministry of health and family welfare.

- **Non-scheduled formulation: It means formulation, the dosage form and strength of which are not specified in the first schedule.**
- **Local taxes: It means any taxes or leavy (Except excise or import duty included in retail price) paid or payable to the govt or the state govt.**
- **Price to retailer: It means the price of a drug at which it is sold to a retailer which include duties but does not include local taxes.**
- **Retail price: It means price fixed by the govt. for a new drugs.**
- **Schedule formulation: It means any formulation include in the first schedule whether referred to by generic version or brand name**

SCHEDULE FORM

Form-I	**Proforma for application for price fixation /revision of a new drug formulation related to NLEM (National list of essential medicine, 2011)**
Form-II	Proforma for submission of revised-prices for schedule formulation.
Form-III	Proforma for quarterly return in respect of production/import and sale of NLEM.
Form-IV	Proforma for submission of the details in respect of discontinuation of the production and import of scheduled formulation
Form-V	Proforma for price list

- **Sale prices of bulk drugs:**
- **First Schedule: it contains the list of 74 bulk drugs.**
- **Second Schedule: it contains various forms for approval or revision of prices of Scheduled formulations.**
- **Third Schedule: it specifies the maximum pre-tax (of income or profits) considered or calculated before the deduction of taxes) return on sales turnover of manufacturer/importers of formulations under A, B & C categories.**

❖ SCHEDULED FORMULATION PRICE

CALCULATION OF PRICE OF A SCHEDULE FORMULATION

- Step 1: Calculation of average price of schedule formation i.e. P(s) to retailer

Average price to retailer P(S) =

- Sum of price to retailer of all the brands and generic version of the medicine having market share more than or equal to 1% of the total market turnover on the basis of moving annual turnover of the medicine

Total number of such brands and generic version of the medicine having market share more than or equal to 1 % of total market turnover on the basis of moving annual turnover for that medicine

Step 2 : Calculation of ceiling price

$$P(C) = P(S)\ (1+\frac{m}{100})$$

P(s) Average price to retailer for the same strength and dosage.

M= % of margin to retailer and its rule = 16

MRP = Pc + Local taxes

- **Final MRP of the drug at retailer is increased with factor of 16%.**
- **(B) CEILING PRICE OF A SCHEDULED FORMULATION IN CASE OF NO REDUCTION IN PRICE DUE TO ABSENCE OF COMPETITION.**
- **If there are less than 5 manufactures for that formulation having 1% or more market share.**

Step 1: Calculation of average price of scheduled formulation i.e. P(s) to retailer

$$Ps = \frac{Pm(1-(Pi1+ Pi2 + ...}{(N\times100)}$$

Where,

- **Pm= Price to retailer of highest priced scheduled formulation under consideration.**
- **Pi=% Reduction in average price to retailer of other strength and dosage forms**
- **N = Number of such other strength or dosage forms or both in the list of schedule formulation.**

Step2: Calculation of ceiling price

$$P(C) = P(S)\frac{1+M}{100}$$

Where

- **P(s) = Average price to retailer for the same strength and dosage.**
- **M =% of margin to retailer and its value = 16**
- **Margin to retail : A margin of 16 % to retail shall be allowable**

MAXIMUM RETAIL PRICE

MRP of schedule formation = Celling price + local taxes as applicable

MRP of new drug = Retail price + Local taxes as applicable

S.NO	DPCO 1995	DPCO 2013
(a)	Governed by essential commodity act - 1995	It is governed by National Pharmaceutical Pricing Authorities (NPAA). (DPCO has enable NPPA regulate price of 348 drugs that come under national list of essential medicines)
(b)	They regulate price of only 74 drugs	They regulate price of 652 drugs

(c)	**If once price is 3 fixed they cannot change according to act**	**Pricing is mainly based on simple average price be lowered dependency upon margin**
(d)	Government fix price "industries cannot dominate" ↓ price were fixed accordingly to manufacture cost only	Price are fixed both by mutual agreement of government and industries

Formula: Calculation of Retail price

$$R.P = (M.C + C.C + P.M + P.C) \times \frac{1 + MAPE}{100} + ED$$

Where,

R.P= Retail price

M.C = Material cost

C.C = Conversion price

P.M= Packing material cost

P.C = Packing charges

MAPE = Maximum allowable post manufacturing expenses (NMT 100%)

E.D= Excise duty

New pricing in 2015 is

MRP = Ceiling price + Local taxes

Celling price + $Ps(\frac{1+M}{100})$

National List of Essential Medicines (NLEM): Key Points

- The National List of Essential Medicines (NLEM) is a list of medicines prepared by the Ministry of Health and Family Welfare to ensure that the most necessary, safe, effective, and affordable medicines are available to the majority of the population.

Purpose and Importance:

- **Promotes Rational Use: Guides doctors in prescribing appropriate medicines, which helps reduce medication errors and combat antimicrobial resistance.**
- **Ensures Affordability: The government often caps the prices of drugs listed in the NLEM through the Drugs (Prices Control) Order, making essential healthcare more affordable.**
- **Guides Procurement: Serves as a primary guide for the procurement and supply of medicines in the public healthcare sector (government hospitals and clinics).**
- **Optimizes Healthcare: Helps in the optimal utilization of healthcare resources and budget.**
- **Sets Quality Standards: Ensures that the medicines on the list meet high standards of quality and safety.**

Criteria for Inclusion:

- A medicine is included in the NLEM based on several factors:
- It must be useful in treating diseases that are a public health priority in India.
- It must have proven efficacy and a well-defined safety profile.
- It should be cost-effective.
- It must be approved by the Drugs Controller General of India (DCGI).

Key Facts:

- The first NLEM was created in 1996.
- It is a dynamic list, revised every few years to reflect the changing public health needs and advancements in medicine. The latest revision was in 2022.
- The list is often referred to as a "cornerstone of a healthy nation" because of its critical role in public health.

Table with examples of medicines from the National List of Essential Medicines 2015:

Category	Medicine	Dosage Form
General Anesthetics and Oxygen	Halothane	Inhalation
	Isoflurane	Inhalation
	Ketamine	Injection 10 mg/ml, 50 mg/ml
Local anesthetics	Bupivacaine	Injection 0.25% & 0.5% & Injection 0.5% with 7.5% glucose

	Lignocaine	**Topical forms 2-5% Injection 1% & 2% Injection 5% with 7.5% Glucose**
Non-opioid analgesics, antipyretics and no steroidal anti -inflammatory medicines	Acetylsalicylicacid	Tablet 300 mg to 500 mg Effervescent/Dispersible/ Enteric coated Tablet 300 mg to 500 mg
	Ibuprofen	Tablet 200 mg & 400 mg Oral liquid 100 mg/5 ml
	Paracetamol	Tablet 500 mg & 650 mg All licensed oral liquid dosage forms and strengths Injection 150 mg/ml Suppository 80 mg & 170 mg

	Fentanyl	Injection 50 mcg/ml
Opioid analgesics	Morphine	Tablet 10 mg Injection 10 mg/ml Injection 15 mg/ml
Medicines used to treat gout	Allopurinol	Tablet 100 mg & 300 mg
Antiallergics and medicines used in anaphylaxis	Adrenaline	Injection 1 mg/ml

Nonspecific	Activated charcoal	Powder (as licensed)
Specific	Atropine	Injection 1 mg/ml
	Calcium gluconate	Injection 100 mg/ml
Anticonvulsants/Antiepileptics	Carbamazepine	Tablet 100 mg, 200 mg & 400 mg CR Tablet 200 mg & 400 mg Oral liquid 100 mg/5 ml & 200 mg/5 ml
	Diazepam	Oral liquid 2 mg/5 ml Injection 5 mg/ml Suppository 5 mg

Intestinal anthelminthic	**Albendazole**	**Tablet 400 mg Oral liquid 200 mg/5 ml**
	Mebendazole	Tablet 100 mg Oral liquid 100 mg/5 ml
Beta lactam medicines	Amoxicillin	Capsule 250 mg & 500 mg Oral liquid 250 mg/5 ml
	Ampicillin	Powder for Injection 500 mg Powder for Injection 1 g

Other antibacterials	Azithromycin	Tablet 250 mg, 500 mg Oral liquid 200 mg/5 ml Powder for Injection 500mg
	Ciprofloxacin	Tablet 250 mg, 500 mg Oral liquid 250mg/5ml Injection 200 mg/100ml