BP606T · B.Pharm Semester VI · Theory Notes

Pharmaceutical Jurisprudence

Unit I — Drugs and Cosmetics Act: Manufacture

Unit I (10 hours)

Pills & Python Notes

From-zero teaching standard: every technical term is defined before use.

Syllabus coverage: Unit I (10 hours).

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(Unit I: Objectives, Definitions, Legal definitions of schedules to the Act and Rules, CDSCO guidelines for import & export of pharmaceuticals)

1.1 Learning Objectives

After studying this chapter, you will be able to:

1 State the objectives of the Drugs and Cosmetics Act, 1940 in your own words.

2 Define, in simple language: drug, cosmetic, misbranded drug, adulterated drug, spurious drug, patent or proprietary medicine, manufacturer, and new drug.

3 Explain why a law needs its own special definitions ("legal definitions").

4 List the important Schedules to the Act and Rules and state the purpose of each.

5 Describe the role of CDSCO and its guidelines for import and export of pharmaceuticals.

6 Answer MCQs, viva and application-based questions on this chapter.

1.2 The Big Picture — What Is "Pharmaceutical Jurisprudence"?

Technical concept: Pharmaceutical jurisprudence is the study of laws that govern drugs and pharmacy practice.

Simple explanation: "Jurisprudence" means the study of law. "Pharmaceutical jurisprudence" means the study of **laws related to medicines and pharmacists**. A pharmacist does not just dispense medicines — he must know which medicines need a prescription, which licences a shop needs, what must be printed on a label, and what happens if the law is broken. This chapter begins with the most important drug law of India: the **Drugs and Cosmetics Act, 1940**.

INFOGRAPHIC CONCEPT — The Law Tree: Imagine one big tree called *Drug Law of India*. Its trunk is the **Drugs and Cosmetics Act, 1940** (the main law). Its branches are the **Drugs and Cosmetics Rules, 1945** (the detailed "how-to" rules made under the Act). Its leaves are the **Schedules** (lists and standards attached at the end). When you are confused, ask: *is this from the trunk (Act), a branch (Rule), or a leaf (Schedule)?*

1.3 Objectives of the Drugs and Cosmetics Act, 1940

Technical concept: The Act was passed to regulate the import, manufacture, distribution and sale of drugs and cosmetics.

Simple explanation: Before 1940, anyone could make and sell "medicines" in India with no quality check. Fake and harmful drugs were common. The Act was made to protect the public. Its objectives are:

1 **To regulate the import of drugs** — so that only safe, quality drugs enter India from other countries.

2 **To regulate the manufacture of drugs** — so that medicines are made in clean, proper factories by qualified people.

3 **To regulate the distribution and sale of drugs** — so that medicines reach patients through licensed shops and qualified pharmacists.

4 **To control the quality of drugs and cosmetics** — through standards, testing, and punishment for bad-quality or fake drugs.

5 **To protect public health** — the single biggest objective behind all the above.

EASY ANALOGY: Think of the Act as the **traffic police of medicines**. Traffic police do not stop you from driving — they make sure everyone drives safely, with a licence, following signals. Similarly, the Act does not stop the drug business — it makes sure medicines are safe, made properly, and sold properly.

Key takeaway: The Act = control over import + manufacture + sale + quality of drugs and cosmetics = protection of public health.

1.4 The Act and the Rules — What Is the Difference?

Point	The Act (1940)	The Rules (1945)
Full name	Drugs and Cosmetics Act, 1940	Drugs and Cosmetics Rules, 1945
Nature	The main law passed by the legislature	Detailed rules made **under** the Act by the Government
Content	Broad provisions: what is prohibited, who can inspect, what are offences	Step-by-step detail: forms of application, fees, label formats, standards
Power	Higher authority — Rules cannot go against the Act	Must follow the Act
Change	Needs the legislature to amend	Can be amended more easily by the Government

Common confusion: Students mix up "Act" and "Rules." Remember: the **Act says WHAT the law is**; the **Rules say HOW to follow it**.

1.5 Definitions — The Legal Dictionary

Technical concept: The Act gives special legal definitions to words like "drug" and "cosmetic." These definitions are wider than everyday meanings.

Simple explanation: In daily life, "drug" means "medicine." But the law's definition is **wider** — it also covers things like empty gelatin capsules, surgical dressings, and even devices used to diagnose disease. Why? Because if the definition were narrow, clever sellers would escape the law by saying "this is not a medicine, so the law does not apply." A wide definition closes that escape door.

1.5.1 Drug (as defined in the Act)

The Act defines "drug" to include:

1 All medicines for **internal or external use** of human beings or animals.

2 All substances intended to be used for **diagnosis, treatment, mitigation (reducing) or prevention** of any disease in humans or animals.

3 All substances (other than food) intended to **affect the structure or any function** of the human or animal body — for example, contraceptives.

4 All substances intended for use as **components of a drug** — including **empty gelatin capsules**.

5 **Devices** intended for internal or external use in diagnosis or treatment — for example, certain diagnostic devices.

6 Substances in the **Ayurvedic, Siddha or Unani (ASU)** systems, intended for the same purposes as above.

Simple explanation: If it is used to treat, prevent, diagnose disease, or change how the body works — the law calls it a "drug," even if you would not call it a medicine in daily life.

EXAMPLE: An empty gelatin capsule has no medicine inside. In daily life you would not call it a drug. But the law calls it a drug, because bad-quality capsules can harm patients. A surgical bandage used on wounds is also treated as a drug for the same reason.

1.5.2 Cosmetic (as defined in the Act)

"Cosmetic" means any article intended to be **rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to the human body** or any part of it for **cleansing, beautifying, promoting attractiveness, or altering the appearance** — and includes any article intended for use as a component of a cosmetic.

Simple explanation: Anything used to clean, beautify or change how you look — creams, lipsticks, shampoos, toothpaste, soaps, hair oils — is a "cosmetic" under the law.

Common confusion: A **medicated shampoo** (e.g., anti-dandruff shampoo with a drug ingredient) may be treated as a **drug**, not a cosmetic, because it claims to treat a condition. The **claim on the label** decides.

1.5.3 Misbranded Drug

A drug is **misbranded** if:

- It is coloured, coated, powdered or polished so that **damage is hidden**, or it is made to appear of better quality than it really is; or
- It is **not labelled in the prescribed manner** (label rules not followed); or
- Its label or container bears any **false or misleading statement**, design or device about the drug.

Simple explanation: "Misbranded" = the **label lies or hides the truth**. The medicine inside may be fine, but the outside (label/pack) cheats the buyer.

EXAMPLE: A cough syrup label says "100% herbal, no side effects" when it actually contains a synthetic drug. The syrup may work, but the label is false misbranded.

1.5.4 Adulterated Drug

A drug is **adulterated** if:

- It consists wholly or partly of any **filthy, putrid (rotten) or decomposed substance**; or
- It has been prepared, packed or stored under **insanitary conditions** where it may have become contaminated or harmful to health; or
- Its container is made of any **poisonous or harmful substance** that may make the contents injurious; or
- It contains a colour **other than a permitted colour**; or
- It contains any **harmful or toxic substance** that makes it injurious to health; or
- Any substance has been **mixed with it to reduce its quality or strength**.

Simple explanation: "Adulterated" = the **medicine itself is dirty, contaminated or weakened**. Think "adult + rated"? No — think **"adulterated = added bad things."**

EXAMPLE: A factory makes tablets in a dirty room full of dust and insects. The tablets get contaminated adulterated, even if the formula on paper is correct.

1.5.5 Spurious Drug

A drug is **spurious** if:

- It is manufactured under a name that **belongs to another drug**; or
- It is an **imitation of, or a substitute for**, another drug, or resembles another drug in a manner likely to deceive, and bears a name that is **fictitious**; or
- It has been **substituted wholly or partly by another drug or substance**; or
- It purports to be the product of a manufacturer of whom it is not truly a product.

Simple explanation: "Spurious" = **fake drug**. It pretends to be something it is not — a duplicate, a copy, a look-alike sold to cheat.

EXAMPLE: A tablet strip printed with the name of a famous company's paracetamol brand, but made by an unknown factory with chalk powder inside spurious.

1.5.6 Patent or Proprietary Medicine

A "patent or proprietary medicine" means a drug which is a remedy or prescription **presented in a form ready for internal or external administration** of human beings or animals, and which is **not included in the official pharmacopoeias** (like the Indian Pharmacopoeia) — in other words, a manufacturer's own branded formula.

Simple explanation: Your company's own special formula, sold under your brand name, not listed in the official books patent/proprietary medicine.

1.5.7 Manufacturer

"Manufacturer" in relation to drugs includes any person who is engaged in the **manufacture** of drugs — and "manufacture" includes any process or part of a process for making, altering, finishing, packing, labelling, breaking up or otherwise treating a drug, with a view to its sale or distribution. **It does not include a compounder or dispenser** who prepares a drug on a doctor's prescription in the ordinary course of retail business.

Simple explanation: A manufacturer makes drugs for sale. But a pharmacist who **mixes a medicine on a doctor's prescription** for one patient is **not** a manufacturer — he is a dispenser.

1.5.8 New Drug

A "new drug" includes a drug whose composition is such that it is **not generally recognised among experts as safe and efficacious** for the proposed use, or a drug already known but proposed to be used in a **new way** (new indication, new dose, new route, new combination) — as per the latest rules/notifications; confirm current definition.

Simple explanation: Anything not already accepted as safe-and-effective by experts = new drug = needs special permission and testing before sale.

Summary table — the three "bad drug" categories

Category	Meaning in one line	Fault is in...	Memory hook
Misbranded	Label lies or hides truth	The **label/pack**	"Mis- = wrong words"
Adulterated	Drug is dirty, contaminated, weakened	The **drug itself** (quality)	"Adulterated = added bad things"
Spurious	Fake, duplicate, look-alike drug	The **identity** of the drug	"Spurious = suspicious copy"

COMMON MISTAKE: Students write "spurious" when they mean "adulterated." Remember: a drug can be adulterated (dirty) but genuine; a spurious drug is always a **cheat on identity**.

1.6 Legal Definitions of Schedules to the Act and Rules

Technical concept: Schedules are lists, standards and requirements attached at the end of the Act and Rules. They have the force of law.

Simple explanation: A Schedule is like an **appendix with legal power**. Instead of writing long lists inside the main law, the Government puts them at the end as numbered Schedules (A, B, C, G, H, M, X, Y...). Each Schedule serves a different purpose: some list dangerous drugs, some give factory standards, some give label formats.

Why schedules matter for exams: Questions like "What is Schedule H?" or "Which schedule deals with Good Manufacturing Practices?" are favourites. Learn each schedule as **letter one-line purpose**.

1.6.1 Overview of important Schedules (details in Chapter 3)

Schedule	One-line purpose (learn this first)
G	List of substances that need a special caution label — "dangerous to take except under medical supervision"
H	List of drugs to be sold **only on a registered medical practitioner's prescription**
H1	List of higher-risk prescription drugs (certain antibiotics, habit-forming drugs) with extra controls
M	**Good Manufacturing Practices (GMP)** — factory premises, equipment, hygiene requirements
N	List of **minimum equipment** required for a pharmacy (retail/wholesale premises)
P	**Life period (expiry)** of drugs — how long a drug remains stable
T	**Good Manufacturing Practices for Ayurvedic, Siddha and Unani (ASU) drugs**
U	Particulars to be shown in **manufacturing records**
V	**Standards for patent or proprietary medicines**
X	List of **narcotic/psychotropic-type drugs** needing the strictest control
Y	Requirements for **clinical trials** and permission for new drugs
F	Standards for **surgical dressings, bandages, and related products**
Part XII B	Requirements for **blood banks / blood components** (as per latest rules — confirm current edition)

MNEMONIC — "Good Habits Make Nice Pharmacists Take Up Various eXtra Yummy Fruits, Part 12B": G, H, H1, M, N, P, T, U, V, X, Y, F — in syllabus order. Or make your own: **"GHT H1 MNOP TUV XY F"** — say it as "Gut-Hut H-one, M-N-O-P, T-U-V, X-Y, F."

Key takeaway: Schedules are the law's ready-made lists. Chapter 3 studies each one in detail; for now, fix the **letter purpose** pairs in memory.

1.7 CDSCO — The Central Drugs Standard Control Organisation

Technical concept: CDSCO, headed by the Drugs Controller General (India) [DCGI], is the central authority for drug regulation in India.

Simple explanation: India has two levels of drug control: **Central** (for the whole country) and **State** (each state has its own drug control department). CDSCO is the central body. It works under the Ministry of Health and Family Welfare, Government of India. Its head is called the **Drugs Controller General (India)** — DCG(I).

Main functions of CDSCO (simple list):

1. **Approval of new drugs** and clinical trials.
2. **Import control** — issuing licences/registration for importing drugs.
3. **Coordination** with State drug control authorities.
4. **Quality control** through Central Drugs Laboratories.
5. Laying down **standards** for drugs.
6. Bringing uniformity in enforcement of the Act across states.

EASY ANALOGY: If state drug departments are the **traffic police of each city**, CDSCO is the **national traffic headquarters** — it makes the national rules, controls what enters the country, and approves new vehicles (new drugs).

1.8 CDSCO Guidelines for Import and Export of Pharmaceuticals

Technical concept: The Act and Rules control import of drugs; CDSCO issues guidelines for import registration and export certification.

Simple explanation: Medicines cross borders. India both **imports** (buys from other countries) and **exports** (sells to other countries) huge quantities of drugs. Both directions are controlled.

Import of drugs — key points

1. **Licence/registration is required** to import drugs into India — as per the latest rules/notifications, confirm current procedure and forms.
2. Certain drugs are **prohibited from import**: misbranded, adulterated, spurious drugs; drugs not of standard quality; drugs whose manufacture, sale or distribution is prohibited in the country of origin (with exceptions as per rules).
3. Imported drugs must meet the **same quality standards** as Indian-made drugs.

4 Imports are allowed only through **notified places** (specified ports/airports) and are subject to inspection and sampling by drug authorities.

Simple explanation: You cannot just courier medicines into India. The importer needs permission, the drug must be of standard quality, and banned-in-its-own-country drugs are generally not allowed in.

Export of drugs — key points

1 CDSCO issues **Certificates of Pharmaceutical Product (CoPP)** and related export certificates as per WHO norms — these certify that the product is approved for marketing in India and manufactured as per GMP.

2 Exporters must comply with the **requirements of the importing country** as well as Indian law.

3 Export-oriented units follow the same manufacturing quality standards.

Simple explanation: When India sells medicines abroad, CDSCO gives a "quality certificate" (CoPP) that foreign buyers trust — like a report card for the medicine.

INDIA CONTEXT: India is called the **"pharmacy of the world"** because it supplies affordable generic medicines to many countries. That is exactly why import/export control under CDSCO matters so much — one bad batch can damage trust worldwide.

PHARMACY RELEVANCE: As a pharmacist in industry, you may handle import licences, registration dossiers, or CoPP applications. Knowing that CDSCO is the authority — and that procedures change with notifications — saves you from working with outdated forms.

Common confusion: CDSCO (central) vs **State drug control** — remember: **new drug approval and imports = CDSCO/central**; **retail/wholesale shop licences = state**. (Details in Chapter 5.)

1.9 Key Points — Chapter 1

1 The Drugs and Cosmetics Act, 1940 regulates **import, manufacture, distribution and sale** of drugs and cosmetics to protect public health.

2 The **Act** states the law; the **Rules (1945)** give the detailed "how-to."

3 Legal definitions are deliberately **wide** (e.g., empty gelatin capsules = drug).

4 **Misbranded** = label lies; **Adulterated** = drug is dirty/weakened; **Spurious** = fake drug.

5 A pharmacist dispensing on prescription is a **dispenser, not a manufacturer**.

6 Schedules are legally binding lists/standards — learn **letter purpose** pairs.

7 **CDSCO (headed by DCGI)** controls new drug approval and imports; issues export certificates (CoPP).

1.10 Exam Summary — Chapter 1

- **Objectives of the Act:** regulate import, manufacture, sale/distribution of drugs and cosmetics; ensure quality; protect public health.
- **Act vs Rules:** Act = main law (what); Rules = details (how); Rules made under the Act.
- **Drug:** wide legal definition — medicines, diagnostic/treatment substances, substances affecting body structure/function, components (empty gelatin capsules), devices, ASU substances.

- **Cosmetic:** articles for cleansing, beautifying, promoting attractiveness, altering appearance.
- **Misbranded:** false/misleading label, hidden damage, unprescribed labelling.
- **Adulterated:** filthy/decomposed, insanitary preparation, poisonous container, non-permitted colour, toxic substance, quality reduced by mixing.
- **Spurious:** fake — wrong name, imitation, substitution, false manufacturer claim.
- **Patent/proprietary medicine:** manufacturer's own branded formula not in official pharmacopoeias.
- **New drug:** not generally recognised as safe and efficacious for the proposed use (confirm latest definition).
- **Schedules G/H/H1/M/N/P/T/U/V/X/Y/F + Part XII B:** letter purpose (see table).
- **CDSCO:** central drug authority under Ministry of Health & Family Welfare; head = DCG(I); functions = new drug approval, import control, standards, coordination, export certification (CoPP).

1.11 One-Minute Revision — Chapter 1

Act 1940 = drug law trunk; Rules 1945 = branches; Schedules = leaves. Objectives: control import, manufacture, sale + quality = public health. Drug definition is WIDE (capsules, devices included). Misbranded = label lies. Adulterated = drug dirty/weak. Spurious = fake. Schedules: G = caution label, H = prescription only, H1 = extra-control Rx, M = GMP, N = pharmacy equipment, P = expiry life, T = ASU GMP, U = manufacturing records, V = patent medicine standards, X = strictest control list, Y = clinical trials, F = surgical dressings, XII B = blood banks. CDSCO/DCGI = central authority; imports need permission; exports get CoPP certificates.

1.12 Practice Questions — Chapter 1

MCQs (answers in brackets):

1 The main objective of the Drugs and Cosmetics Act, 1940 is: (a) To increase drug prices (b) To regulate import, manufacture, sale and quality of drugs and cosmetics (c) To ban all imported drugs (d) To promote only Ayurvedic drugs **[b]**

2 The Drugs and Cosmetics Rules were framed in the year: (a) 1940 (b) 1945 (c) 1948 (d) 1955 **[b]**

3 Under the Act, an empty gelatin capsule is treated as: (a) Not a drug (b) A drug (c) A cosmetic (d) A device only **[b]**

4 A drug with a false claim on its label is: (a) Adulterated (b) Spurious (c) Misbranded (d) Patent medicine **[c]**

5 A duplicate drug sold under a famous brand name is: (a) Misbranded (b) Adulterated (c) Spurious (d) Genuine **[c]**

6 Tablets made in an insanitary, contaminated factory are: (a) Misbranded (b) Adulterated (c) Spurious (d) Standard quality **[b]**

7 Schedule M of the Rules prescribes: (a) Prescription drugs list (b) Good Manufacturing Practices (c) Expiry periods (d) Label formats **[b]**

8 Schedule H drugs: (a) Can be sold without prescription (b) Can be sold only on a registered medical practitioner's prescription (c) Are banned (d) Are cosmetics **[b]**

9 The head of CDSCO is designated as: (a) Drug Inspector (b) Drugs Controller General (India) (c) State Drug Controller (d) Health Minister **[b]**

10 The certificate issued by CDSCO for exporting pharmaceuticals as per WHO norms is: (a) CoPP (b) GMP certificate only (c) Import licence (d) Loan licence **[a]**

Viva questions:

1 Why does the Act define "drug" so widely?

2 Differentiate between misbranded, adulterated and spurious drugs with one example each.

3 What is the difference between the Act and the Rules?

4 Name any five Schedules and their purposes.

5 What is the role of CDSCO in import of drugs?

Application-based questions:

1 A shopkeeper sells a famous company's vitamin tablets, but the tablets were actually made in an unlicensed unit and only the strip carries the famous brand name. Which category of "bad drug" is this? Justify. *(Spurious — false manufacturer identity/imitation.)*

2 A manufacturer uses a colour not permitted under the Rules in a tablet coating. The tablet is otherwise of standard quality. How will it be classified? *(Adulterated — non-permitted colour.)*

3 An importer wants to bring a drug into India that is banned in its country of manufacture. What will CDSCO's stand generally be? *(Prohibited from import, as per rules — confirm current provisions.)*

1.13 References — Chapter 1

- The Drugs and Cosmetics Act, 1940 (bare Act — latest edition/amendments; confirm current edition).
- The Drugs and Cosmetics Rules, 1945 (bare Rules — latest edition; confirm current edition).
- CDSCO guidelines on import and export of pharmaceuticals (as issued/notified from time to time — confirm current guidelines).

(Unit I: Prohibition of manufacture and sale of certain drugs, conditions for grant of license and conditions of license for manufacture of drugs, manufacture of drugs for test/examination/analysis, manufacture of new drug, loan license and repacking license)

2.1 Learning Objectives

After studying this chapter, you will be able to:

1 List the categories of drugs whose manufacture and sale are prohibited.

2 Explain the conditions for grant of a manufacturing licence and the conditions of the licence.

3 Describe manufacture of drugs for test, examination and analysis.

4 Explain the special requirements for manufacture of a new drug.

5 Differentiate between a loan licence and a repacking licence.

6 Answer MCQs, viva and application-based questions on this chapter.

2.2 The Big Picture — Why Manufacture Needs a Licence

Technical concept: No person can manufacture drugs for sale or distribution without a licence granted under the Act and Rules.

Simple explanation: Making medicines is not like making biscuits. A small mistake can kill. So the law says: **no licence = no manufacturing**. The licence is granted only if the factory, the people, and the processes meet fixed standards (mainly Schedule M — GMP).

EASY ANALOGY: A driving licence is given only after you prove you can drive safely. A drug manufacturing licence is given only after you prove your factory can make safe medicines. And just as breaking traffic rules can cancel your driving licence, breaking drug rules can cancel your manufacturing licence.

FLOWCHART — Getting a manufacturing licence (general steps; confirm current forms/fees):

```
Applicant decides product category (allopathic / ASU / cosmetics / etc.)
        |
        v
Applies to the Licensing Authority with prescribed form + fee + documents
        |
        v
Premises inspected (must meet Schedule M / Schedule T requirements)
        |
        v
Competent technical staff verified (qualified persons as per Rules)
        |
        v
Licence GRANTED with conditions  ---- or ----  Application REJECTED with reasons
        |
        v
Licence holder must FOLLOW all licence conditions (or face suspension/cancellation)
```

2.3 Prohibition of Manufacture and Sale of Certain Drugs

Technical concept: The Act prohibits the manufacture for sale, and the sale/distribution, of certain categories of drugs.

Simple explanation: Some drugs are so dangerous or useless that the law simply says **"do not make, do not sell."** The prohibited categories are:

1 **Misbranded drugs** (label lies or hides truth).

2 **Adulterated drugs** (dirty, contaminated, weakened).

3 **Spurious drugs** (fake/duplicate drugs).

4 Drugs **not of standard quality** (fail the official quality standards).

5 **Patent or proprietary medicines without displaying the true formula** or list of ingredients on the label/container (as required by the Rules).

6 Drugs whose **import is prohibited** (Chapter 1).

7 Drugs manufactured in **contravention of licence conditions**.

Simple explanation in one line: If a drug is fake, dirty, mislabelled, substandard, or made without/breaking a licence — making or selling it is an **offence**.

EXAMPLE: A company makes paracetamol tablets that contain only half the labelled strength. These are "not of standard quality" their manufacture and sale are prohibited offence.

Key takeaway: Prohibition list = misbranded + adulterated + spurious + not of standard quality + patent medicine without true formula + import-prohibited drugs.

2.4 Conditions for Grant of Licence (Manufacture)

Technical concept: A manufacturing licence is granted only if the applicant satisfies the conditions laid down in the Rules.

Simple explanation: The licensing authority checks **four things** before saying yes:

Condition	What is checked	Simple meaning
1. Premises	Factory building, space, ventilation, water, drainage — as per Schedule M (or T for ASU)	The factory must be clean and properly built
2. Equipment	Machinery and instruments needed for the products applied for	You must own the right machines
3. Technical staff	Qualified competent persons (as prescribed — e.g., graduates in pharmacy/chemistry with experience, as per latest rules)	Qualified people must supervise
4. Records & procedures	Ability to maintain manufacturing records (Schedule U), testing facilities	You must test and keep records

Additional general points:

- The applicant must not have been convicted of an offence under the Act (as per rules — confirm current disqualifications).
- Separate licences may be needed for different categories (e.g., allopathic drugs, ASU drugs, cosmetics, blood products — confirm current licensing categories).

- The licence is granted in the **prescribed form** on payment of the **prescribed fee**, valid for the prescribed period and renewable (confirm current forms/fees/validity).

COMMON MISTAKE: Students write "anyone can get a licence by paying the fee." Wrong — fee is only one part; **premises + equipment + qualified staff** are the real tests.

2.5 Conditions of Licence (After It Is Granted)

Technical concept: The licence is granted subject to conditions; breach can lead to suspension or cancellation.

Simple explanation: Getting the licence is not the end — it comes with **rules to follow every day**:

1 **Manufacture only the drugs** covered by the licence (no unapproved products).

2 **Maintain GMP** (Schedule M) at all times — premises, hygiene, equipment.

3 **Test** raw materials and finished products; maintain records (Schedule U).

4 **Qualified staff** must supervise manufacture and testing continuously.

5 **Report** any change in staff, premises or constitution to the authority (as required).

6 **Allow inspection** — do not obstruct the Drugs Inspector.

7 **Comply with labelling/packing rules** (Chapter 4).

8 Keep the licence **displayed/available** at the premises as required.

Simple explanation: A licence is like a school admission — admission (grant) is step one; following school rules every day (conditions) keeps you in the school.

FLOWCHART — What happens on violation:

```
Breach of licence condition detected (inspection / complaint / sample failure)
        |
        v
Show-cause notice / opportunity to explain (as per procedure)
        |
        v
Licence SUSPENDED or CANCELLED  +  possible prosecution (offences & penalties, Chapter 4)
```

2.6 Manufacture of Drugs for Test, Examination and Analysis

Technical concept: Drugs may be manufactured in small quantities for test, examination and analysis without a regular manufacturing licence, under a special licence.

Simple explanation: Sometimes a company needs to make a **small trial batch** — to test a formula, to analyse stability, or to prepare samples for licence application. The law allows this under a **special test licence** (confirm current form), so that genuine testing is not blocked by the full licence procedure.

Key points:

- The quantity is limited to what is needed for the test/analysis.
- The drugs made under this licence are **not for sale**.

- Records of manufacture and use must be maintained.

EXAMPLE: A company developing a new cough syrup makes 100 bottles for stability testing before applying for a full manufacturing licence. It uses the test-manufacture licence — it cannot sell those 100 bottles.

2.7 Manufacture of a New Drug

Technical concept: A new drug requires prior permission/approval as per the latest rules (clinical trial and new drug approval framework under CDSCO).

Simple explanation: A new drug = not yet accepted as safe and effective. So the law is extra careful:

1. **Permission for clinical trials** (Schedule Y requirements) must be obtained before testing in humans.
2. **Data on safety and efficacy** (quality, animal studies, clinical trial results) must be submitted to CDSCO.
3. Only after approval can the drug be **manufactured for sale** — and then also under a manufacturing licence.

Simple explanation: New drug = new student joining the school — needs admission test (trials), report card (data), and principal's approval (CDSCO) before joining regular classes (manufacture for sale).

Cautious note: New-drug approval procedures are updated through rules and notifications (e.g., the New Drugs and Clinical Trials framework — confirm the current rules and the authority's current guidelines).

2.8 Loan Licence

Technical concept: A loan licence allows a person who does not own a factory to get drugs manufactured by another licensed manufacturer, using the loan licensee's own staff supervision arrangements as per Rules.

Simple explanation: Suppose you have a great medicine formula and a brand name, but **no factory**. You "borrow" another company's licensed factory to make your product. The law permits this through a **loan licence**.

Key points:

1. The loan licensee must have qualified technical staff as required.
2. The **manufacturing premises belong to the lender** (the licensed manufacturer), who must hold a valid manufacturing licence.
3. The product is manufactured **under the loan licensee's licence**, with proper records.
4. Quality responsibility is shared as per the Rules — the loan licensee must ensure standards.

EASY ANALOGY: You want to bake cakes to sell but have no oven. Your friend has a bakery. You take a "loan licence" to use his oven for your cakes, but **your** baker (qualified staff) supervises, and the cakes carry **your** brand. The bakery must still be a licensed bakery.

Common confusion: Loan licence buying ready-made drugs and re-labelling. In a loan licence, the drug is **manufactured for you** in the lender's factory under your licence.

2.9 Repacking Licence

Technical concept: A repacking licence permits the repacking of drugs (from bulk packs into smaller retail packs) under licence.

Simple explanation: Some drugs arrive in **big bulk containers**. A repacking licence allows a licensee to **divide them into small retail packs** (e.g., bulk tablets into strips) under hygienic conditions with proper labelling.

Key points:

1. Repacking must be done in **licensed premises** meeting hygiene/space requirements.
2. Every repacked pack must carry the **full legal label** (Chapter 4).
3. Records of repacking must be maintained.
4. Repacking is **not manufacturing a new drug** — it is only changing the pack size.

Loan licence vs Repacking licence — comparison table:

Point	Loan licence	Repacking licence
What happens	Drug is **manufactured** in someone else's factory	Bulk drug is **divided into smaller packs**
Factory	Lender's licensed factory	Licensee's own repacking premises
Product	New finished product made	Same product, smaller pack
Example	Your brand tablets made in another company's plant	Bulk bottle of 1000 tablets repacked into strips of 10

2.10 Key Points — Chapter 2

1. **No licence = no manufacture for sale** — licence is compulsory.
2. **Prohibited:** misbranded, adulterated, spurious, not-of-standard-quality drugs (and patent medicines without true formula).
3. **Grant conditions:** proper premises (Schedule M/T) + equipment + qualified technical staff + testing/records ability.
4. **Licence conditions:** make only approved drugs, maintain GMP, test and keep records, allow inspection, follow label rules.
5. **Test/analysis manufacture:** allowed in small quantities under special licence — **not for sale**.
6. **New drug:** needs clinical-trial permission and CDSCO approval before manufacture for sale (Schedule Y).
7. **Loan licence** = manufacture your product in another's licensed factory. **Repacking licence** = divide bulk packs into retail packs.

2.11 Exam Summary — Chapter 2

- **Licence compulsory** for manufacture for sale/distribution.

- **Prohibition of manufacture and sale:** misbranded, adulterated, spurious, not of standard quality, patent/proprietary medicine without true formula, import-prohibited drugs.
- **Conditions for grant:** Schedule M/T premises, equipment, competent technical staff, testing facilities and records; prescribed form and fee (confirm current).
- **Conditions of licence:** only licensed products, continuous GMP, testing + Schedule U records, qualified supervision, no obstruction of inspectors, label compliance; breach suspension/cancellation + prosecution.
- **Test/examination/analysis manufacture:** special licence, small quantity, not for sale.
- **New drug manufacture:** clinical trial permission (Schedule Y) + safety/efficacy data + CDSCO approval.
- **Loan licence:** manufacture by another licensed manufacturer under your licence; qualified staff required.
- **Repacking licence:** bulk retail packs in licensed premises with full labelling and records.

2.12 One-Minute Revision — Chapter 2

No licence, no manufacturing. Prohibited = fake/dirty/mislabelled/substandard. Grant needs factory (Schedule M) + machines + qualified staff + testing. Licence conditions = follow GMP, test, keep records, allow inspection daily. Test licence = small trial batches, not for sale. New drug = trials + CDSCO approval first. Loan licence = your product made in another's factory. Repacking = bulk into small packs.

2.13 Practice Questions — Chapter 2

MCQs (answers in brackets):

1 Manufacture of drugs for sale without a licence is: (a) Allowed for small scale (b) Prohibited (c) Allowed for herbal drugs only (d) Allowed with pharmacist's permission **[b]**

2 Which of the following is prohibited from manufacture and sale? (a) Standard quality drug (b) Spurious drug (c) Licensed patent medicine (d) Drug with proper label **[b]**

3 Good Manufacturing Practices for allopathic drugs are given in: (a) Schedule H (b) Schedule M (c) Schedule P (d) Schedule Y **[b]**

4 A licence for manufacture of drugs for test and analysis: (a) Allows sale of the batch (b) Does not allow sale (c) Is the same as a loan licence (d) Needs no application **[b]**

5 A loan licence permits: (a) Import of drugs (b) Manufacture of the licensee's product in another licensed manufacturer's premises (c) Retail sale (d) Repacking only **[b]**

6 Repacking licence is required for: (a) Manufacturing a new drug (b) Dividing bulk packs into smaller retail packs (c) Importing drugs (d) Clinical trials **[b]**

7 Breach of licence conditions can lead to: (a) Nothing (b) Suspension or cancellation of licence (c) Automatic renewal (d) Fee refund **[b]**

8 Approval for manufacture of a new drug for sale requires: (a) Only a trade licence (b) Clinical trial data and CDSCO approval (c) Pharmacist's signature (d) Nothing special **[b]**

Viva questions:

1 Why is a licence compulsory for drug manufacture?

2 List the drugs whose manufacture and sale are prohibited.

3 What are the conditions for grant of a manufacturing licence?

4 What is a loan licence? How is it different from a repacking licence?

5 Why is a special licence needed for manufacture for test and analysis?

Application-based questions:

1 A businessman wants to launch his own brand of vitamin tablets but owns no factory. A friend owns a licensed tablet factory. What legal route is available, and what conditions must be met? *(Loan licence; friend's factory must be licensed, applicant needs qualified technical staff, manufacture under loan licence with records.)*

2 An inspector finds that a licensed factory is manufacturing a product not covered by its licence. What action can follow? *(Breach of licence condition show-cause suspension/cancellation + possible prosecution.)*

3 A company makes 50 bottles of a trial syrup for stability studies before applying for a manufacturing licence. Can it sell these bottles? Why? *(No — test/analysis licence; manufacture for test only, not for sale.)*

2.14 References — Chapter 2

- The Drugs and Cosmetics Act, 1940 (bare Act — latest edition/amendments; confirm current edition).
- The Drugs and Cosmetics Rules, 1945 (bare Rules — latest edition; confirm current edition, especially Schedules M, T, U and licensing forms/fees).
- CDSCO guidelines on new drugs and clinical trials (as notified from time to time — confirm current guidelines).