

GPAT

2027-28



PHARMACEUTICAL JURISPRUDENCE

CLASS- 12



TIME- 8 : 30 P.M

DRUGS AND COSMETICS ACT & RULES

UPDATED QUESTIONS TILL GPAT 2026

GPAT



VIDEO
LECTURE



PDF



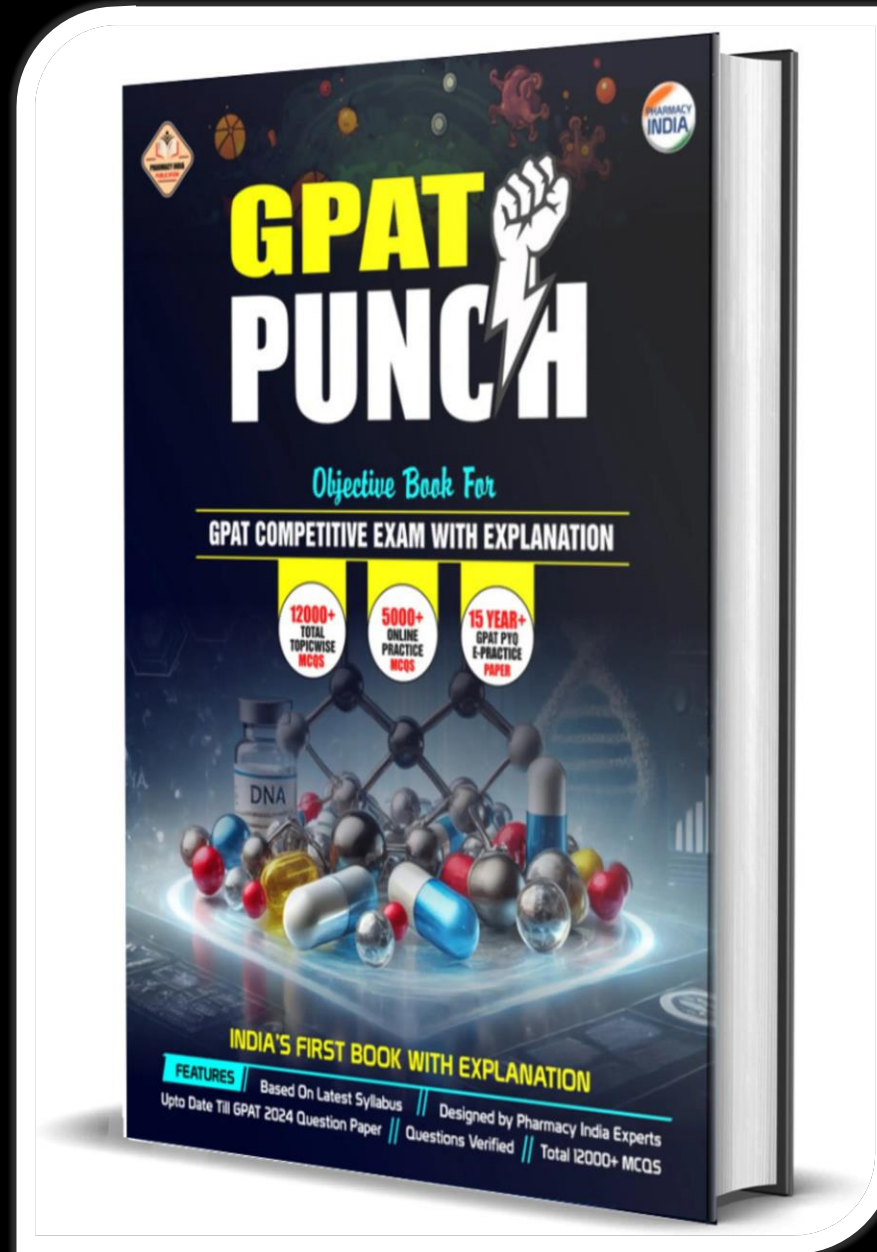
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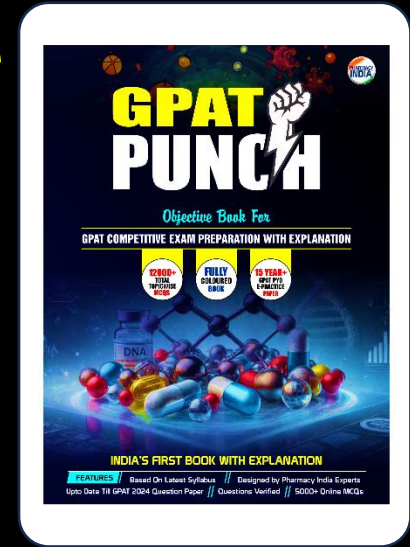


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01.

Which form is required to apply for a registration certificate to import cosmetics into India under the Drugs and Cosmetics Rules, 1945? [GPAT 2026]

- (a) Form 41
- (b) Form 43
- (c) Form 40
- (d) Form 42



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01.

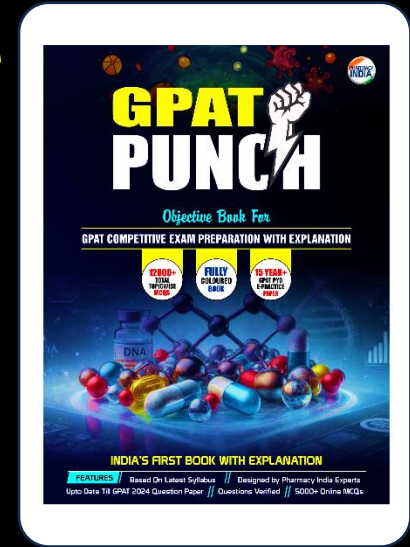
Which form is required to apply for a registration certificate to import cosmetics into India under the Drugs and Cosmetics Rules, 1945? [GPAT 2026]

(a) Form 41

(b) Form 43

(c) Form 40

(d) Form 42



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FORM 42 – COSMETIC IMPORT APPLICATION



UNDER DRUGS AND COSMETICS RULES, 1945



KEY POINTS

1



Application for registration certificate for import of cosmetics is made in **FORM 42**.

2



The registration certificate for import of cosmetics is issued in **FORM 43**.

3



This registration certificate is required **BEFORE** lawful import of cosmetics into India.

4



Import without a valid registration certificate is not permitted and is **punishable**.

5



Remember the distinction:
FORM 42 = Application,
FORM 43 = Certificate.



LEGAL BASIS

Drugs and Cosmetics Act, 1940
Read with Drugs and Cosmetics Rules, 1945



PROCESS: FROM APPLICATION TO LAWFUL IMPORT



IMPORTANT TO KNOW



Rule Reference:
Drugs and Cosmetics Rules, 1945
(Rule 20)



Validity:
As specified in the Registration Certificate (Form 43).



Applies to:
Imported cosmetics (not manufactured in India).



Authority:
Licensing Authority of the State/UT.



EXAM MEMORY LINE

“42 APPLY, 43 CERTIFY”



NO FORM 43 = NO LAWFUL IMPORT

Always obtain Registration Certificate (Form 43) **before** importing cosmetics into India.



QUICK GLANCE

FORM 42 → Application

FORM 43 → Certificate



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02.

Match the following schedules with their correct descriptions: [GPAT 2025]

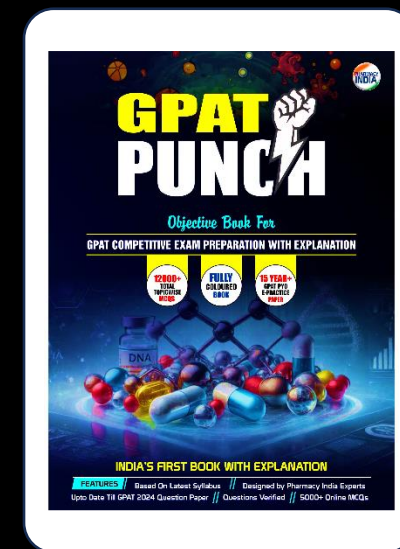
1. Schedule FF	P. Standard for sterilized umbilical tapes
2. Schedule F3	Q. Requirements and guidelines on clinical trials for import and manufacture of new drug
3. Schedule V	R. Standard for ophthalmic preparations
4. Schedule Y	S. Standard for patent or proprietary medicines

(a) 1-R, 2-P, 3-S, 4-Q

(b) 1-P, 2-R, 3-S, 4-Q

(c) 1-R, 2-Q, 3-P, 4-S

(d) 1-P, 2-Q, 3-R, 4-S



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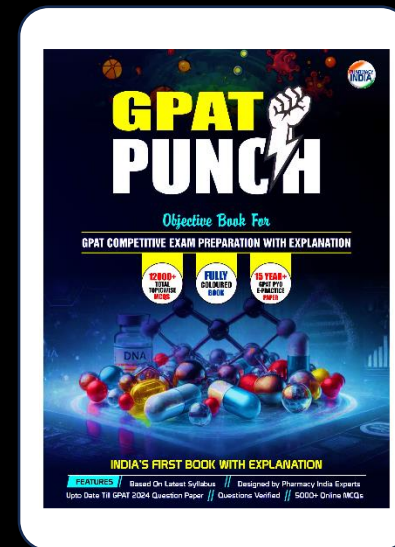
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(c) 1-R, 2-Q, 3-P, 4-S

(d) 1-P, 2-Q, 3-R, 4-S



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KEY SCHEDULE MATCHES

IMPORTANT SCHEDULES UNDER DRUGS AND COSMETICS RULES

SCHEDULE FF

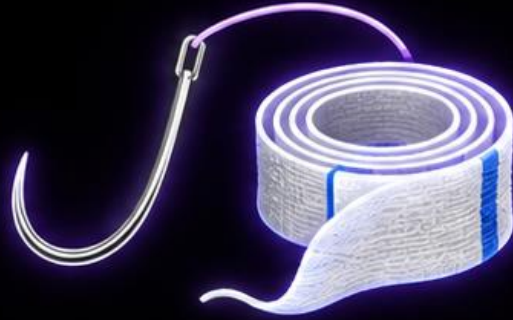
STANDARDS FOR
OPHTHALMIC PREPARATIONS



- ✓ Covers eye drops, ointments, lotions and other ophthalmic forms
- ✓ Quality, safety and efficacy standards
- ✓ Sterility, clarity and pH requirements
- ✓ Packaging and labeling norms

SCHEDULE F3

STANDARDS FOR STERILIZED
SURGICAL LIGATURES, SUTURES
AND UMBILICAL TAPES



- ✓ Applies to ligatures, sutures and umbilical tapes
- ✓ Sterility and strength requirements
- ✓ Material and construction standards
- ✓ Packaging and storage conditions

SCHEDULE V

STANDARDS FOR PATENT OR
PROPRIETARY MEDICINES



- ✓ Standards for composition, quality and labelling
- ✓ Ensures uniformity and safety
- ✓ Includes registration requirements
- ✓ Protects consumer interests

SCHEDULE Y

REQUIREMENTS AND GUIDELINES
FOR CLINICAL TRIALS AND FOR
IMPORT/MANUFACTURE OF NEW DRUGS



- ✓ Governs clinical trials in India
- ✓ Ethical, safety and scientific guidelines
- ✓ For import/manufacture of new drugs
- ✓ Approvals and documentation required



MEMORY NOTE:

FF = eye, **F3** = sterile surgical items, **V** = proprietary, **Y** = clinical trials





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03.

Match the following: [GPAT 2025]

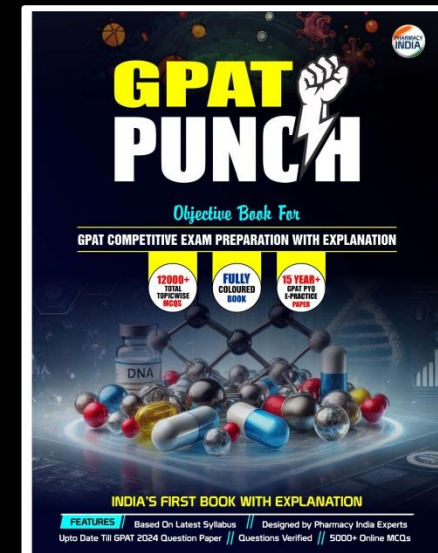
A. Schedule G	P. Life period of drugs
B. Schedule H	Q. Standards for surgical dressing
C. Schedule F-2	R. Drugs to be used under RMP
D. Schedule P	S. List of prescription drugs

(a) A-R, B-S, C-Q, D-P

(b) A-R, B-S, C-P, D-Q

(c) A-P, B-Q, C-R, D-S

(d) A-P, B-Q, C-S, D-R



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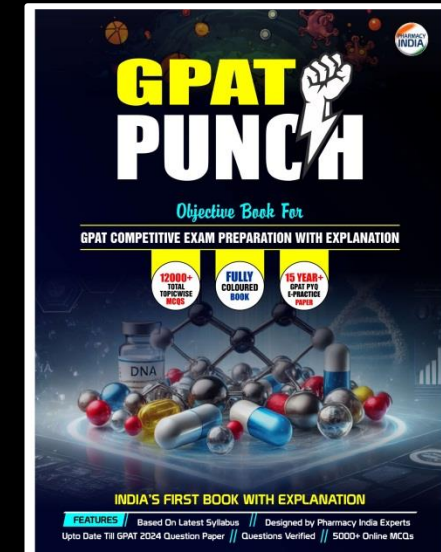
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(c) A-P, B-Q, C-R, D-S

(d) A-P, B-Q, C-S, D-R



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SCHEDULE G • H • F-2 • P

IMPORTANT SCHEDULE MATCHING UNDER DRUGS AND COSMETICS RULES

SCHEDULE G



DRUGS TO BE USED UNDER MEDICAL SUPERVISION / RMP

-  May have risks if used inappropriately
-  Require medical supervision
-  Risk Management Plan (RMP) / precautions
-  Dispensed only by registered pharmacist

SCHEDULE H



PRESCRIPTION DRUGS SOLD ONLY ON PRESCRIPTION

-  To be sold by retail on prescription only
-  Must be issued by a registered medical practitioner
-  Ensures safe and rational use of medicines
-  Not to be advertised to the public

SCHEDULE F-2



STANDARDS FOR SURGICAL DRESSINGS

-  Specifies quality standards for surgical dressings
-  Includes gauze, cotton, absorbent cotton, etc.
-  Ensures sterility, purity, and safety
-  Quality control & packaging requirements

SCHEDULE P



LIFE PERIOD AND SHELF LIFE OF DRUGS

-  Specifies life period of drugs
-  Includes shelf life after opening / reconstitution
-  Storage conditions to be mentioned
-  Ensures potency, safety and effectiveness



EXAM TIP



G =
caution under medical supervision



H =
prescription only



F-2 =
dressings



P =
shelf life



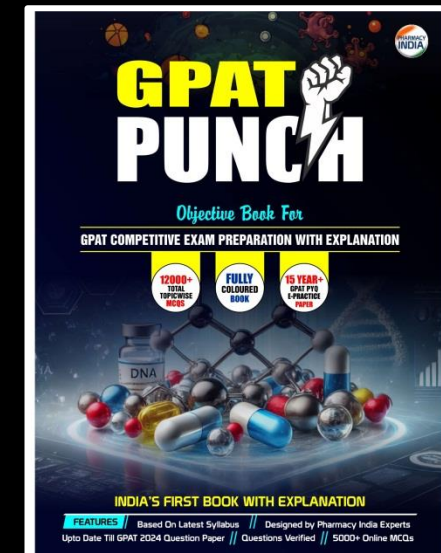
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04.

If the label or container bears the name of an individual or company purporting to be the manufacturer of the drug where the individual or company is fictitious or does not exist, such a drug is called: **[GPAT 2025]**

- (a) Adulterated drug
- (b) Mixed drug
- (c) Misbranded drug
- (d) Spurious drug



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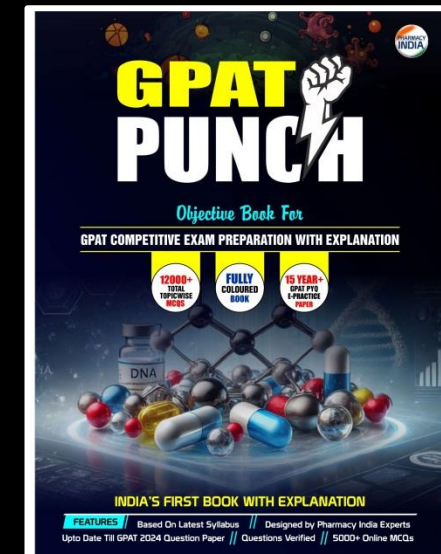
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- (d) Spurious drug**



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SPURIOUS DRUG



DEFINITION

A drug is spurious when it **falsely claims** to be manufactured by a manufacturer that is **fictitious** or **does not exist**.



KEY POINTS

-  **False identity issue** – the name of the manufacturer is fake.
-  May **imitate** a genuine product to deceive consumers.
-  Violates trust and **public health**.
-  Subject to **legal action**, seizure and **penalties**.



Under the Drugs and Cosmetics Act, 1940 & Rules



WHY IT MATTERS



Threatens patient **safety**



Undermines drug **authenticity**



May contain unknown or **harmful** contents



A **punishable** offence under the law

KNOW THE DIFFERENCE

GENUINE PRODUCT



- ✓ Real manufacturer name & address
- ✓ Valid licence number
- ✓ Proper contact details
- ✓ Authentic packaging
- ✓ Reliable source

VS

SPURIOUS (FAKE) PRODUCT



- ✗ Fictitious or non-existent manufacturer
- ✗ No valid licence number
- ✗ Incomplete or false address
- ✗ Poor / misleading packaging
- ✗ Unreliable source



WHAT YOU SHOULD DO



Always check the manufacturer identity



Verify licence number on the official portal



Purchase medicines from authorised sources only



Report any suspicious product to authorities



EXAM ALERT: Fake manufacturer name = spurious drug



BE INFORMED. BE ALERT. PROTECT YOUR HEALTH.





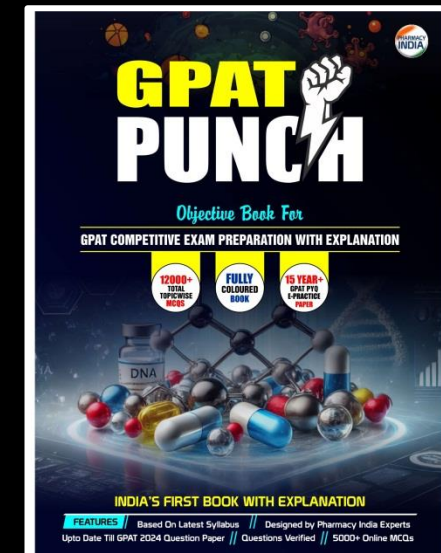
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05.

Schedule E of the Drugs and Cosmetics Rules, 1945 refers to which category of substances? [GPAT 2026]

- (a) List of poisonous substances under Ayurvedic, Siddha and Unani medicines
- (b) List of prescription drugs requiring medical supervision
- (c) List of cosmetics permitted for import into India
- (d) List of biological products like vaccines and sera



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05.

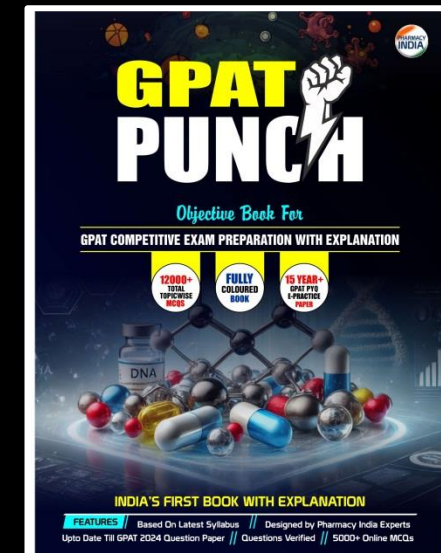
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SCHEDULE E

OF THE DRUGS AND COSMETICS RULES, 1945



1. SCHEDULE E LISTS POISONOUS SUBSTANCES

It contains poisonous substances that are used in Ayurvedic, Siddha and Unani medicines.



2. NEED SPECIAL CAUTION

These ingredients need special caution in their formulation and use to ensure safety.



3. NOT ORDINARY ALLOPATHIC PRESCRIPTION SCHEDULES

Schedule E is specific to ASU medicines and is not the same as the allopathic prescription schedules (e.g., H, H¹, X, etc.).



4. IMPORTANT IN ASU DRUG REGULATION

It plays a key role in regulating the safe use of poisonous substances in ASU systems of medicine.



EXAM MEMORY: Schedule E = *poisonous ASU substances*



WHY IT MATTERS?

Helps ensure that traditional medicines made with poisonous substances are safe, effective and reliable.



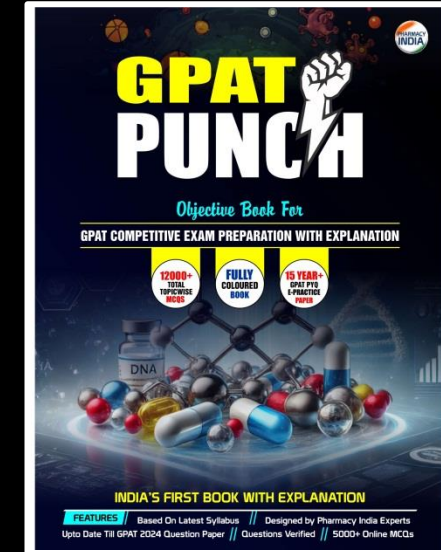
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06.

Minimum manufacturing space required for “Habb-Unani medicine” as per Schedule T of Drugs and Cosmetics Rules is: [GPAT 2025]

- (a) 100 sq. ft.
- (b) 150 sq. ft.
- (c) 200 sq. ft.
- (d) 50 sq. ft.



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HABB – MINIMUM SPACE

Minimum manufacturing space for **Habb** (pills/tablets) in Unani medicine under **Schedule T**.



For Habb (pills/tablets) in Unani medicine, the minimum manufacturing space required is **100 sq. ft.**



This requirement is specified under **Schedule T** GMP requirements.



Dosage-form-wise space and equipment are defined for **ASU manufacturing**.



Adequate space ensures **organized, systematic** and **hygienic** production.



Helps in maintaining product **quality, safety** and **compliance** with GMP.

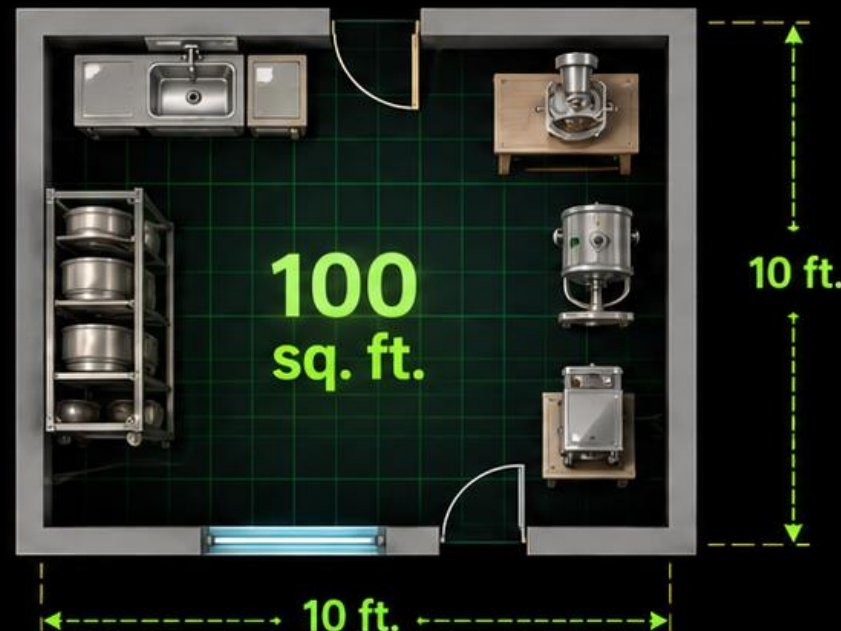


MEMORY NOTE

**Habb =
100 sq. ft.**



MINIMUM MANUFACTURING SPACE FOR HABB



GMP COMPLIANCE



CLEANLINESS



VENTILATION



**ORDERLY
WORKFLOW**



**CONTAMINATION
CONTROL**



**QUALITY
ASSURANCE**



**REGULATORY
COMPLIANCE**

UNANI MEDICINE



Schedule T (Drugs & Cosmetics Rules, 1945) lays down **minimum space, equipment and facilities** for different dosage forms.



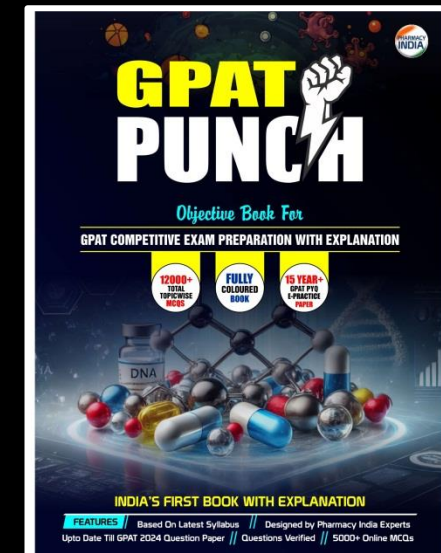
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07.

Schedule T of Drugs and Cosmetics Rules, 1945 deals with: [GPAT-2024]

- (a) GMP for ASU drugs
- (b) GMP for pharmaceutical products
- (c) GLP and requirement of premises and equipment
- (d) GMP for homeopathy medicine



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07.

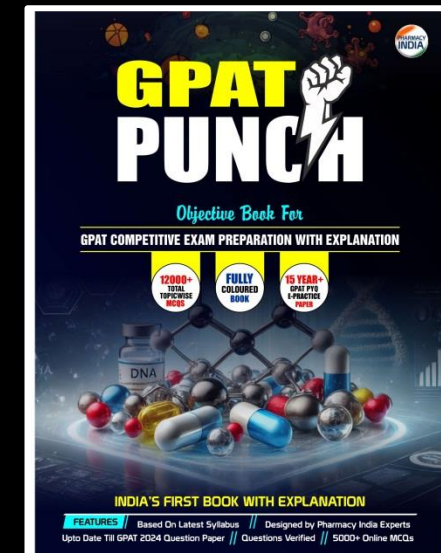
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(c) GLP and requirement of premises and equipment

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SCHEDULE T – GMP FOR ASU DRUGS

Schedule T of the Drugs and Cosmetics Rules, 1945

1

WHAT IT IS



Schedule T lays down Good Manufacturing Practices for **Ayurvedic**, **Siddha** and **Unani** medicines.

COVERS TRADITIONAL SYSTEMS



AYURVEDA



SIDDHA



UNANI

2

WHAT IT COVERS

- ✓ Premises
- ✓ Equipment
- ✓ Hygiene
- ✓ Documentation
- ✓ Quality-related practices



3

ITS AIM

To ensure **safe**, **standardized** and **hygienic** manufacturing of ASU medicines.



SAFE



STANDARDIZED



HYGIENIC



QUALITY



WELL-DESIGNED
PREMISES



SUITABLE
EQUIPMENT



CLEAN &
HYGIENIC



PROPER
DOCUMENTATION



QUALITY
ASSURANCE



TRAINED
PERSONNEL

4

WHY IT IS IMPORTANT

It is a key schedule that ensures **consistent quality**, **safety** and public confidence in ASU drug units.



MEMORY TIP

T = Traditional systems **GMP**





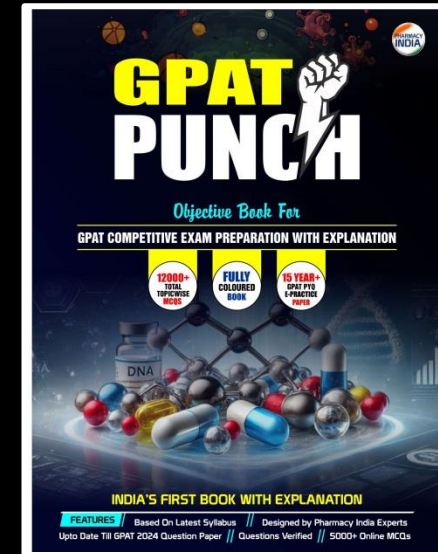
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08.

Central Government approved factory premises where opium alkaloids are processed are situated at: [GPAT-2024]

- (a) Ghazipur and Kota
- (b) Neemuch and Ghazipur
- (c) Gwalior and Kota
- (d) New Delhi and Ghaziabad



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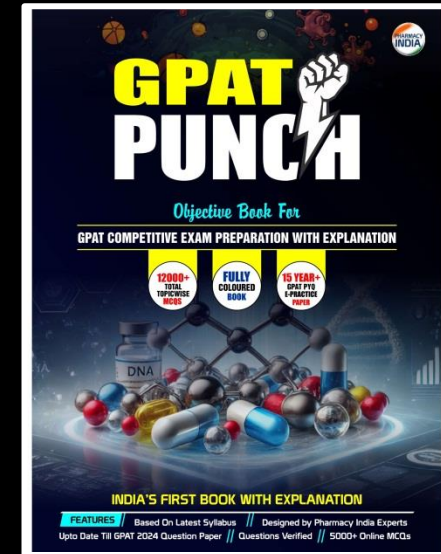


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OPIUM ALKALOID FACTORIES



GOVERNMENT-APPROVED FACTORIES

Opium alkaloid processing is carried out in **government-approved** factories.



LOCATIONS

These factories are located at **Neemuch** and **Ghazipur**.



IMPORTANT CENTERS

Neemuch and Ghazipur are **important centers** in opium and alkaloid processing in India.



PROCESSING ACTIVITY



Opium is processed to extract valuable alkaloids such as Morphine, Codeine, Thebaine, Noscapine, Papaverine.



WHY IMPORTANT?

Ensure quality control, legal production, and supply of essential medicinal alkaloids.



EXAM TIP

Remember both names together for exams.



MEMORY LINE:



Neemuch + Ghazipur





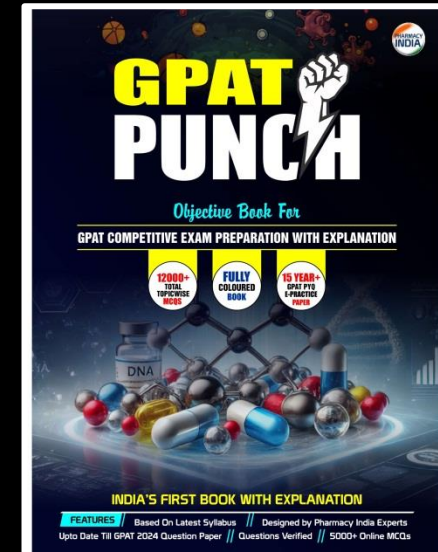
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09.

Drugs covered under which schedule are not permitted for repacking licence? [GPAT-2023 Shift I]

- (a) Schedule H
- (b) Schedule G
- (c) Schedule O
- (d) Schedule C and C1



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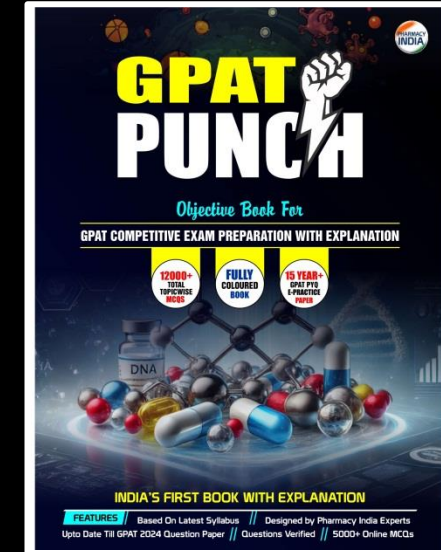
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Drugs covered under which schedule are not permitted for repacking licence? [GPAT-2023 Shift I]

- (a) Schedule H
- (b) Schedule G
- (c) Schedule O
- (d) Schedule C and C1**



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REPACKING LICENCE – EXCLUSION



 **BIOLOGICALS & SPECIAL PRODUCTS**
Requiring Strict Control

1



Drugs in **Schedule C** and **Schedule C(1)** are not permitted for repacking licence.

2



These schedules mainly include **biological and special products** requiring strict control.

3



Such products need **higher standards** for handling and manufacture.

4



Repacking is **restricted** to protect **quality and sterility**.



QUALITY



STERILITY



MEMORY LINE:

No repacking licence for **Schedule C & C(1)**





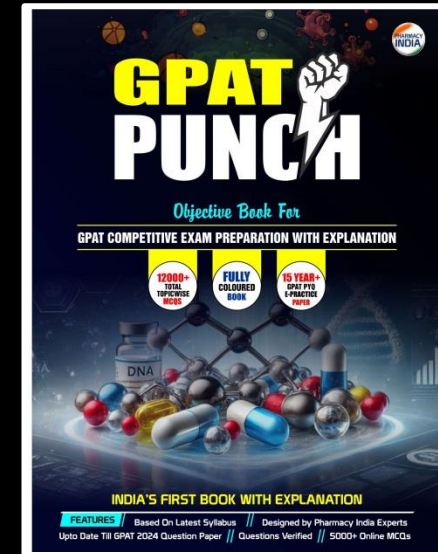
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10.

Requirements of factory premises for manufacture of cosmetics are mentioned under which schedule of the Drugs and Cosmetics Rules, 1945? [GPAT-2023 Shift I]

- (a) Schedule M
- (b) Schedule M-1
- (c) Schedule M-2
- (d) Schedule M-3



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10.

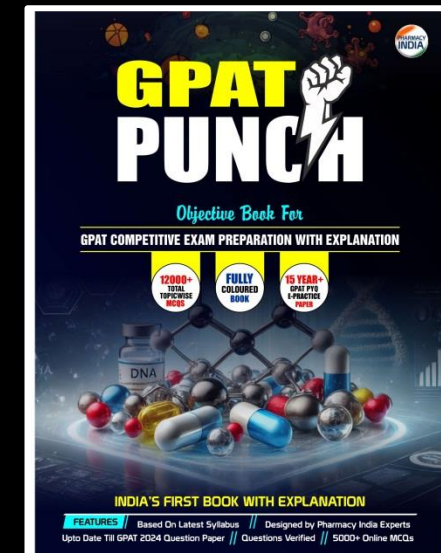
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(a) Schedule M

(b) Schedule M-1

(c) Schedule M-2

(d) Schedule M-3



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SCHEDULE M-II – COSMETIC FACTORY PREMISES

Requirements for manufacture of cosmetics under Drugs and Cosmetics Rules, 1945



Requirements of factory premises for manufacture of cosmetics are prescribed under **Schedule M-II** of the Drugs and Cosmetics Rules, 1945.



1 Schedule M-II specifically deals with **factory premises** for cosmetic manufacturing.



2 It lays down **sanitary and hygienic** requirements for the **location and surroundings**.



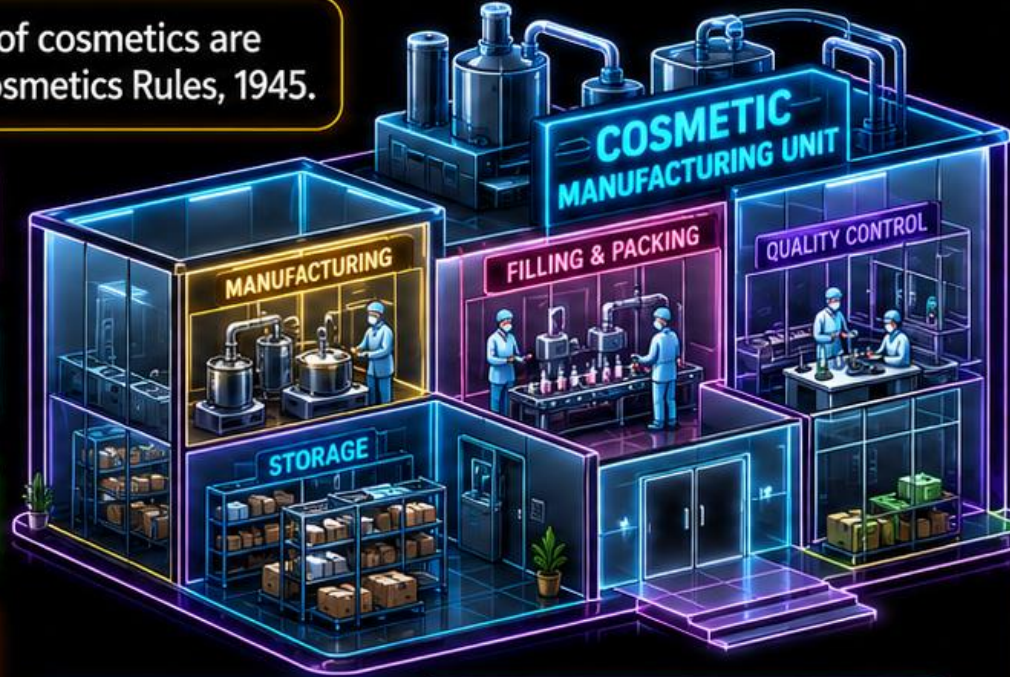
Premises should have adequate **ventilation**, **lighting**, **water supply** and **waste disposal**.



4 Separate and orderly areas should be available for **manufacturing**, **storage**, **filling**, **packing** and **quality control**.



5 The purpose is to ensure **safe**, **clean** and **quality** cosmetic production.



CLEAN
SAFE
HYGIENIC



KEY PREMISES REQUIREMENTS



GOOD
VENTILATION



ADEQUATE
LIGHTING



SAFE
WATER SUPPLY



EFFECTIVE
WASTE DISPOSAL



CLEANLINESS &
MAINTENANCE



SANITARY &
HYGIENIC
SURROUNDINGS



MEMORY TIP: **M-II** = Manufacture premises for cosmetics



Rule reference:
Schedule M-II



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11.

Match List I with List II: [GPAT-2023 Shift I]

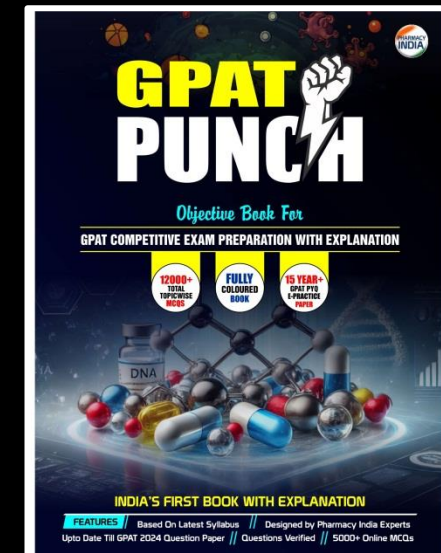
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2. Schedule FF	Q. Requirements for clinical trials
3. Schedule O	R. Disinfectant liquids
4. Schedule P	S. Ophthalmic ointments

(a) 1-P, 2-Q, 3-R, 4-S

(b) 1-Q, 2-R, 3-S, 4-P

(c) 1-S, 2-R, 3-Q, 4-P

(d) 1-Q, 2-S, 3-R, 4-P



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Match List I with List II: [GPAT-2023 Shift I]

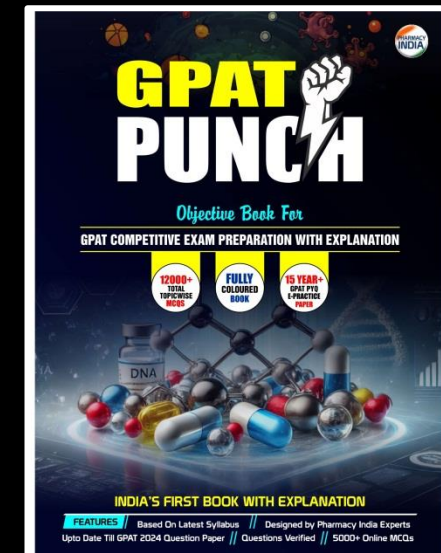
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(b) 1-Q, 2-R, 3-S, 4-P

(c) 1-S, 2-R, 3-Q, 4-P

(d) 1-Q, 2-S, 3-R, 4-P



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SCHEDULES Y, FF, O & P

Y SCHEDULE Y

REQUIREMENTS FOR CLINICAL TRIALS AND NEW DRUGS



- ✓ Regulates clinical trials in humans.
- ✓ Requires Ethics Committee approval.
- ✓ Informed consent must be obtained.
- ✓ Insurance cover for trial subjects.
- ✓ Safety, rights & well-being of subjects protected.

FF SCHEDULE FF

STANDARDS FOR OPHTHALMIC PREPARATIONS / OPHTHALMIC OINTMENTS



- ✓ Defines quality standards for ophthalmic products.
- ✓ Sterility, isotonicity & suitability ensured.
- ✓ Safety, efficacy & uniformity mandated.
- ✓ Applies to eye drops, eye ointments, etc.

O SCHEDULE O

STANDARDS FOR DISINFECTANT FLUIDS



- ✓ Specifies quality standards for disinfectant fluids.
- ✓ Ensures germicidal efficacy & safety.
- ✓ Used for hospitals, instruments, surfaces, etc.
- ✓ Must meet prescribed tests & acceptance criteria.

P SCHEDULE P

LIFE PERIOD AND STORAGE OF DRUGS



- ✓ Specifies the expiry period of drugs.
- ✓ Defines proper storage conditions.
- ✓ Ensures quality, safety & efficacy till expiry.
- ✓ Follow FEFO – First Expiry, First Out.



EXAM PEARL

Easy memory cue to recall:



Y = trials



O = disinfectant



P = period / shelf life



FF = eye preparations



Ensures **QUALITY & SAFETY**



Protects **PUBLIC HEALTH**



Ensures **REGULATORY COMPLIANCE**



Exam Relevant, **High Yield**



Remember **Smart**, Score **Smart!**

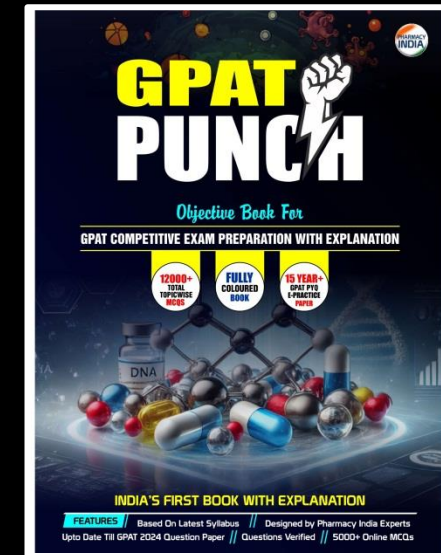


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12.

Specific requirements for manufacture of sterile products and parenteral preparations are prescribed in which part of Schedule M? [GPAT-2023 SHIFT-II]

- (a) Part IV
- (b) Part IB
- (c) Part II
- (d) Part ID



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12.

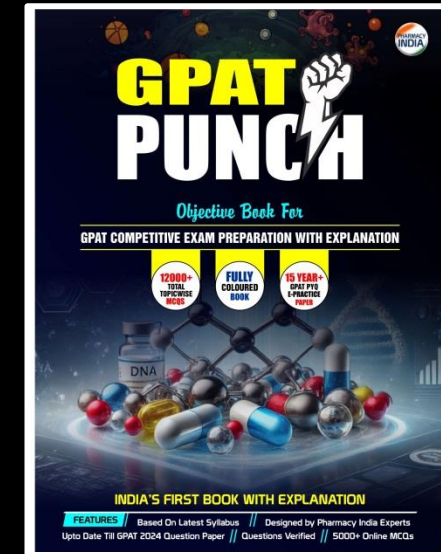
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(b) Part IB

(c) Part II

(d) Part ID



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SCHEDULE M – PART II



Part II of Schedule M lays down **specific requirements** for the manufacture of the following **STERILE PRODUCTS**



Parenteral Preparations
(Small-Volume Injectables)



Parenteral Preparations
(Large-Volume Parenterals)



Sterile Ophthalmic Preparations

KEY REQUIREMENTS

1

CLEAN AREAS AND AIRLOCKS



Segregated clean areas with airlocks to prevent entry of contaminants.

2

HEPA-FILTERED AIR



HEPA filtration ensures supply of high-quality, particle-free air.

3

ASEPTIC PROCESSING



Aseptic techniques and validated processes to maintain sterility.

4

CONTAMINATION CONTROL



Controls for personnel, materials, equipment and process to minimize contamination risk.

5

STRICT ENVIRONMENTAL MONITORING



Regular monitoring of air particles, viable organisms, temperature, humidity and pressure differentials.



WHY IT MATTERS



Ensures sterility, prevents contamination and protects patient safety.



SCHEDULE M – PART II upholds the highest standards for sterile manufacturing

QUALITY. STERILITY. PATIENT SAFETY.



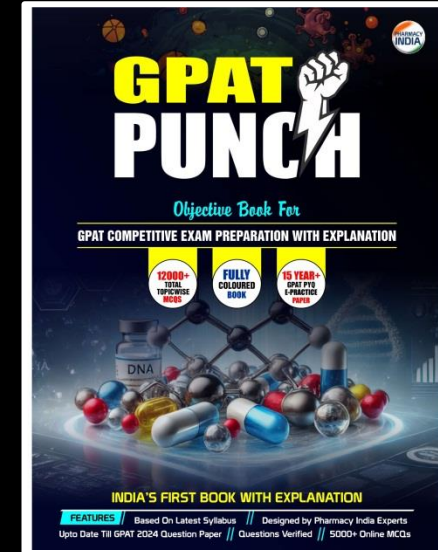
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13.

India's first Central Drug Laboratory was established at: [GPAT-2022]

- (a) Mumbai
- (b) Lucknow
- (c) Kolkata
- (d) Hyderabad



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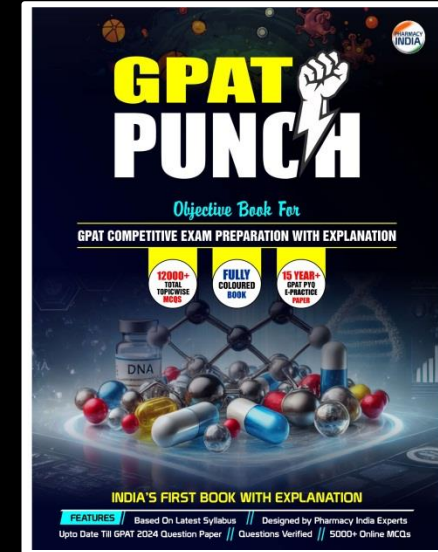
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- (d) Hyderabad



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CENTRAL DRUGS LABORATORY, KOLKATA



India's **first and oldest**
Central Drugs Laboratory
was established at **KOLKATA**.

It is a national statutory drug
testing laboratory functioning
under the **Drugs and Cosmetics Act**.

1



NATIONAL STATUTORY LABORATORY

Operates under the Drugs and Cosmetics Act, 1940
and associated Rules.

2



TESTS DRUGS & COSMETICS

Evaluates quality, safety, strength, purity and
compliance with pharmacopoeial standards.

3



SUPPORTS QUALITY CONTROL & STANDARDS

Provides scientific support to regulators, enforces quality
benchmarks and ensures consumer protection.

4



NATIONAL REFERENCE & CAPACITY BUILDER

Acts as a reference laboratory, develops methods,
trains personnel and collaborates with state labs.



KOLKATA

The heritage of trust.
The safeguard of quality.



KEY ROLE



TESTING

Physicochemical,
microbiological &
biological testing
of drugs and
cosmetics.



ANALYSIS

Advanced
instrumental
analysis for
accurate and
reliable results.



REFERENCE STANDARDS

Preparation, characterization
and maintenance of
reference standards
and reagents.



QUALITY ASSURANCE

Ensures safe, effective
and high-quality
medicines and
cosmetics for all.



Central Drugs Laboratory, Kolkata – **Science. Standards. Safety.** Serving the Nation.





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14.

The schedule in the Drugs and Cosmetics Act that deals with standards for disinfectant fluids is:

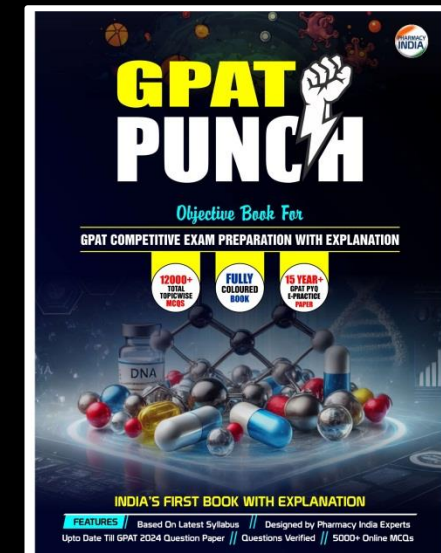
[GATE-2004, GPAT-2023 SHIFT-II]

(a) Schedule B

(b) Schedule F

(c) Schedule O

(d) Schedule M



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14.

The schedule in the Drugs and Cosmetics Act that deals with standards for disinfectant fluids is:

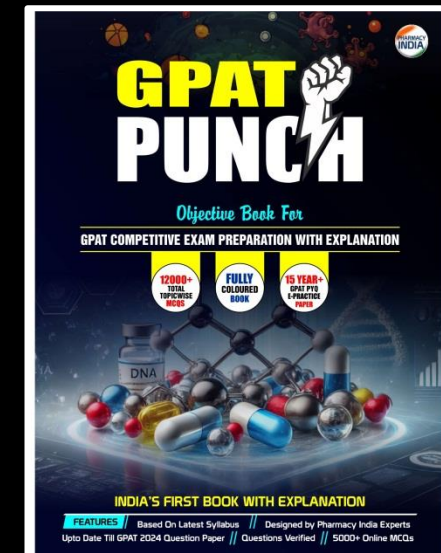
[GATE-2004, GPAT-2023 SHIFT-II]

(a) Schedule B

(b) Schedule F

(c) Schedule O

(d) Schedule M



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SCHEDULE O – DISINFECTANT FLUIDS



Schedule O lays down the standards for **disinfectant fluids**.

KEY POINTS



IDENTITY

Specifies requirements and tests to confirm the correct disinfectant is present.



QUALITY

Confirms the product meets purity and quality requirements.



STRENGTH

Specifies tests to determine the strength or potency.



EFFECTIVENESS

Requires tests to demonstrate ability to kill or inhibit microbes.



SAFETY & RELIABILITY

Ensures consistent, safe and reliable disinfectant fluids for intended use.



RELEVANT FOR

Disinfectant fluids intended for destruction or inhibition of **harmful microorganisms**.



Hospitals



Laboratories



Surfaces



Instruments



Public Areas

WHAT IT ENSURES



IDENTITY

Correct disinfectant identified.



QUALITY

Meets purity and quality requirements.



STRENGTH

Has the required potency.



EFFECTIVENESS

Proven ability to kill or inhibit microbes.



REMEMBER

Disinfectant standards =
Schedule O.



SCHEDULE O ENSURES EVERY DROP **DISINFECTS** CONFIDENTLY.



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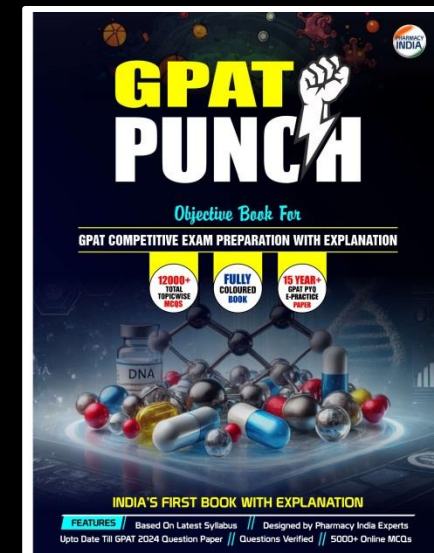
15.

Given below are two statements: [GPAT-2022]

Statement I: Drugs Controller General of India is the Chairman of DTAB.

Statement II: In DTAB, there are eight ex-officio members, five nominated and five elected members.

- (a) Both statements are correct
- (b) Both statements are incorrect
- (c) Statement I is correct but Statement II is incorrect
- (d) Statement I is incorrect but Statement II is correct



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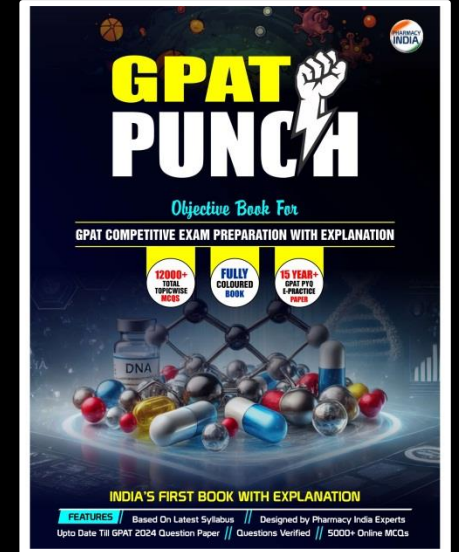
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- (a) Both statements are correct
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- (c) Statement I is correct but Statement II is incorrect
- (d) Statement I is incorrect but Statement II is correct**



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DTAB – CHAIRMAN & COMPOSITION



DTAB is the **DRUGS TECHNICAL ADVISORY BOARD**



CHAIRMAN

The Director General of Health Services (DGHS)

NOT DCGI



EX-OFFICIO MEMBER

DCGI / Drugs Controller India is an **ex-officio** member



WHAT IS DTAB?

A statutory expert body constituted under the **Drugs and Cosmetics Act, 1940** to advise the Central Government on technical matters.

COMPOSITION OF DTAB



8

EX-OFFICIO
MEMBERS



5

NOMINATED
MEMBERS



5

ELECTED
MEMBERS



DTAB provides expert and independent advice to support **safe, effective and quality** medicines for public health protection.

ROLE OF DTAB – ADVISORY ON TECHNICAL MATTERS

1



POLICY & STANDARDS

Advises on technical policies, guidelines and standards for drugs.

2



SAFETY, EFFICACY & QUALITY

Advises on safety, efficacy, quality and rational use of drugs.

3



NEW DRUGS & CLINICAL STUDIES

Advises on new drugs, clinical trials and other technical evaluations.

4



ANY OTHER MATTER

Advises on any other technical matter referred to under the Drugs and Cosmetics Act, 1940.



LEGAL BASIS: Constituted under Section 5 of the Drugs and Cosmetics Act, 1940.

PURPOSE: To ensure scientific, technical and regulatory decisions for safeguarding public health.





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16.

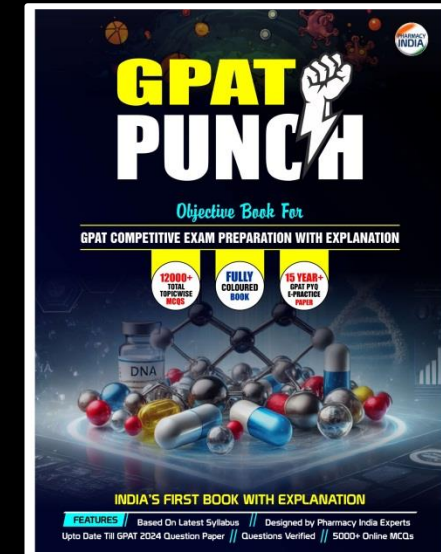
Powers of Drug Inspectors appointed under the Drugs and Cosmetics Act, 1940 are mentioned under which section? [GPAT-2021]

(a) Section 20

(b) Section 21

(c) Section 22

(d) Section 23



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16.

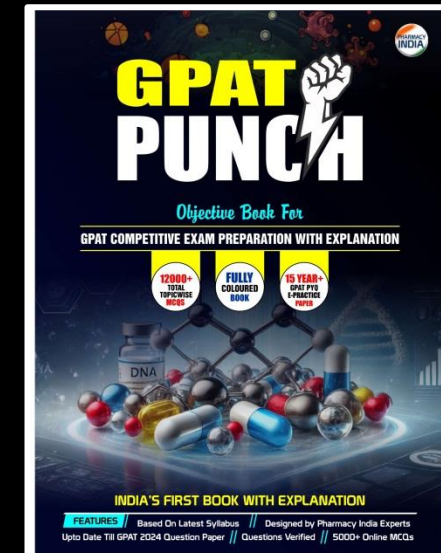
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(a) Section 20

(b) Section 21

(c) Section 22

(d) Section 23



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SECTION 22 – POWERS OF DRUG INSPECTORS

1

ENTER & INSPECT PREMISES

May enter and inspect any place where drugs are manufactured, stored, or sold.



3 TAKE DRUG SAMPLES

May take samples of drugs for analysis or test as required under the Act and Rules.



4 SEIZE STOCK, DOCUMENTS OR EVIDENCE

May seize drugs, raw materials, documents, records, labels, or any other article that may be evidence of an offence.



2

SEARCH FOR SUSPECTED CONTRAVENTIONS

May search premises, vehicles, containers, or persons if there is reason to suspect a contravention of the Act or Rules.



5

EXAMINE RECORDS / REGISTERS

May examine and take extracts or copies of records, registers, licenses, and other documents relevant to drug activities.



PURPOSE



These powers help enforce the **Drugs and Cosmetics Act** and Rules, ensure **quality, safety, and compliance**, and most importantly, **protect public health**.





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17.

Application for issue of a permit to import small quantities of drugs for personal use shall be made

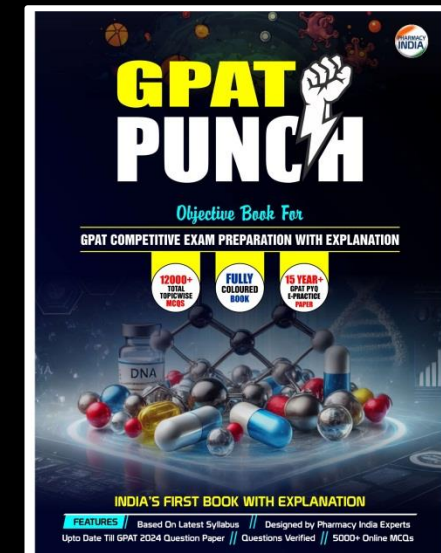
in: [GPAT-2021]

(a) Form 12

(b) Form 12A

(c) Form 12AA

(d) Form 13



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17.

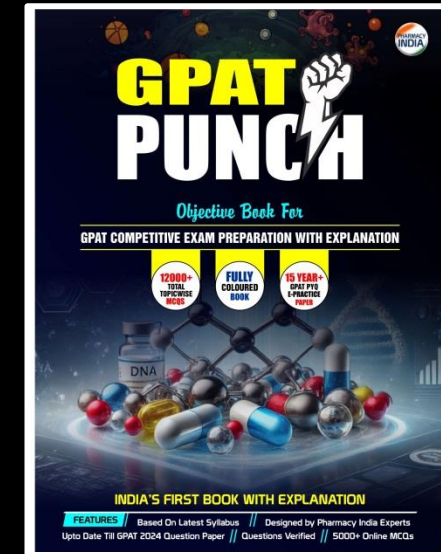
Application for issue of a permit to import small quantities of drugs for personal use shall be made in: [GPAT-2021]

(a) Form 12

(b) Form 12A

(c) Form 12AA

(d) Form 13



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FORM 12A & FORM 12B

IMPORT OF DRUGS FOR BONA FIDE PERSONAL USE

FORM 12A

APPLICATION



Application for issue
of a permit to

**IMPORT SMALL
QUANTITIES OF DRUGS**
for personal use.

FORM 12B

PERMIT



Permit issued by the
Competent Authority
allowing import of the
specified drugs for
**BONA FIDE
PERSONAL USE.**

FLOW

APPLY IN FORM 12A



PERMIT IN FORM 12B



KEY CONDITIONS



For **BONA FIDE
PERSONAL USE**
only.



Quantity should be
REASONABLE
and proportional
to personal use.



Usually supported
by a valid
PRESCRIPTION
from a registered
medical practitioner.



Covers medicines
for treatment of
personal ailment,
**not for sale or
distribution.**



Forms **12A** & **12B** ensure that only **genuine personal use** quantities of medicines are imported,
for legitimate treatment needs, with **proper documentation.**



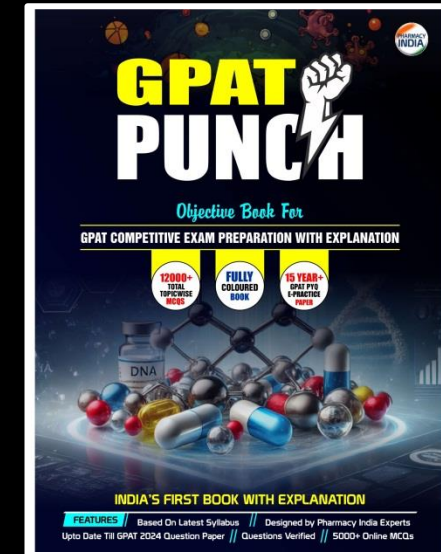
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18.

Which of the following drugs can be imported without a licence? [GPAT-2021]

- (a) Drugs specified in Schedule H
- (b) Drugs specified in Schedule X
- (c) Drugs in Schedule C1, required for manufacturing and not for medicinal use
- (d) Drugs in Schedule C, required for manufacturing and for medicinal use



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18.

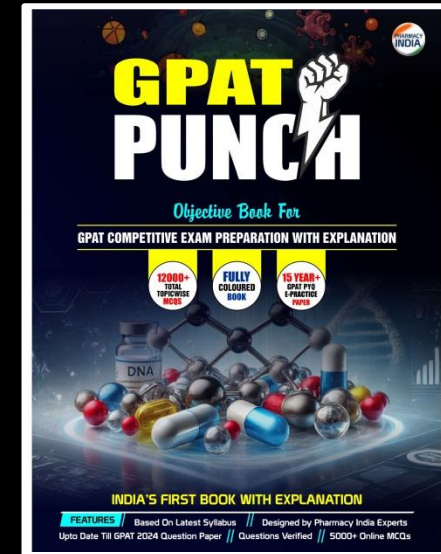
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(b) Drugs specified in Schedule X

(c) Drugs in Schedule C1, required for manufacturing and not for medicinal use

(d) Drugs in Schedule C, required for manufacturing and for medicinal use



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IMPORT WITHOUT LICENCE – EXEMPTIONS



Certain substances not intended for medicinal use may be exempt from import licence requirements under the conditions specified in **Schedule D**.

1

EXEMPTION BASIS



Substances listed in Schedule D that are **not intended for medicinal use** can be imported without an import licence, subject to specified conditions.

2

NON-MEDICINAL / MANUFACTURING USE



Imports must be solely for **non-medicinal, industrial or manufacturing purposes** as declared or certified by the importer.

3

DECLARATION / CERTIFICATION



A proper **declaration** on the import documents or a **certificate** from the competent authority is required as per Schedule D conditions.

4

LABELLING & IDENTIFICATION



Containers and packages must be clearly marked with “**Not for Medicinal Use**” / “**For Industrial or Commercial Use**” to indicate the purpose.

THE JOURNEY OF EXEMPT IMPORT



GOODS
ARRIVE



CUSTOMS
DECLARATION



SCHEDULE D
CONDITIONS
VERIFIED



EXEMPTION
GRANTED



Import allowed without licence when all conditions are satisfied.

5

ROUTINE MEDICINAL IMPORTS REQUIRE LICENCE



Imports intended for medicinal, therapeutic, prophylactic or diagnostic use, or for resale as such, are **NOT** covered under exemption and must comply with **normal import licence requirements**.



EXAM TIP



Exemption is linked with **non-medicinal or industrial use** under Schedule D, **not** with ordinary therapeutic drug import for use in humans or animals.



INDUSTRIAL
USE



LABORATORY
USE



AGRICULTURAL
USE



COMMERCIAL
USE



MANUFACTURING
USE

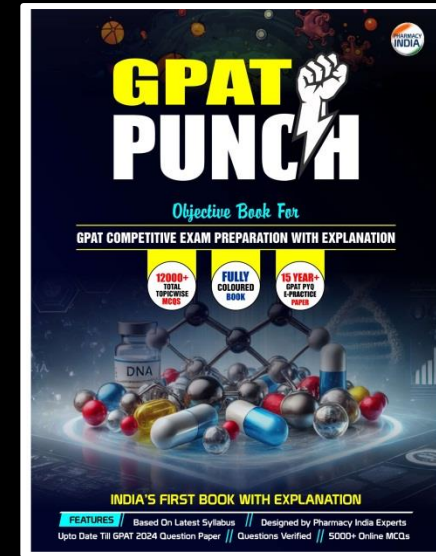


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19.

Which one of the following is exempted from importing requirement of a licence? [GPAT-2021]

- (a) Insulin
- (b) Etoposide
- (c) Lactose
- (d) Glutethimide



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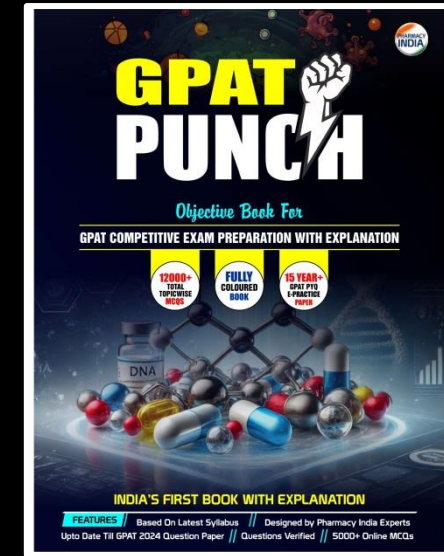


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Which one of the following is exempted from importing requirement of a licence? [GPAT-2021]

- (a) Insulin
- (b) Etoposide
- (c) Lactose
- (d) Glutethimide



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LACTOSE – IMPORT LICENCE EXEMPTION

Regulatory status of Lactose under import provisions



FOOD ARTICLE

Used as an ingredient in foods and beverages.



DRUG-RELATED SUBSTANCE

Used in formulation of medicines as an excipient.



FOOD / NUTRITIVE PREPARATIONS

Similar items in this class are food or nutritive preparations.

COMMON USES OF LACTOSE



Beverages



Bakery



Infant Formula



Tablet
Excipients



Nutritional
Supplements

1



DUAL STATUS

Lactose is treated as both a food article and a drug-related substance.

2



IMPORT LICENCE EXEMPTION

It is covered under exemption from import licence requirements when **not intended for parenteral use**.

3



NOT FOR PARENTERAL USE

The exemption specifically applies when lactose is not intended for parenteral (injection) use.

4



SAME CLASS ITEMS

Other substances in this class are food or nutritive preparations.



REMEMBER

Lactose exemption applies when **not for parenteral use**.



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20.

Match the following: [GPAT-2021]

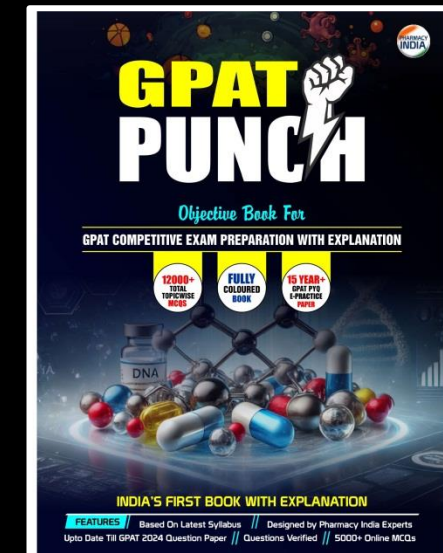
1. Schedule M	P. Life period and storage of drugs
2. Schedule FF	Q. GMP requirements of premises, plant and equipment
3. Schedule G	R. Drugs used under medical supervision
4. Schedule P	S. Standards for ophthalmic preparations

(a) 1-P, 2-Q, 3-R, 4-S

(b) 1-Q, 2-S, 3-R, 4-P

(c) 1-S, 2-Q, 3-R, 4-P

(d) 1-R, 2-P, 3-Q, 4-S



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20.

Match the following: [GPAT-2021]

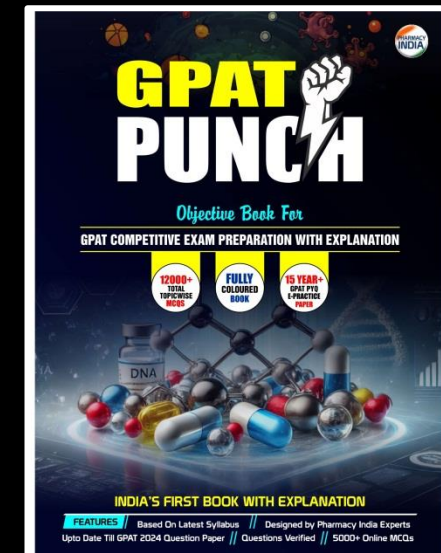
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2. Schedule FF	Q. GMP requirements of premises, plant and equipment
3. Schedule G	R. Drugs used under medical supervision
4. Schedule P	S. Standards for ophthalmic preparations

(a) 1-P, 2-Q, 3-R, 4-S

(b) 1-Q, 2-S, 3-R, 4-P

(c) 1-S, 2-Q, 3-R, 4-P

(d) 1-R, 2-P, 3-Q, 4-S



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SCHEDULES M, FF, G & P

M

SCHEDULE M

GMP REQUIREMENTS FOR PREMISES, PLANT AND EQUIPMENT



- ✓ Proper design, construction and maintenance of premises
- ⚙️ Suitable plant and equipment of appropriate design
- ✨ Cleanliness, hygiene and sanitation
- 📋 Validation, calibration and documentation
- 👤 Trained personnel and standard operating procedures

FF

SCHEDULE FF

STANDARDS FOR OPHTHALMIC PREPARATIONS



- 💧 Sterile, isotonic and non-irritant
- 🧪 Freedom from visible particles and contamination
- 🛡️ Appropriate containers and closures
- 📋 Quality control and labelling requirements
- 🌡️ Storage and stability as per specifications

G

SCHEDULE G

DRUGS TO BE USED UNDER MEDICAL SUPERVISION / CAUTION



- 👤 Drugs likely to cause misuse, abuse or dependency
- ⚠️ To be sold by retail on prescription of a Registered Medical Practitioner only
- 🚫 **CAUTION** Must carry "Caution" label on the container
- 📖 Records of sale to be maintained by the pharmacist

P

SCHEDULE P

LIFE PERIOD AND STORAGE OF DRUGS



- 🕒 Specifies the period for which a drug remains effective and safe
- 📦 Storage conditions to be stated on the label
- 🌡️ Protect from light, heat, moisture as required
- 🛡️ Ensures quality and safety throughout shelf life
- 📅 Expiry date to be declared on the label



MEMORY TIP



M = MANUFACTURING
(GMP & FACILITIES)



G = GUIDANCE /
MEDICAL SUPERVISION



P = PERIOD
(LIFE & STORAGE)



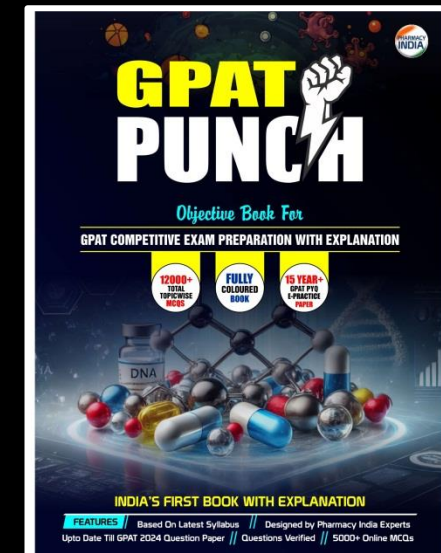
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21.

As per the definition of Drugs and Cosmetics Act,
Gudakhu rubbed against human teeth is
considered as: [GPAT-2020]

- (a) Food
- (b) Drug
- (c) Sweetening gum
- (d) Cosmetic



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GUDAKHU AS A COSMETIC



Under the Drugs and Cosmetics Act, 1940



EXAM PEARL

Topical application to teeth for cleansing or beautifying makes Gudakhu fall under the **COSMETIC** classification under the Drugs and Cosmetics Act, 1940.



RUBBED ON HUMAN TEETH

Gudakhu is applied and rubbed on the teeth and gums for cleansing and oral care.



TREATED AS A COSMETIC

Under the Drugs and Cosmetics Act, Gudakhu is treated as a cosmetic, not as a food.



DEFINITION OF COSMETIC

Cosmetic means any article applied to the human body for cleansing, beautifying, promoting attractiveness, or altering appearance.



NOT TREATED AS FOOD

Though some ingredients may be edible, Gudakhu is not taken as food; it is used externally on teeth.



EXTERNAL APPLICATION MATTERS

The legal classification depends on the nature of use—topical application to teeth, not ingestion.



LEGAL CONSEQUENCE

Manufacture, sale, and labelling of Gudakhu must comply with the provisions applicable to cosmetics.



REMEMBER: Use determines classification — External (topical) use on the body/teeth → Cosmetic.



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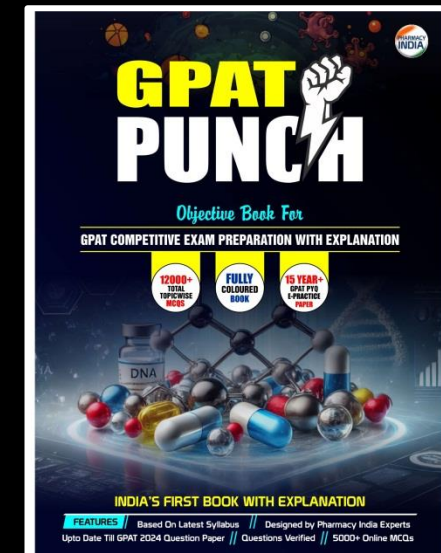


22.

Standards to be complied with under D&C Act, 1940 for drugs imported, manufactured, stocked and exhibited for sale or distribution are covered under:

[GPAT-2020]

- (a) Schedule M
- (b) Second Schedule
- (c) First Schedule
- (d) Schedule L



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22.

Standards to be complied with under D&C Act, 1940 for drugs imported, manufactured, stocked and exhibited for sale or distribution are covered under:

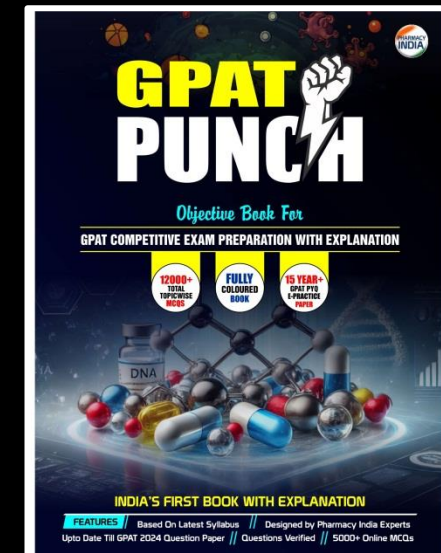
[GPAT-2020]

(a) Schedule M

(b) Second Schedule

(c) First Schedule

(d) Schedule L



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SECOND SCHEDULE - DRUG STANDARDS

Under the Drugs and Cosmetics Act, 1940



1. LAYS DOWN STANDARDS

It lays down the standards to be complied with for drugs.



2. WIDE APPLICATION

Applies to drugs imported, manufactured, stocked, exhibited for sale, or distributed.



3. DEFINES QUALITY REQUIREMENTS

Helps define standard quality requirements such as identity, purity, strength, quality, tests and limits.



4. ENSURES LEGAL QUALITY COMPLIANCE

Ensures that drugs meet minimum legal quality requirements for public safety and therapeutic efficacy.



5. OFFICIAL REFERENCE UNDER THE ACT

Serves as an official and authoritative reference for manufacturers, regulators, inspectors and courts.



REMEMBER

The standards of drugs under the Drugs and Cosmetics Act are covered in the **Second Schedule**.



Protects public health



Promotes uniform quality



Ensures scientific evaluation



Builds trust in drug quality



Supports regulation and enforcement



Second Schedule = Standard Quality Benchmarks for Drugs under the Drugs and Cosmetics Act, 1940

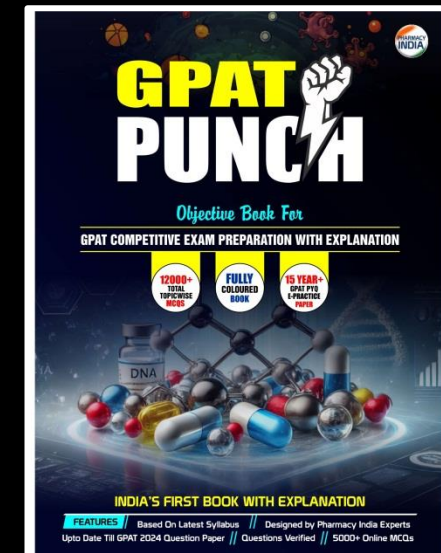


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23.

As per the Drugs and Cosmetics Act, 1940, if a drug is not labelled in the prescribed manner, it is: **[GPAT-2020]**



- (a) Spurious drug
- (b) Substandard drug
- (c) Adulterated drug
- (d) Misbranded drug



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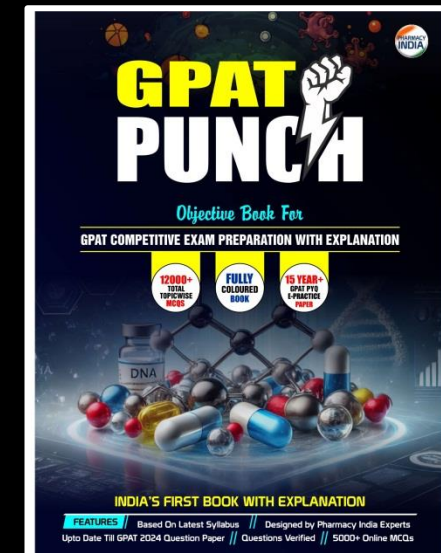


23.

As per the Drugs and Cosmetics Act, 1940, if a drug is not labelled in the prescribed manner, it is:

[GPAT-2020]

- (a) Spurious drug
- (b) Substandard drug
- (c) Adulterated drug
- (d) Misbranded drug



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MISBRANDED DRUG

A LEGAL & LABELING NON-COMPLIANCE



1 NOT LABELLED AS PRESCRIBED

A drug not labelled in the prescribed manner is misbranded.



2 VIOLATES LEGAL REQUIREMENTS

Improper or incomplete labelling violates statutory labeling requirements.



3 MISLEADING OR DEFICIENT INFO

Any misleading, false, or deficient label information can misbrand a product.



4 PROTECTS SAFE IDENTIFICATION & USE

Label compliance ensures correct identification, proper use, and patient safety.



5 LEGAL QUALITY & LABELING ISSUE

Misbranding is not about efficacy or purity—it is a legal and labeling issue.



6 RISK OF PENALTIES

Misbranded drugs are subject to regulatory action, seizure, recall, and penalties.



EXAM PEARL

Failure to follow prescribed labeling rules makes a drug misbranded.



LABEL RIGHT. PROTECT PATIENTS. STAY COMPLIANT.



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24.

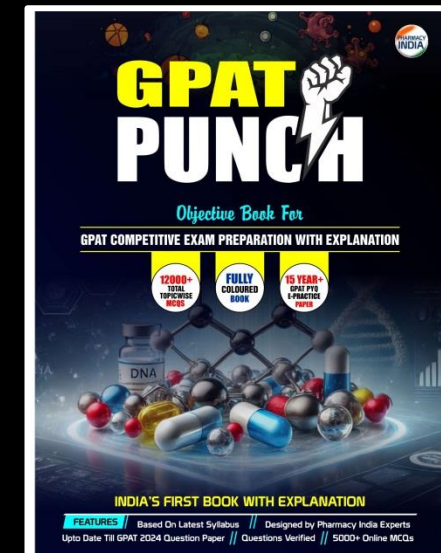
GMP regulations pertain to minimum requirements to be met by industry when: [GPAT-2019]

(a) Manufacturing, packaging and holding of human drugs and veterinary drugs

(b) Manufacturing of human drugs and veterinary drugs

(c) Manufacturing and packaging of human drugs and veterinary drugs

(d) Manufacturing and holding of human drugs and veterinary drugs



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24.

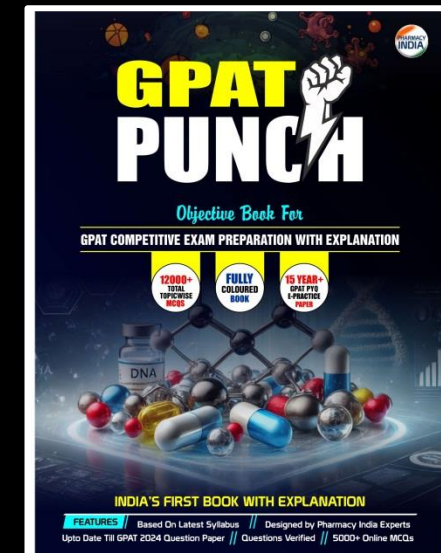
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(d) Manufacturing and holding of human drugs and veterinary drugs



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GMP - MINIMUM INDUSTRY REQUIREMENTS

GOOD MANUFACTURING PRACTICES



1 SETS MINIMUM QUALITY STANDARDS

GMP sets the minimum quality requirements for the pharmaceutical industry.



2 COVERS KEY ACTIVITIES

It covers the manufacturing, packaging, and holding of human and veterinary drugs.



3 ENSURES QUALITY AND SAFETY

Aims to ensure identity, quality, purity, and safety of the drug products.



4 INCLUDES ESSENTIAL PRACTICES

Includes sanitation, documentation, process control, personnel hygiene, equipment maintenance, and storage practices.



5 PREVENTS RISKS

Helps prevent contamination, mix-ups, errors, and ensures consistent product quality.



REMEMBER

GMP covers

MANUFACTURING + PACKAGING + HOLDING



QUALITY IS BUILT IN, NOT TESTED IN



TRAINED PEOPLE FOLLOW THE SYSTEM



DOCUMENT WHAT YOU DO, DO WHAT YOU DOCUMENT



MONITOR CONTROL IMPROVE



CONSISTENT QUALITY, EVERY TIME

★ GMP COMPLIANCE = QUALITY PRODUCTS + PATIENT SAFETY + REGULATORY CONFIDENCE ★



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25.

Which of the following agencies is not classified as an executive agency for administration of the Act under Drugs and Cosmetics Act, 1940? [GPAT-2018]

- (a) Licensing Authority
- (b) Drug Inspectors
- (c) Drugs Consultative Committee
- (d) Customs Collectors



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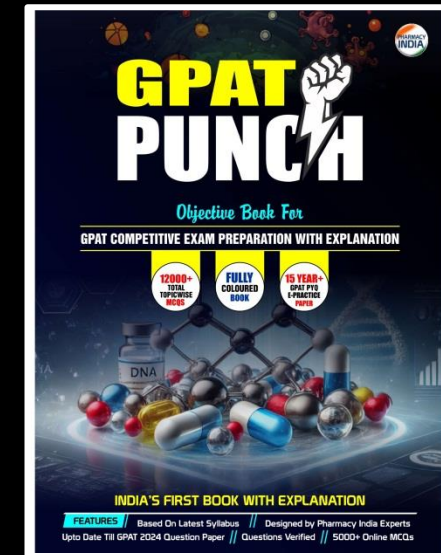


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- (b) Drug Inspectors
- (c) Drugs Consultative Committee
- (d) Customs Collectors



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DRUGS CONSULTATIVE COMMITTEE (DCC)

ADVISORY BODY UNDER THE DRUGS & COSMETICS ACT, 1940

01



ADVISORY BODY UNDER THE ACT

Constituted under the Drugs & Cosmetics Act, 1940.

02



ADVISES CENTRAL & STATE GOVERNMENTS

Provides expert advice on matters related to the Act.

03



PURPOSE: UNIFORMITY IN ADMINISTRATION

Aims to secure uniformity in the administration of the Act across India.

04



NOT AN EXECUTIVE AGENCY

It does not implement or enforce the provisions of the Act.

05



EXECUTIVE AGENCIES HANDLE ENFORCEMENT

Authorities like licensing, inspection, regulation, and enforcement are executive functions.

ADVISORY ROLE

DRUGS CONSULTATIVE COMMITTEE (DCC)

Experts from medicine, pharmacy, pharmacology, law & public health



ADVISES



CENTRAL GOVERNMENT



STATE GOVERNMENTS

On all major matters relating to the implementation of the Drugs & Cosmetics Act, 1940.

EXECUTIVE AGENCIES

Implement and enforce the Act



LICENSING AUTHORITIES

Grant licenses for manufacture, sale, or distribution of drugs.



INSPECTING AUTHORITIES

Inspect premises, examine records, and ensure compliance.



REGULATORY AUTHORITIES

Ensure standards of quality, safety, and efficacy.



ENFORCEMENT AUTHORITIES

Take legal action for violations and prosecute offenders.



OTHER EXECUTIVE BODIES

Drug Controllers, State FDAs, CDSCO, and related bodies.



KEY DISTINCTION

The DCC is **CONSULTATIVE**, not **EXECUTIVE**. It advises; executive agencies act.

ARJUNA SERIES

GPAT 2027 - 28

ADMISSION OPEN

FEATURES



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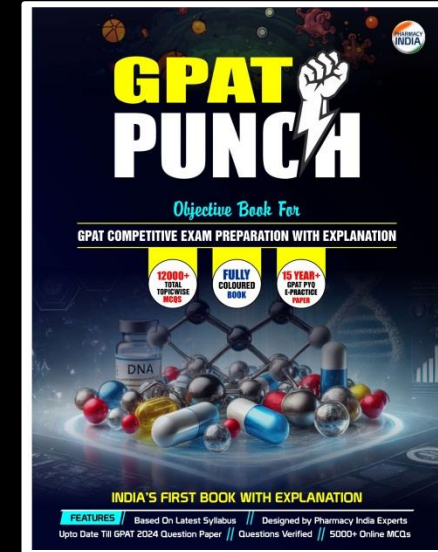
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26.

If a drug substance has been substituted wholly or in part by another drug or substance, it is called:

[GPAT-2017]

- (a) Spurious drug
- (b) Adulterated drug
- (c) Misbranded drug
- (d) Mixed drug



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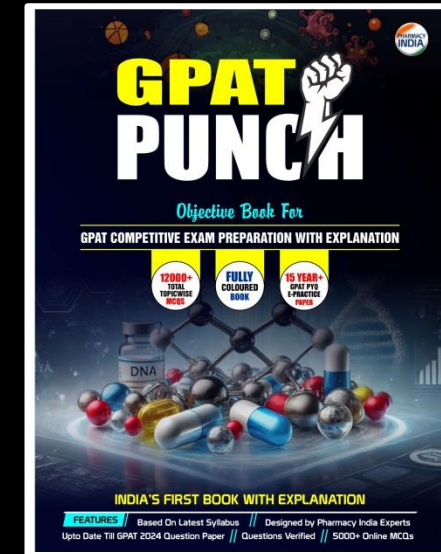
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[GPAT-2017]

- (a) Spurious drug
- (b) Adulterated drug
- (c) Misbranded drug
- (d) Mixed drug



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SPURIOUS DRUG



KEY POINTS

1



If a drug is **substituted** wholly or partly by another drug or substance, it is deemed **spurious**.

2



Spurious drugs **imitate** or **substitute** genuine products.

3



They may **mislead** consumers about the true identity.

4



Substitution affects **authenticity** and **safety**.

5



The Act treats such identity fraud **seriously**.

SUBSTITUTION THAT BETRAYS TRUST, ENDANGERS HEALTH.

ORIGINAL DRUG

Genuine • Authentic • Safe

SUBSTITUTED BY

Different • Unknown • Risky



EXAM PEARL

Substitution of one drug by another points to **spurious drug**.



CONSEQUENCES



Compromises patient **safety** and health.



Leads to **therapeutic failure**.



Destroys **trust** in medicines and healthcare.



Cheats consumers and is **unethical**.



Punishable under the **Drugs & Cosmetics Act**.



Remember: Identity matters. Substitution is not just a change—it is a **fraud**.



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27.

Schedule N is related with: [GPAT-2015]

- (a) Furniture and apparatus in pharmacy
- (b) Water bath in pharmacy
- (c) Indian Pharmacopoeia in pharmacy
- (d) Good manufacturing practice



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27.

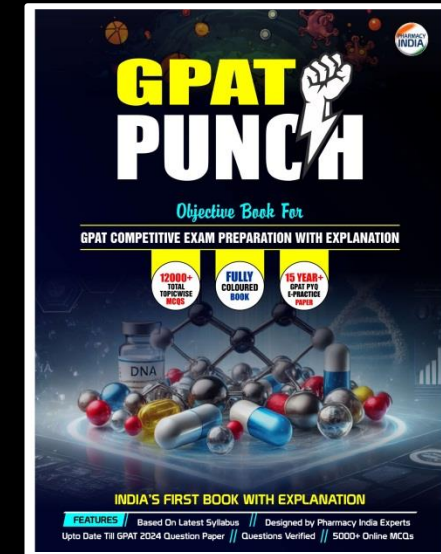
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(d) Good manufacturing practice



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SCHEDULE N

1



SPECIFIES FURNITURE AND APPARATUS

Schedule N specifies the minimum furniture and apparatus required in a pharmacy.

2



ENSURES PROPER DISPENSING SETUP

It ensures an efficient and well-organized dispensing area for safe service.

3



SUPPORTS SAFE STORAGE AND COMPOUNDING

It supports safe storage of medicines and proper compounding practices.

4



COVERS ESSENTIAL EQUIPMENT AND FACILITY REQUIREMENTS

It covers essential equipment, apparatus, and facility requirements.

5



IMPORTANT FOR MINIMUM PHARMACY STANDARDS

It is important for maintaining the minimum standards of a pharmacy.

FURNITURE AND APPARATUS IN PHARMACY



REMEMBER

Schedule N = Furniture and Apparatus in Pharmacy

ESSENTIAL FURNITURE & APPARATUS



SHELVES & CUPBOARDS
For storage of medicines, containers and records.



DISPENSING COUNTER
For receiving prescriptions and dispensing medicines.



BALANCES
For accurate weighing of medicines.



REFRIGERATOR
For storage of temperature-sensitive medicines (2–8°C).



SINK WITH RUNNING WATER
For hand washing and cleaning purposes.



ESSENTIAL APPARATUS
Mortar & pestle, measuring cylinders, beakers, etc.



SAFETY EQUIPMENT
Fire extinguisher and safety provisions.



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28.

A licence to import drugs specified in Schedule X to the Drugs and Cosmetics Rules, 1945 shall be issued in: **[GPAT-2015]**

- (a) Form 8
- (b) Form 8A
- (c) Form 10
- (d) Form 10A



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28.

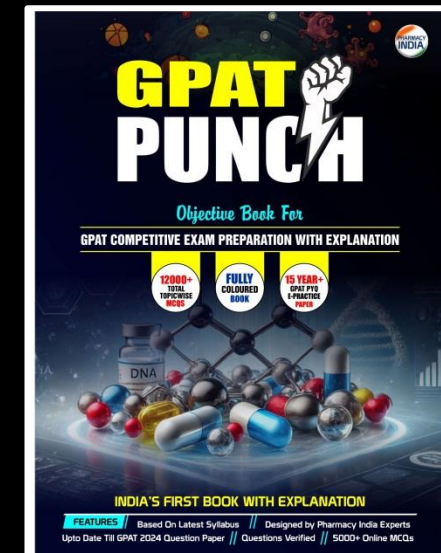
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(a) Form 8

(b) Form 8A

(c) Form 10

(d) Form 10A



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FORM 10A - IMPORT OF SCHEDULE X DRUGS



- 1** Schedule X drugs are **under strict control**
High abuse potential.
Special safeguards apply.



- 2** Import licence for Schedule X drugs is issued in **Form 10A**
Mandatory approval before import.



- 3** Form 10 is used for **non-Schedule X** drugs
Different form, different control level.



- 4** Stricter regulation reflects **abuse potential** and **record-control** needs
Protects public health and safety.



- 5** Importers must comply with **licensing requirements** under the Rules
Maintain accurate records and follow conditions.



OVERSEAS
SUPPLIER

GOVERNMENT OF INDIA
DRUGS & COSMETICS ACT, 1940
AND RULES THEREUNDER

**IMPORT LICENCE
FORM 10A**
(For Import of Schedule X Drugs)

Licence No. : _____
Date : _____
Importer : _____
Address : _____
Drug(s) : _____
Quantity : _____
Country of Origin : _____
Conditions : _____

 Signature
Licensing Authority



IMPORT INTO INDIA



EXAM PEARL

Schedule X import licence
=
Form 10A



SCHEDULE X DRUGS



CONTROL



LICENCE



COMPLIANCE



RESPONSIBILITY



SAFETY



PUBLIC HEALTH



ACCOUNTABILITY



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29.

Which one of the following colours is NOT permitted to be used in drugs by the Drugs and Cosmetics Act, 1940? [GPAT-2012]

- (a) Chlorophyll
- (b) Riboflavin
- (c) Tartrazine
- (d) Amaranth



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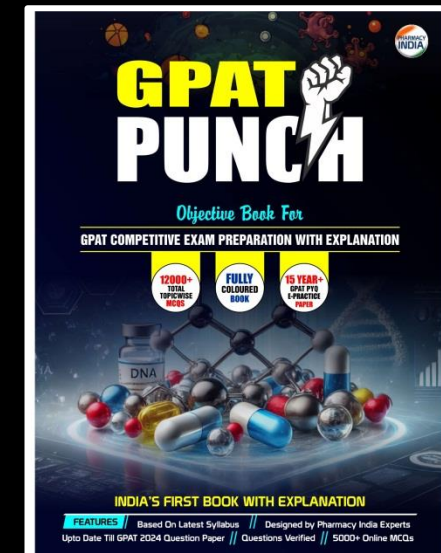
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- (a) Chlorophyll
- (b) Riboflavin
- (c) Tartrazine
- (d) Amaranth



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AMARANTH - NOT PERMITTED IN DRUGS

Only Approved Colours. Safe Drugs. Compliant Quality.

1



ONLY APPROVED COLOURS

Only colours approved by the regulatory authority may be used in drugs.

2



PERMITTED EXAMPLES

Chlorophyll, Riboflavin, and Tartrazine are permitted colours used in drugs.

3



AMARANTH IS NOT PERMITTED

Amaranth (FD&C Red No. 2) is not permitted for use in any drug product.

4



COLOUR CONTROL IS IMPORTANT

It ensures patient safety, product quality, and regulatory compliance.

5



UNAUTHORIZED COLOURS MAKE PRODUCTS NON-COMPLIANT

Use of non-permitted colours can lead to rejection and legal action.



Permitted Colours
Approved for use in drugs



Non-Permitted Colour
Not allowed in drugs



REMEMBER

Amaranth is the **NON-PERMITTED** colour in drugs.



Protects Patients



Ensures Quality



Meets Regulations



Safe & Effective Drugs



Right Colour. Right Product.



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30.

Secobarbital is a _____ drug. [GPAT-2014]

- (a) Schedule G
- (b) Schedule H
- (c) Schedule Q
- (d) Schedule X



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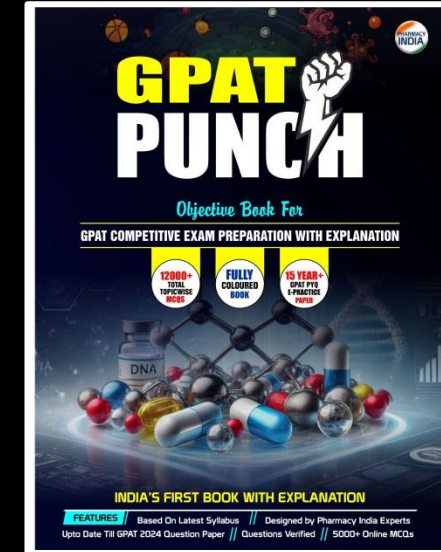
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Secobarbital is a _____ drug. [GPAT-2014]

- (a) Schedule G
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- (c) Schedule Q
- (d) Schedule X



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SECOBARBITAL - SCHEDULE X DRUG

STRICTER CONTROL. SAFER SOCIETY.

1



SECOBARBITAL FALLS UNDER SCHEDULE X

Secobarbital is classified as a Schedule X drug under the law.

2



SCHEDULE X COVERS CERTAIN DRUGS

Schedule X includes certain habit-forming / controlled drugs.

3



STRICTER PRESCRIPTION, STORAGE & RECORDS

These drugs require stricter prescription, storage, and record maintenance.

4



SALE IS CLOSELY REGULATED

Sale, distribution, and possession are closely regulated and limited to authorized persons.

5



CONTROLS PREVENT MISUSE & ABUSE

Strict control helps prevent misuse, abuse, and protects public health and safety.



QUICK FACTS



Legal Basis

Drugs & Cosmetics Act, 1940 & Rules, 1945



Purpose

To ensure safe medical use and prevent abuse and trafficking.



Key Requirements

Proper prescription, safe storage, and record maintenance.



Who Can Sell

Only licensed retailers with valid authorization.



Penalty

Violation can lead to severe legal action.



EXAM PEARL

Secobarbital belongs to **Schedule X**.

REMEMBER: SCHEDULE X = STRONG CONTROL FOR A SAFER TOMORROW



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31.

Which of the following schedules includes shelf life of drugs? [GPAT-2011, 2013]

- (a) Schedule F
- (b) Schedule M
- (c) Schedule G
- (d) Schedule P



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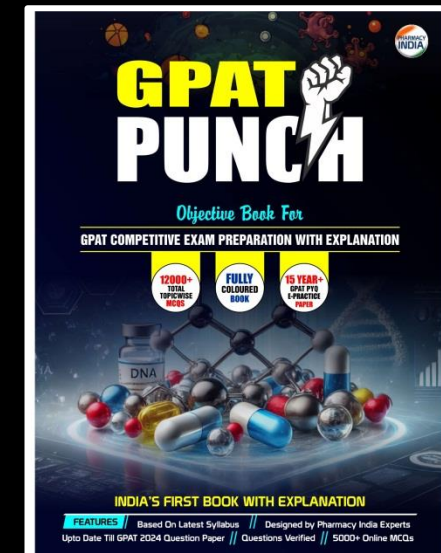
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Which of the following schedules includes shelf life of drugs? [GPAT-2011, 2013]

- (a) Schedule F
- (b) Schedule M
- (c) Schedule G
- (d) Schedule P



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SCHEDULE P – LIFE PERIOD OF DRUGS



Schedule P of the Drugs Rules, 1945 specifies the **LIFE PERIOD (SHELF LIFE)** of every drug.

1



GIVES THE LIFE PERIOD

Schedule P specifies the **shelf life** of each drug.

2



MENTIONS STORAGE CONDITIONS

It also includes the recommended **storage conditions** for each drug.



3



HELPS DECIDE EXPIRY & PROPER STORAGE

It helps determine **expiry date** and ensures drugs are stored under correct conditions.

4



SUPPORTS QUALITY & SAFETY

It supports the **quality, efficacy** and **safety** of drugs during marketing.

15-25°C



EXAM PEARL: | **SCHEDULE P = SHELF LIFE + STORAGE CONDITIONS.**



LEGAL REQUIREMENT

Mandatory under Drugs Rules, 1945.



GUIDES HEALTHCARE

Helps healthcare professionals & patients.



ENSURES CORRECT HANDLING

Ensures proper storage throughout distribution.



PROTECTS PUBLIC HEALTH

Ensures only safe, effective drugs are used.



PRESERVES POTENCY

Maintains stability and effectiveness till the expiry.



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32.

Manufacture and sale of which of the following drugs is prohibited in India? [GPAT-2012]

[P] Fixed dose combination of atropine and antidiarrhoeals

[Q] Penicillin eye ointment

[R] Nimesulide paediatric drops

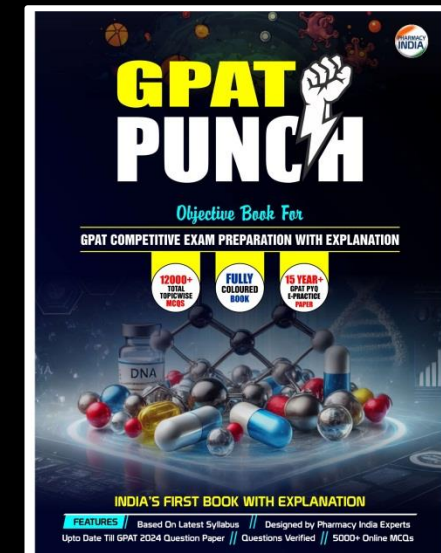
[S] Gatifloxacin tablets

(a) P, Q and R

(b) Q, S and R

(c) R, S and P

(d) P, Q, R and S



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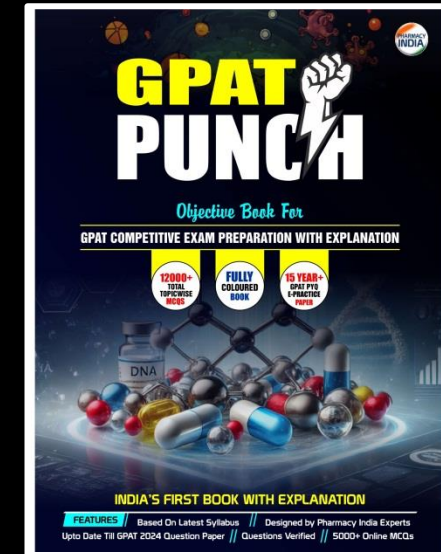
[S] Gatifloxacin tablets

(a) P, Q and R

(b) Q, S and R

(c) R, S and P

(d) P, Q, R and S



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PROHIBITED DRUGS IN INDIA



KEY POINTS

1



Manufacture and sale of banned drugs is **not permitted**.

2



Such drugs are restricted due to **safety, irrationality, or public health** concerns.

3



Regulatory bans **protect patients** from potential harm.

4



Manufacturers and sellers must **comply with** government notifications.



KEY POINT:

These listed products are treated as **prohibited for legal manufacture and sale.**

PROHIBITED DRUGS (EXAMPLES)



1. ATROPINE + ANTIDIARRHOEAL FIXED-DOSE COMBINATION

Banned due to irrational fixed-dose combination.



2. PENICILLIN EYE OINTMENT

Banned due to safety and hypersensitivity risk.



3. NIMESULIDE PAEDIATRIC DROPS

Banned due to risk of serious liver toxicity in children.



4. GATIFLOXACIN TABLETS

Banned due to safety concerns and risk of serious side effects.

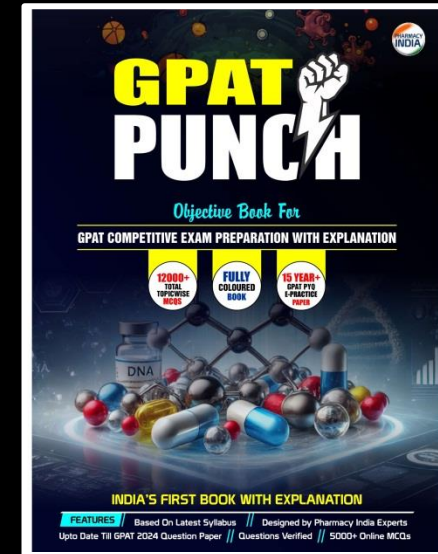


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33.

A sample of paracetamol tablets claims to contain 500 mg paracetamol but contains only 200 mg on analysis. As per D&C Act, this product is categorized as: [GPAT-2012]

- (a) Misbranded drug
- (b) Adulterated drug
- (c) Spurious drug
- (d) Unethical drug



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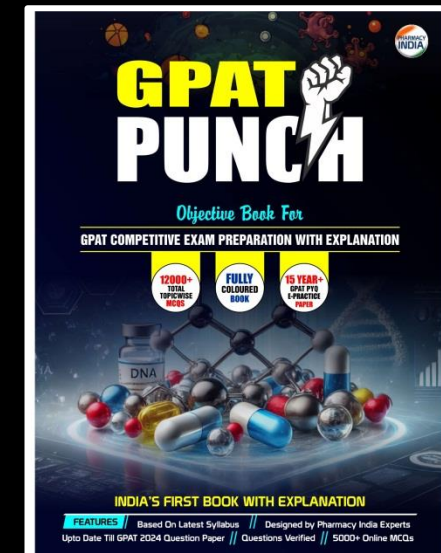
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- (c) Spurious drug
- (d) Unethical drug



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MISBRANDED DRUG



EXAMPLE: WRONG STRENGTH CLAIM (PARACETAMOL TABLETS)

LABEL CLAIM

(DECLARED STRENGTH)



TEST REPORT

(ASSAY RESULT)



ASSAY RESULT

Paracetamol Content
Found:

200 mg
per tablet

Acceptance Limit:
90.0% – 110.0% of 500 mg
Result: **BELOW LIMIT**



WARNING: DECLARED 500 mg, BUT CONTAINS ONLY 200 mg
→ **MISBRANDED DRUG**

KEY POINTS

①



A false or misleading label claim is a hallmark of **misbranding** in this exam context.

②



The declared strength **does not match** the actual content.

③



Such mismatch **misleads** users and regulators, compromising trust and safety.

④



Proper labeling is essential for **safe drug** use and **legal compliance**.



EXAM PEARL: Wrong label claim about strength = **misbranding concept**.





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34.

Which one of the following would be an offence under the Drugs and Cosmetics Act, 1940? [GPAT-2012]

- (a) Packing paediatric oral drops in 30 mL pack
- (b) Packing oxytocin injection in a single unit blister pack
- (c) Packing Schedule X drugs in 5 mL injection pack
- (d) Packing aspirin tablets 75 mg in 14 tablet strip pack



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- (b) Packing oxytocin injection in a single unit blister pack
- (c) Packing Schedule X drugs in 5 mL injection pack
- (d) Packing aspirin tablets 75 mg in 14 tablet strip pack



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PACKING OFFENCE UNDER D&C ACT



..... Oversized pack. Wrong message. Legal offence.



1

Paediatric oral drops are intended for **small-volume dosing**.

Children require precise, low-dose administration for safety and effectiveness.



2

Packing paediatric oral drops in an oversized 30 mL pack is treated **as an offence**.

It violates the provisions of the Drugs & Cosmetics Act and Rules.



3

Child formulations need suitable pack size for **safe dosing**.

Oversized packs can lead to dose errors, wastage, and increased risk to children.



4

Packaging rules help prevent misuse and ensure **regulatory compliance**.

They protect patients, especially children, and uphold public health.



Exam Pearl:

Inappropriate pack size can become a legal offence.



CHILD SAFETY



ACCURATE DOSING



REGULATORY COMPLIANCE



LEGAL OBLIGATION



PUBLIC HEALTH

.....



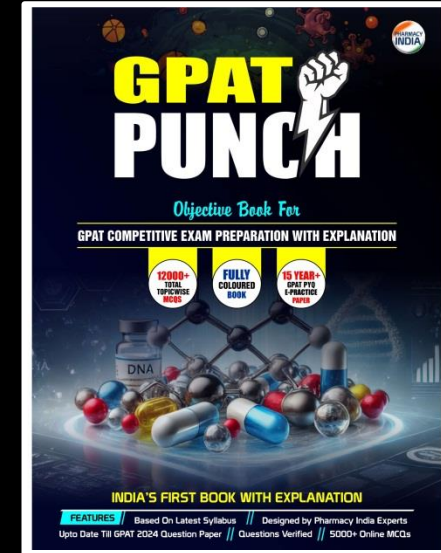
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35.

Good Manufacturing Practice is included under which schedule of Drugs and Cosmetics Act and Rules? [GATE-2009, GPAT-2010]

- (a) Schedule W
- (b) Schedule P
- (c) Schedule S
- (d) Schedule M



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35.

Good Manufacturing Practice is included under which schedule of Drugs and Cosmetics Act and Rules? [GATE-2009, GPAT-2010]

- (a) Schedule W
- (b) Schedule P
- (c) Schedule S
- (d) Schedule M**



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SCHEDULE M - GMP

GOOD MANUFACTURING PRACTICE UNDER SCHEDULE M



GMP CHECKLIST

- ✓ Qualified Premises
- ✓ Clean & Hygienic Environment
- ✓ Calibrated Equipment
- ✓ Validated Processes
- ✓ Proper Documentation
- ✓ Quality Assurance
- ✓ Continuous Improvement



COVERS KEY AREAS



PREMISES

Suitable location, design, and maintenance of facilities.



PLANT & EQUIPMENT

Appropriate design, qualification, calibration, and maintenance.



PERSONNEL

Qualified, trained, and following hygiene and clothing standards.



MANUFACTURING CONTROLS

Validated processes, documentation, and in-process controls.



QUALITY CONTROL

Testing of raw materials, in-process, and finished products.



EXAM PEARL:
SCHEDULE M = GMP.



QUALITY
At Every Step



HYGIENE
Always



ACCURACY
In Every Action



DOCUMENT
What You Do



VERIFY
What You Do



IMPROVE
Every Day

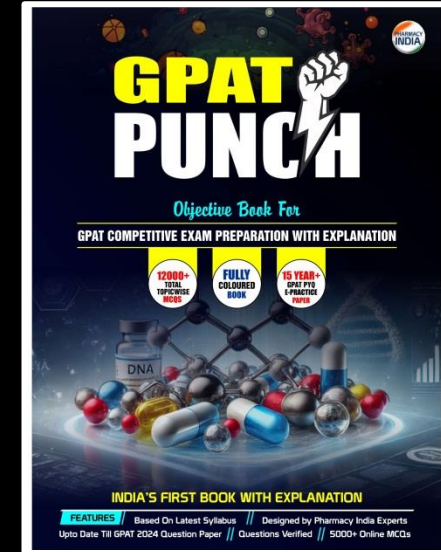


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36.

HEPA Grade A filter is used for: [GATE-2009]

- (a) Aseptic preparation and filling
- (b) Background room used for preliminary activities
- (c) Filtering liquid preparations
- (d) Handling components after washing



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36.

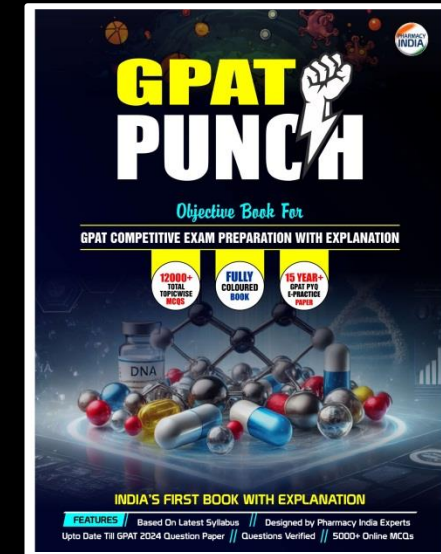
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HEPA GRADE A

THE HIGHEST LEVEL OF CLEANLINESS FOR CRITICAL OPERATIONS

1



HIGHEST CLEANLINESS ZONE

Grade A is the highest cleanliness zone.

2



USED FOR ASEPTIC PREPARATION AND STERILE FILLING

It is used for aseptic preparation and sterile filling.

3



HANDLES CRITICAL EXPOSED PRODUCTS AND COMPONENTS

Critical exposed products and components are handled here.

4



MINIMIZES CONTAMINATION

This area minimizes particulate and microbial contamination.



CRITICAL OPERATION:
Aseptic preparation & filling.



LAMINAR AIRFLOW



HEPA FILTERED AIR



STERILE ENVIRONMENT



LOW PARTICULATE
& MICROBIAL LOAD



PROTECTS
PRODUCT QUALITY



CONTROLLED
TEMPERATURE & HUMIDITY



GOWNING &
BEST PRACTICES



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37.

Two ex-officio members of DTAB under Drugs and Cosmetics Act are: **[GATE-2008]**

[P] Drugs Controller General of India

[Q] President, Medical Council of India

[R] Secretary, Pharmacy Council of India

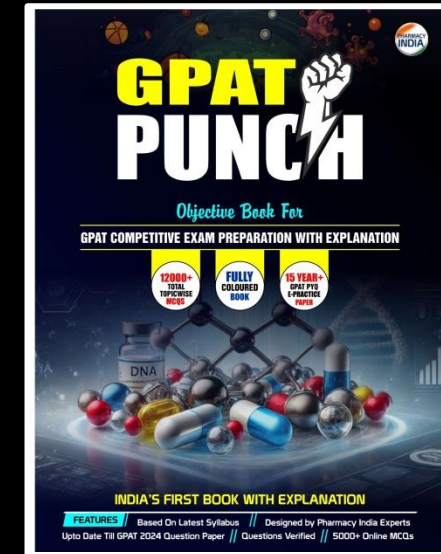
[S] Director, NIPER

(a) P and Q

(b) P and R

(c) R and S

(d) P and S



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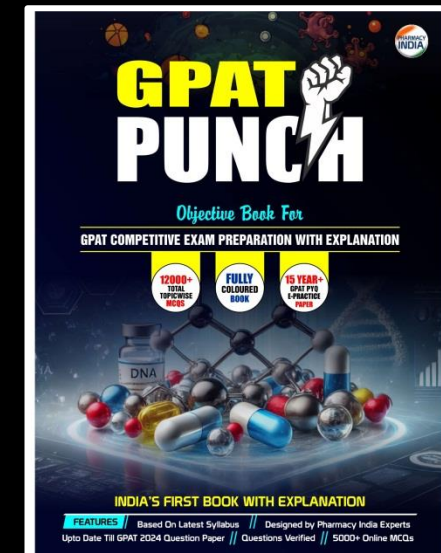
[S] Director, NIPER

(a) P and Q

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(c) R and S

(d) P and S



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DTAB – EX-OFFICIO MEMBERS

.... WHO ARE PART OF DTAB BY VIRTUE OF THEIR OFFICE

1



DTAB is the
**Drugs Technical
Advisory Board.**

2



Ex-officio members
become members
by **virtue of their office.**

3



The **Drugs Controller
General of India (DCGI)**
is one such member.

4



The President of the
Medical Council of India
is another classic
exam-listed ex-officio
member.



EX-OFFICIO MEMBERS



**Drugs Controller
General of India**



**President,
Medical Council of India**



EXAM PEARL:

Ex-officio = member because of official position.





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38.

The schedule dealing with requirements and guidelines for clinical trials, import and manufacture of new drugs is: **[GATE-2003, 2008]**

- (a) Schedule O
- (b) Schedule M
- (c) Schedule F
- (d) Schedule Y



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38.

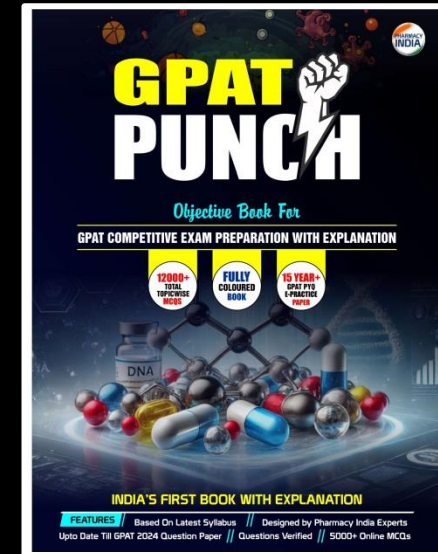
The schedule dealing with requirements and guidelines for clinical trials, import and manufacture of new drugs is: [GATE-2003, 2008]

(a) Schedule O

(b) Schedule M

(c) Schedule F

(d) Schedule Y



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SCHEDULE Y

THE REGULATORY FRAMEWORK FOR CLINICAL TRIALS AND NEW DRUGS

-  1 SCHEDULE Y PROVIDES REQUIREMENTS AND GUIDELINES FOR CLINICAL TRIALS.
-  2 IT APPLIES TO IMPORT AND MANUFACTURE OF NEW DRUGS.
-  3 IT GUIDES DATA SUBMISSION, SAFETY, AND REGULATORY APPROVAL.
-  4 IT SUPPORTS ETHICAL AND SCIENTIFIC EVALUATION OF NEW MEDICINES.
-  5 IT PROTECTS TRIAL PARTICIPANTS AND ENSURES PUBLIC HEALTH SAFETY.



PHASED CLINICAL TRIAL FLOW



 **EXAM PEARL:**
Schedule Y =
Clinical trials + new drugs.

WHY SCHEDULE Y MATTERS



Ensures quality and integrity of clinical trials



Protects rights, safety and well-being of participants



Ensures reliable data for decision making



Enables regulatory oversight and approval



Promotes safe, effective and ethical new medicines



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39.

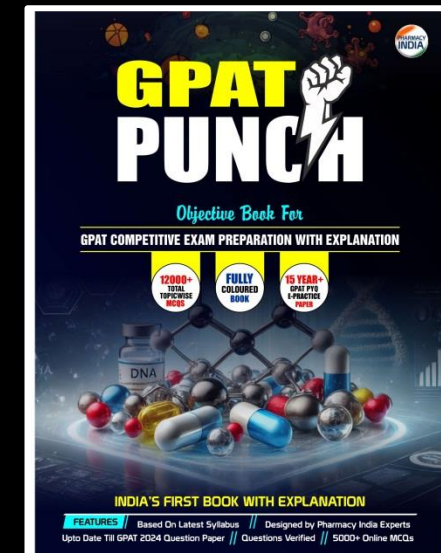
List of diseases and ailments which a drug may not claim to prevent or cure is given under: **[GATE-2007]**

(a) Schedule J

(b) Schedule K

(c) Schedule M

(d) Schedule P



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39.

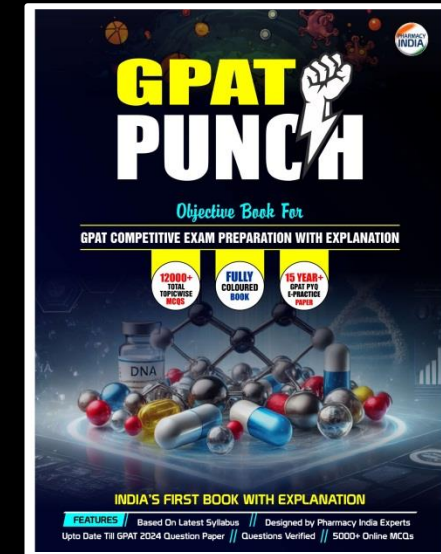
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(a) Schedule J

(b) Schedule K

(c) Schedule M

(d) Schedule P



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SCHEDULE J

NO CURE. NO PREVENTION CLAIMS.

1



Schedule J lists **diseases and ailments** for which a drug may not claim prevention or cure.

2



It prevents **false or misleading** therapeutic claims.

3



It **protects patients** from deceptive promotion.

4



It is important in **labeling and advertisement control**.

SCHEDULE J

LIST OF DISEASES AND AILMENTS
FOR WHICH NO CLAIM OF PREVENTION
OR CURE SHALL BE MADE



Asthma



Hypertension



Arthritis



Ulcer



Epilepsy



Psoriasis



GUARANTEED
RESULTS

100%
CURE

TREATS
ALL

NO SIDE
EFFECTS

PERMANENT
RELIEF



Exam Pearl: Schedule J = no cure/prevention claim list.



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40.

As per Schedule O, minimum Rideal-Walker coefficients for Grade 1 and Grade 3 black disinfectant fluids are: [\[GATE-2007\]](#)

[P] 18

[Q] 10

[R] 5

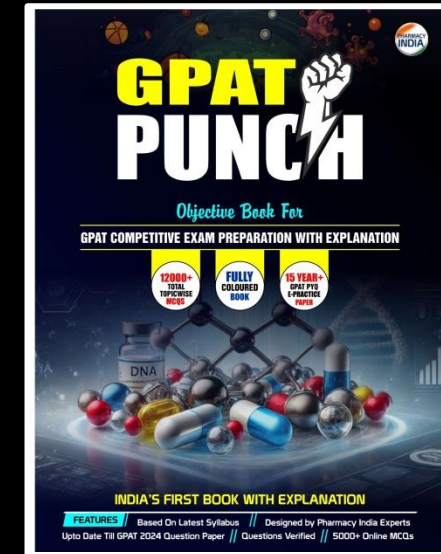
[S] 14

(a) P and R

(b) Q and S

(c) P and S

(d) R and S



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40.

As per Schedule O, minimum Rideal-Walker coefficients for Grade 1 and Grade 3 black disinfectant fluids are: [\[GATE-2007\]](#)

[P] 18

[Q] 10

[R] 5

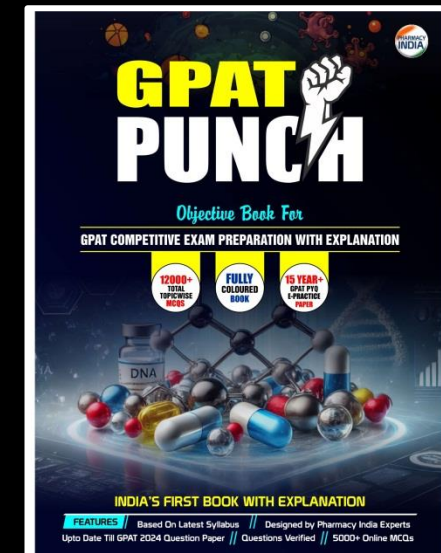
[S] 14

(a) P and R

(b) Q and S

(c) P and S

(d) R and S



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SCHEDULE 0 – DISINFECTANT STANDARDS

• Rideal-Walker Coefficient Values for Black Disinfectant Fluids •

RIDEAL-WALKER COEFFICIENT
COMPARES GERMICIDAL POWER
WITH PHENOL

STRONGER
THAN PHENOL

40



MORE
POTENT

30



EQUAL TO
PHENOL

20

10



LESS
POTENT

WEAKER
THAN PHENOL

HIGHER COEFFICIENT = STRONGER DISINFECTANT



GRADE 1

MINIMUM RIDEAL-WALKER
COEFFICIENT

18

BLACK DISINFECTANT FLUID

GRADE 3

MINIMUM RIDEAL-WALKER
COEFFICIENT

5

BLACK DISINFECTANT FLUID

♦ KEY POINTS ♦

1



Schedule 0 includes
standards for
disinfectant fluids.

2



Rideal-Walker coefficient
compares germicidal
power with **phenol**.

3



Minimum coefficient for
Grade 1 black
disinfectant fluid is **18**.

4



Minimum coefficient for
Grade 3 black
disinfectant fluid is **5**.



REMEMBER:

GRADE 1 = 18, GRADE 3 = 5.



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41.

Schedule C and Schedule N deal with: [GATE-2006]

[P] Standards for cosmetics

[Q] Biological and special products

[R] Life period of drugs

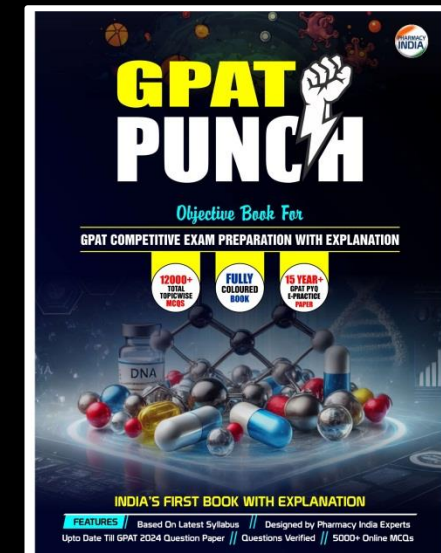
[S] Minimum equipment for efficient running of pharmacy

(a) P and Q

(b) Q and S

(c) R and S

(d) P and R



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Schedule C and Schedule N deal with: [GATE-2006]

[P] Standards for cosmetics

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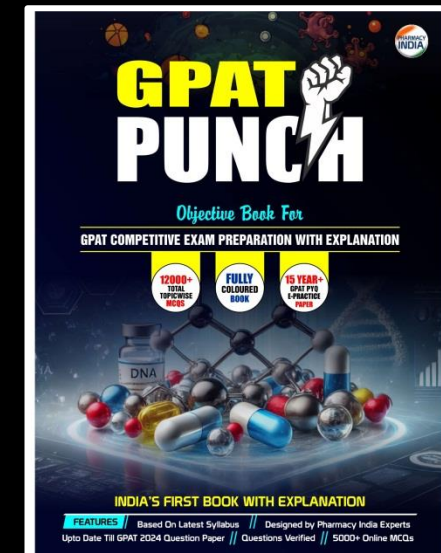
[S] Minimum equipment for efficient running of pharmacy

(a) P and Q

(b) Q and S

(c) R and S

(d) P and R



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SCHEDULE C & SCHEDULE N



IMPORTANT EXPLANATION



1. Schedule C covers **biological** and **special** products.



2. It includes items like **sera**, **vaccines**, **toxins** and similar biologicals.



3. Schedule N specifies the **minimum equipment** and **facilities** for a pharmacy.



4. It guides the **efficient running** of a medical store or pharmacy.



5. QUICK MEMORY:

C = biological category, **N** = pharmacy needs.



EXAM CLUE: **Schedule C** = biological/special products

Schedule N = pharmacy equipment & facilities



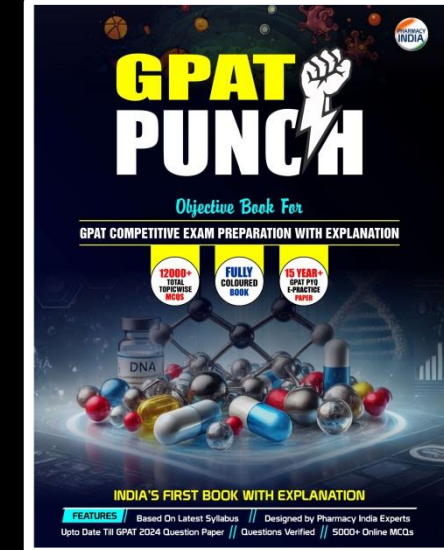


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42.

Metered dose inhaler documentation records shall show which information in addition to GMP? [GATE-2006]

- (a) Portable stirrer
- (b) Records of rejection during online check weighing
- (c) Water distillation unit deionizer
- (d) Electrically operated mixer



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42.

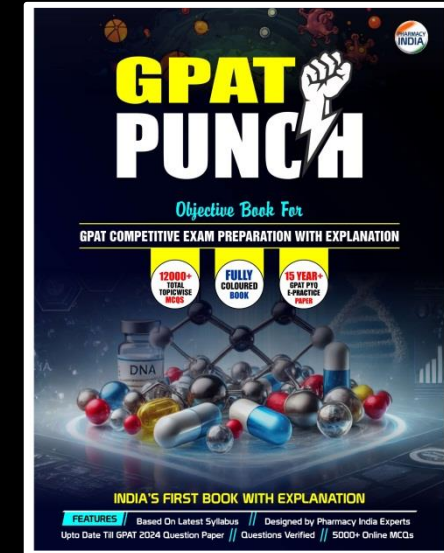
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(a) Portable stirrer

(b) Records of rejection during online check weighing

(c) Water distillation unit deionizer

(d) Electrically operated mixer



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METERED DOSE INHALER DOCUMENTATION



IMPORTANT EXPLANATION



1. MDI records require details **beyond** routine **GMP** entries.



2. A key record is **rejection** during online **check weighing**.



3. This helps monitor **fill-weight uniformity** and **process control**.



4. Proper **documentation** supports **quality assurance** and **batch release**.



5. QUICK MEMORY:

MDI + **check weighing** = **essential** documented control.



EXAM CLUE:

For metered dose inhalers, **rejection** records from online **check weighing** are **important documentation data**.





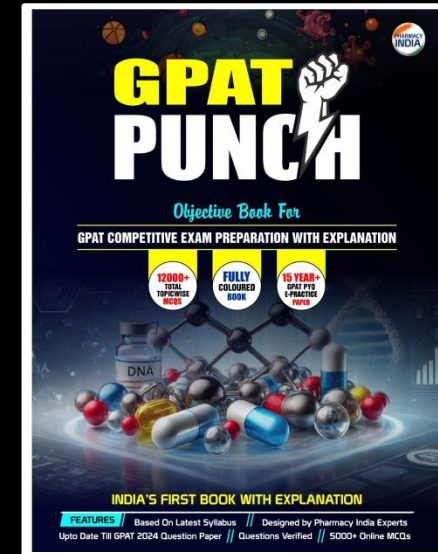
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43.

The Chairman of the Drugs Technical Advisory Board is:

[GATE-2005]

- (a) The Drugs Controller of India
- (b) The Director, Central Drugs Laboratory, Kolkata
- (c) The President, Pharmacy Council of India
- (d) The Director General of Health Services



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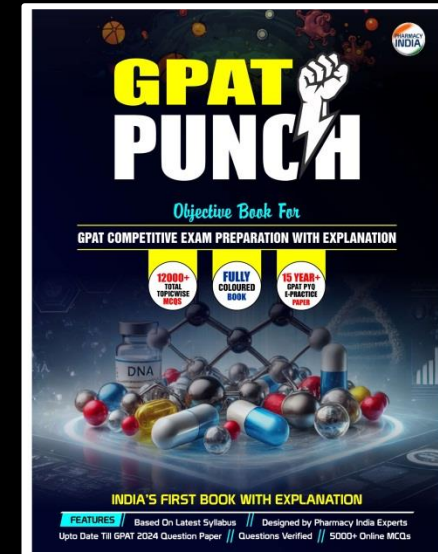


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- (c) The President, Pharmacy Council of India
- (d) The Director General of Health Services**



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CHAIRMAN OF DTAB



IMPORTANT EXPLANATION



1. DTAB stands for **Drugs Technical Advisory Board**.



2. Its Chairman is the **Director General of Health Services**.



LAW & REGULATION



DTAB
DRUGS TECHNICAL
ADVISORY BOARD



PUBLIC HEALTH
& SAFETY



3. DTAB advises the **Central and State Governments** on technical matters under the Act.



4. It is a key expert body in **drug regulation** and **policy**.



5. **QUICK MEMORY:**
DGHS chairs **DTAB**.



EXAM CLUE:

DTAB Chairman = Director General of Health Services.





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44.

Schedule H and Schedule S deal with: [GATE-2004]

[P] Prescription drugs sold by retail only on prescription of RMP

[Q] Standards for cosmetics

[R] Biological and special products

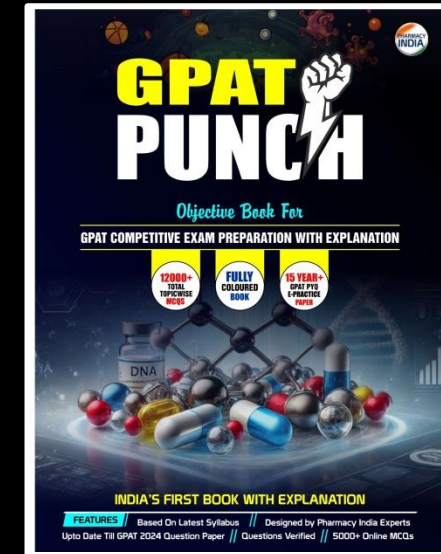
[S] Coal tar colours permitted in cosmetics and soaps

(a) P and Q

(b) P and R

(c) Q and S

(d) R and S



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Schedule H and Schedule S deal with: [GATE-2004]

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[R] Biological and special products

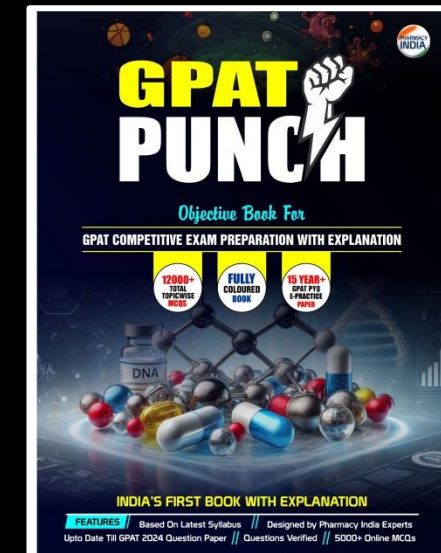
[S] Coal tar colours permitted in cosmetics and soaps

(a) P and Q

(b) P and R

(c) Q and S

(d) R and S



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SCHEDULE H & SCHEDULE S



IMPORTANT EXPLANATION



1. **Schedule H** lists **prescription drugs**.



2. These drugs are sold by **retail only** on the **prescription** of a **Registered Medical Practitioner**.



3. **Schedule S** deals with **standards** for cosmetics.



4. It defines **quality requirements** for cosmetic products.



5. QUICK DISTINCTION:

Schedule Q covers **colours** in cosmetics, while **Schedule S** gives **cosmetic** standards.



EXAM CLUE:

H = prescription drugs

S = standards for cosmetics.





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45.

Schedule FF contains: [GATE-2002]

- (a) Drugs marketed under generic names only
- (b) Habit forming drugs
- (c) Standards for ophthalmic preparations
- (d) Drugs exempt from certain manufacturing provisions



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45.

Schedule FF contains: [GATE-2002]

- (a) Drugs marketed under generic names only
- (b) Habit forming drugs
- (c) Standards for ophthalmic preparations
- (d) Drugs exempt from certain manufacturing provisions



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SCHEDULE FF



IMPORTANT EXPLANATION



1. Schedule FF contains **standards** for **ophthalmic** preparations.



2. It applies to **sterile eye** products such as **eye drops** and **eye ointments**.



3. The focus is **quality, sterility** and **suitability** for ocular use.



4. It helps maintain **safety** in preparations used **directly in the eye**.



5. QUICK MEMORY:
FF = eye formulation standards.



EXAM CLUE: Schedule FF = standards for ophthalmic preparations.





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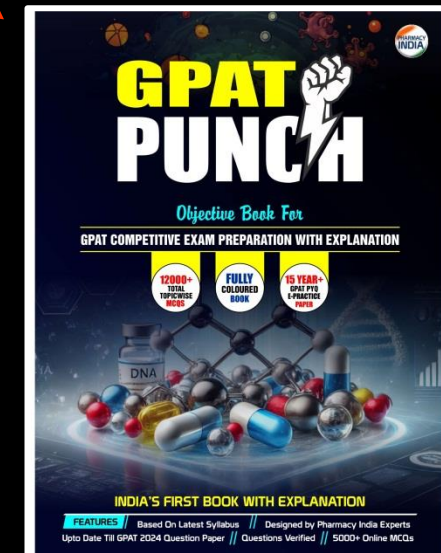


46.

Schedule D as per Drugs and Cosmetics Act is concerned with:

[GATE-2001]

- (a) List of drugs exempted from provisions of import of drugs
- (b) Diseases which a drug may not claim to cure
- (c) Requirements of factory premises
- (d) List of prescription drugs



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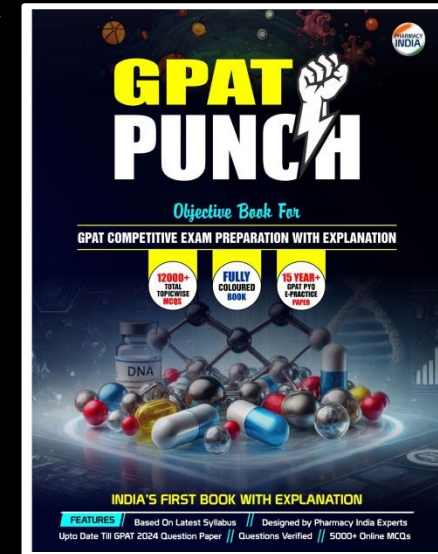


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[GATE-2001]

- (a) List of drugs exempted from provisions of import of drugs**
- (b) Diseases which a drug may not claim to cure**
- (c) Requirements of factory premises**
- (d) List of prescription drugs**



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SCHEDULE D



IMPORTANT EXPLANATION



1. Schedule D lists drugs **exempted** from certain provisions relating to import.



2. It mainly deals with **exemptions** from the import requirements of drugs.



3. Such exemptions apply only under **specified** conditions.



4. It is important in **import control** under the Drugs and Cosmetics Rules.



5. QUICK MEMORY:
D = import exemption list.



EXAM CLUE: Schedule **D** is concerned with drugs **exempted** from import provisions.





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47.

Match the schedules: [GATE-2000]

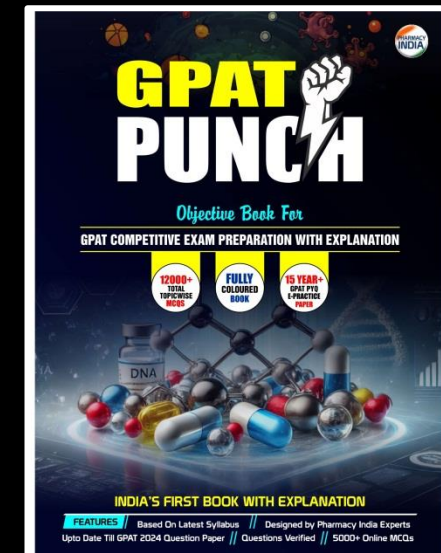
1. Schedule M — P. Standard for disinfectant fluids
2. Schedule O — Q. Standard for ophthalmic preparation
- R. Requirement of factory premises
- S. Standard for cosmetics

(a) 1-Q, 2-S

(b) 1-R, 2-S

(c) 1-R, 2-P

(d) 1-P, 2-S



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47.

Match the schedules: [GATE-2000]

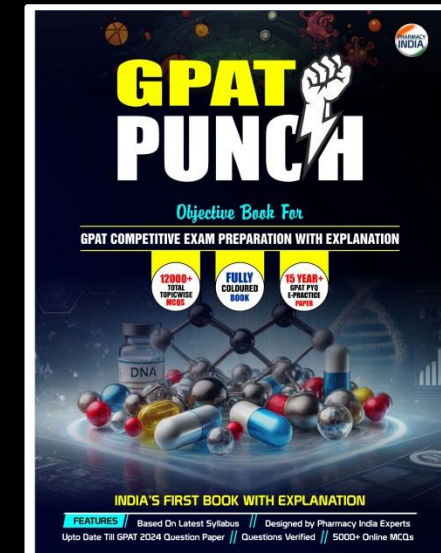
1. Schedule M — P. Standard for disinfectant fluids
2. Schedule O — Q. Standard for ophthalmic preparation
- R. Requirement of factory premises
- S. Standard for cosmetics

(a) 1-Q, 2-S

(b) 1-R, 2-S

(c) 1-R, 2-P

(d) 1-P, 2-S



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SCHEDULE M & SCHEDULE O



IMPORTANT EXPLANATION



1. Schedule M gives requirements for factory premises and GMP.



2. It covers premises, equipment, sanitation and manufacturing controls.



3. Schedule O gives standards for disinfectant fluids.



4. It is used to judge the quality of disinfectant preparations.



5. QUICK MEMORY:

M = manufacturing requirements, **O** = disinfectant standard.



EXAM CLUE:

Schedule M = factory premises/GMP

Schedule O = disinfectant fluids.





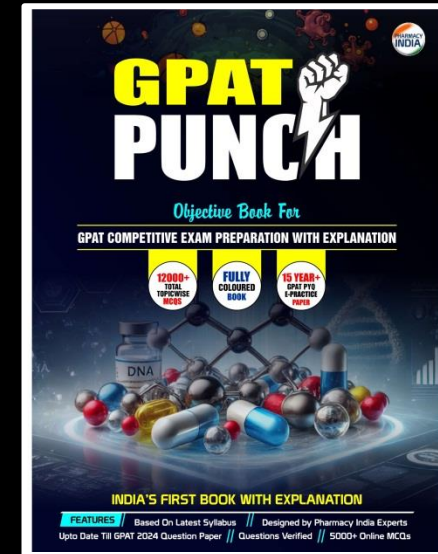
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48.

An original licence or renewed licence to sell drugs remains valid up to: [GATE-2000]

- (a) 31 March next year in which it is granted
- (b) 30 June of the following year in which it is granted or renewed
- (c) 31 January of the same year in which it is granted
- (d) 31 December of the following year in which it is granted or renewed



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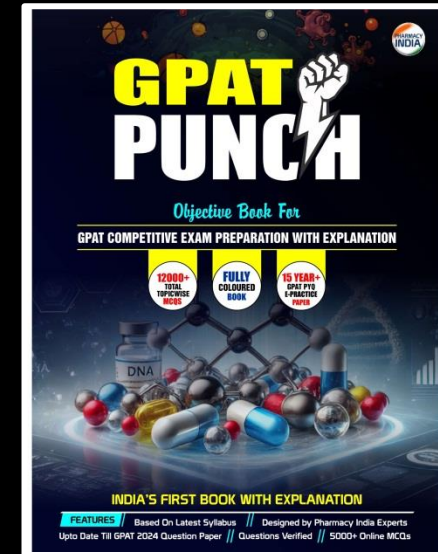


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- (b) 30 June of the following year in which it is granted or renewed
- (c) 31 January of the same year in which it is granted
- (d) 31 December of the following year in which it is granted or renewed**



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VALIDITY OF DRUG SALE LICENCE



IMPORTANT EXPLANATION



1. In the older rule-based framework, an original or renewed sale licence remained valid up to **31 December** of the following year.



2. This was the classic **exam point** asked in older **GPAT/GATE MCQs**.



3. The validity applied after **grant or renewal** under the earlier system.



4. Always read such questions in their **historical rule context**.



5. **QUICK MEMORY:**
grant/renewal → valid till **31 December** of next year.



EXAM CLUE: older exam answer = **valid up to 31 December** of the following year.





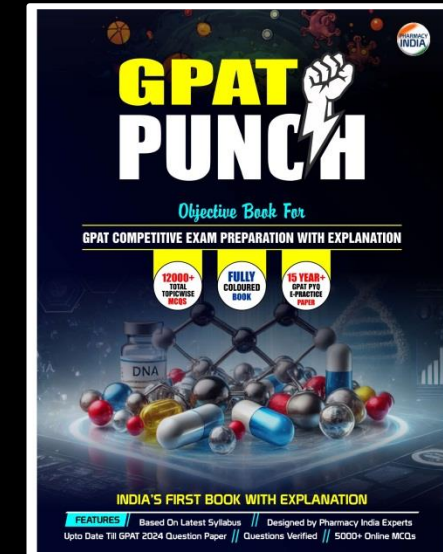
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49.

Match the schedule with label statement: [GATE-2000]

1. Schedule H	P. For external use only
2. Schedule G	Q. For therapeutic use only
	R. Caution: dangerous to take except under medical supervision
	S. To be sold by retail on prescription of RMP only



(a) 1-Q, 2-S

(b) 1-R, 2-S

(c) 1-S, 2-R

(d) 1-P, 2-S



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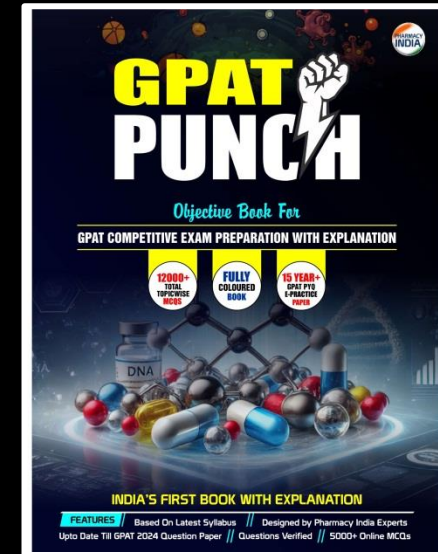


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2. Schedule G	Q. For therapeutic use only
	R. Caution: dangerous to take except under medical supervision
	S. To be sold by retail on prescription of RMP only



(a) 1-Q, 2-S

(b) 1-R, 2-S

(c) 1-S, 2-R

(d) 1-P, 2-S



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SCHEDULE H & SCHEDULE G LABELS



1. Schedule H label:
To be sold by retail
on the prescription
of the **Registered
Medical Practitioner**
only.



2. Schedule G label:
Caution: it is
dangerous to take
this preparation
except under
medical supervision.



3. Schedule H
controls retail
sale of
prescription
medicines.



4. Schedule G
warns that use
requires **medical
supervision.**



5. QUICK MEMORY:

H = prescription sale restriction, **G** = caution under supervision.



EXAM CLUE:

Schedule H = Rx sale statement

Schedule G = medical supervision caution





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50.

Match the schedules: [GATE-1999]

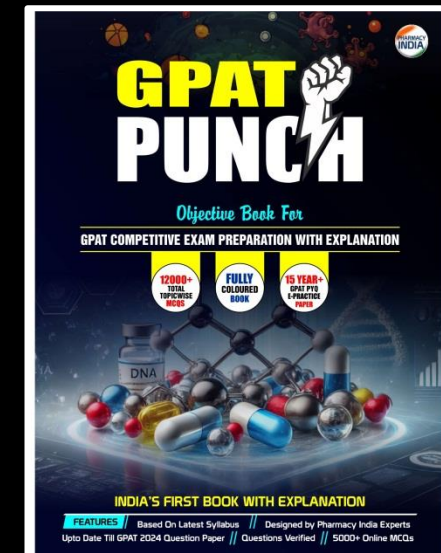
1. Schedule FF	P. Standards for ophthalmic preparations
2. Schedule M	Q. Diseases which a drug may not claim to cure
	R. Life period of drugs
	S. Requirements of factory premises

(a) 1-Q, 2-S

(b) 1-P, 2-Q

(c) 1-R, 2-P

(d) 1-P, 2-S



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50.

Match the schedules: [GATE-1999]

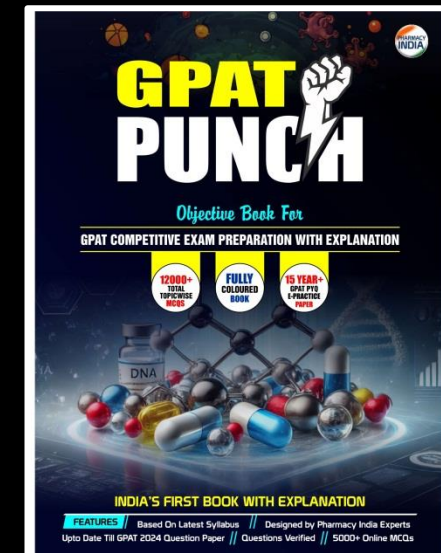
1. Schedule FF	P. Standards for ophthalmic preparations
2. Schedule M	Q. Diseases which a drug may not claim to cure
	R. Life period of drugs
	S. Requirements of factory premises

(a) 1-Q, 2-S

(b) 1-P, 2-Q

(c) 1-R, 2-P

(d) 1-P, 2-S



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SCHEDULE FF & SCHEDULE M



IMPORTANT EXPLANATION



1. **Schedule FF** gives standards for **ophthalmic** preparations.



2. It covers **safe** and **quality** eye preparations.



CLEAN PREMISES



HYGIENE CONTROL



QUALITY MANUFACTURING



DOCUMENTATION & RECORDS



3. **Schedule M** gives requirements of **factory premises** and **GMP**.



4. It governs **facilities, hygiene** and **manufacturing** conditions.



5. QUICK MEMORY:

FF = ophthalmic standards, **M** = manufacturing premises.



EXAM CLUE: **Schedule FF** = ophthalmic preparations

Schedule M = factory premises/GMP.





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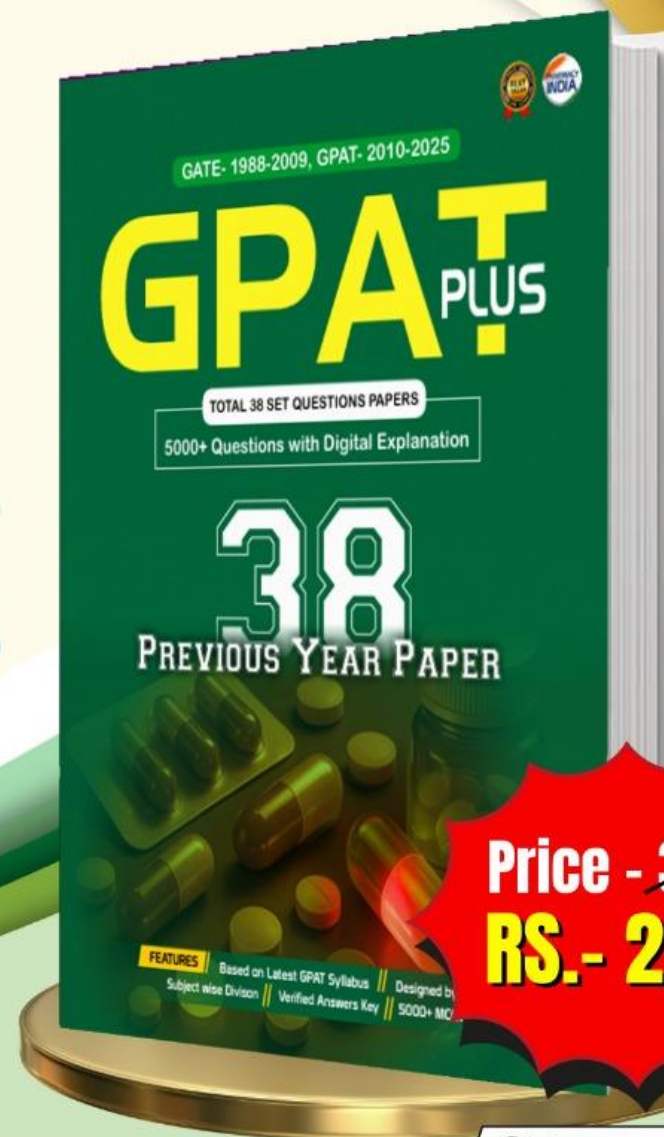
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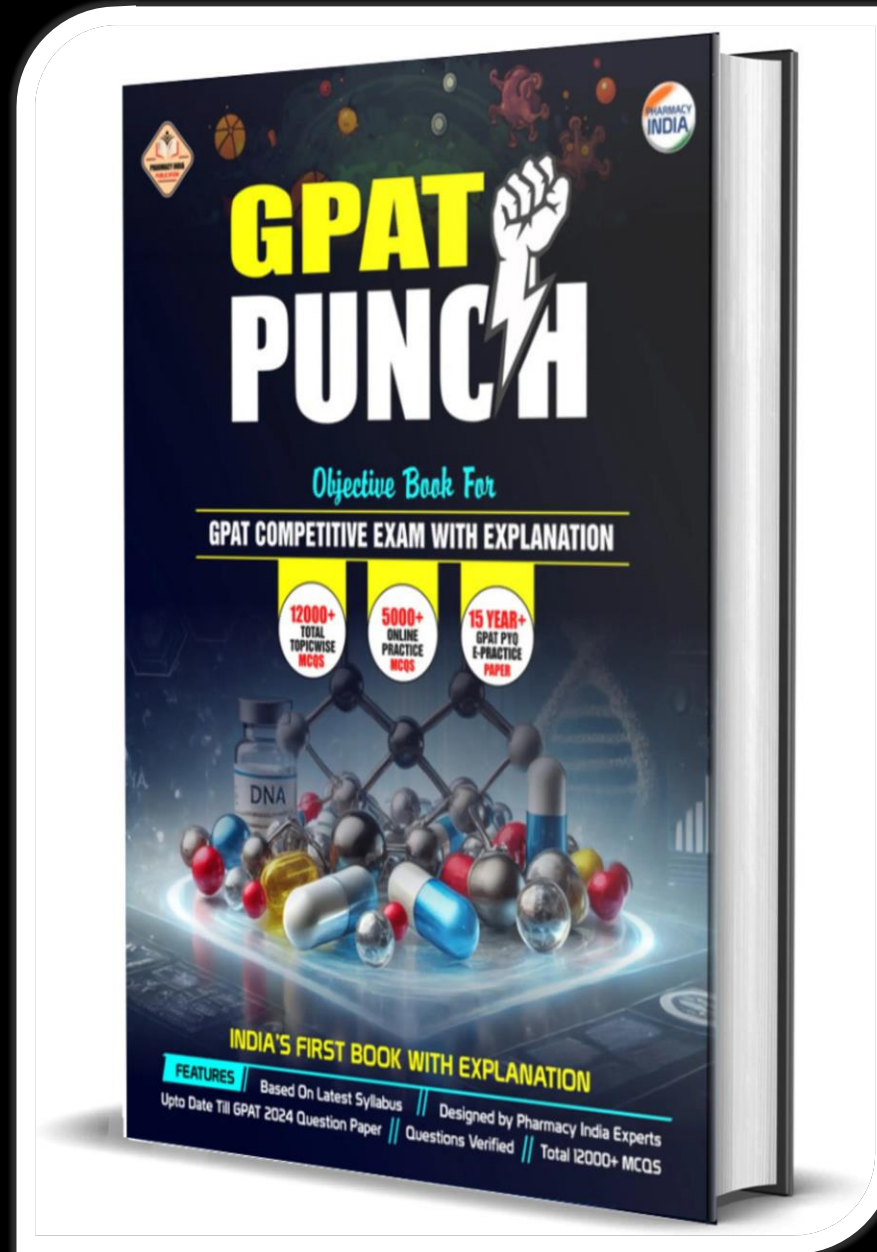


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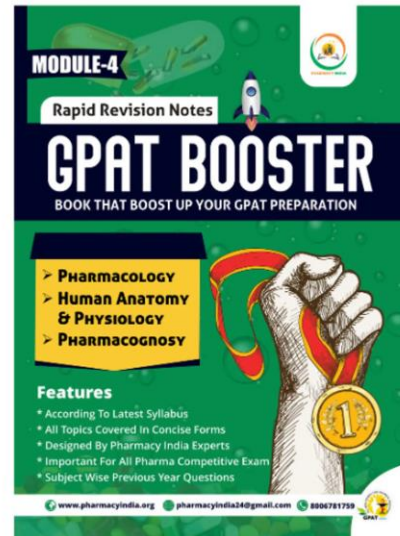
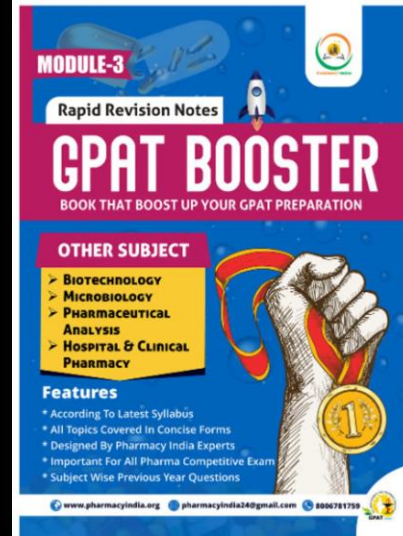
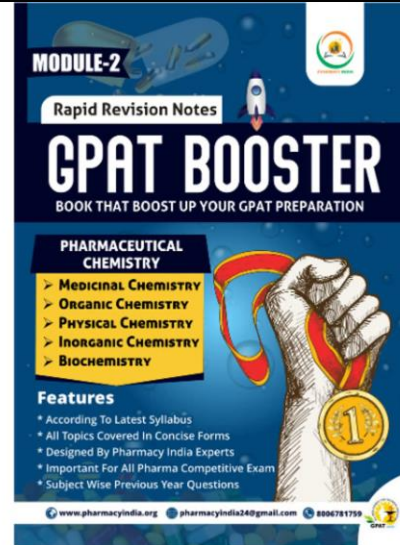
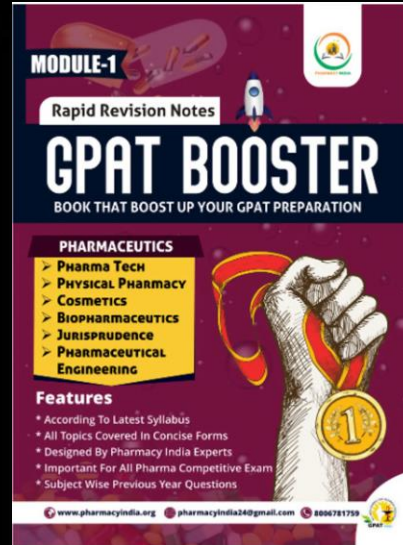
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