



GPAT 2025

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GPAT MANIA 2.0

BY VIJAY SIR

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PHARMACOLOGY

ASPECTS OF PHARMACOTHERAPY, CLINICAL
PHARMACOLOGY AND DRUG DEVELOPMENT & ADR

TOPIC

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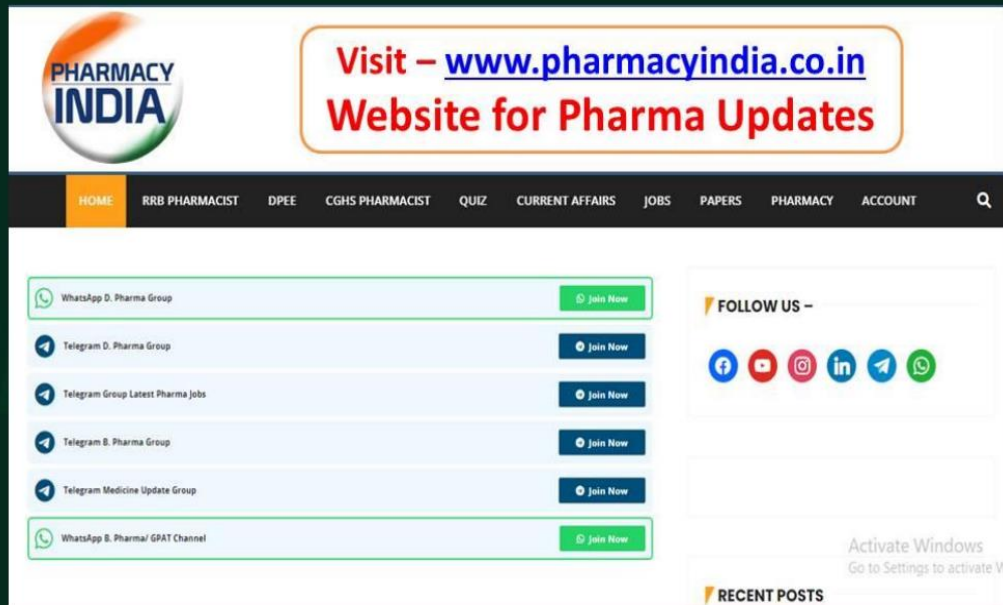


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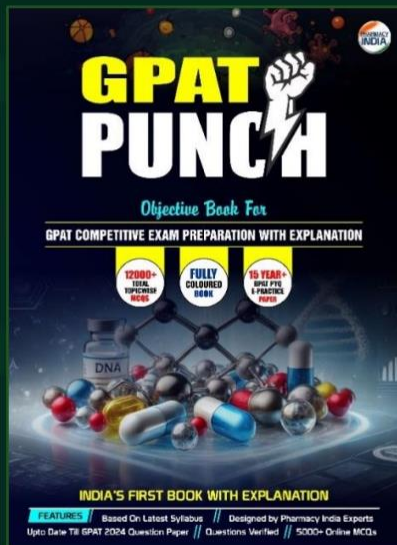
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ASPECTS OF **PHARMACOTHERAPY** **CLINICAL PHARMACOLOGY** **DRUG DEVELOPMENT & ADR**

1.

When is a New Drug Application (NDA) made [GPAT-2023 SHIFT-1]

(a) Once the animal studies are done and drug is declared safe in animals

(b) Once the animal studies are done and drug is declared safe and effective in animal studies

(c) After the phase III clinical trials

(d) After the phase IV clinical trials

1.

When is a New Drug Application (NDA) made [GPAT-2023 SHIFT-1]

(a) Once the animal studies are done and drug is declared safe in animals

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(c) After the phase III clinical trials

(d) After the phase IV clinical trials

Phase	Name	Conducted on	Purpose
I	Human Pharmacology and safety	Healthy volunteers (20 – 100)	To know maximum tolerable dose (MTD) Safety and tolerability
II	Therapeutic exploratory	100 – 150 Patients	To establish therapeutic efficacy Dose ranging and ceiling effect
III	Therapeutic confirmatory	Upto 5000 patients from several centres	To confirm therapeutic efficacy To establish the value of drug in relation to existing therapy
IV	Post marketing surveillance	Large number of patients being treated by practicing physicians	To know rare and long-term adverse effects Special groups like children, pregnancy etc can be tested
Zero	Microdosing studies	Healthy volunteers (small number)	Very low dose 1/100th of human dose; max 100 mg) of drug is administered to know pharmacokinetics. This could avoid costly phase I studies for candidate drugs with unsuitable pharmacokinetics.

A New Drug Application (NDA) is submitted to the U.S. Food and Drug Administration (FDA) after the successful completion of Phase III clinical trials. At this stage, the drug has been tested for safety, efficacy, and dosage in a large population of human subjects, and the data is sufficient to seek approval for marketing the drug.

2.

List I

1. Phase-1

2. Phase-0

3. Phase-3

4. Phase-4

List II

[P] Post marketing surveillance

[Q] Microdosing

[R] First in human dose

[S] Therapeutic confirmation

Choose the correct answer from the options given below (GPAT-2022]

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

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

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

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

2.**List I****1. Phase-1****2. Phase-0****3. Phase-3****4. Phase-4****List II****[P] Post marketing surveillance****[Q] Microdosing****[R] First in human dose****[S] Therapeutic confirmation****Choose the correct answer from the options given below (GPAT-2022]****(a) 1 [R], 2-[Q], 3- [P], 4- [S]****(b) 1-[R], 2-[Q], 3 - [S], 4- [P]****(c) 1-[Q], 2- [S], 3 - [P], 4- [R]****(d) 1-[S], 2- [P], 3- [Q], 4- [R]**

SCHEDULE Y

Schedule Y is a part of the **Drugs and Cosmetics Rules, 1945** in India, which provides comprehensive guidelines for the conduct of clinical trials.

3.

The objective of the Abbreviated New Drug Application is to [GPAT-2022]

- (a) Get approval to conduct clinical trials**
- (b) Get market approval of new chemical entities**
- (c) Get market approval of generics**
- (d) Get approval for animal studies of new chemical entities**

3.

The objective of the Abbreviated New Drug Application is to [GPAT-2022]

- (a) Get approval to conduct clinical trials**
- (b) Get market approval of new chemical entities**
- (c) Get market approval of generics**
- (d) Get approval for animal studies of new chemical entities**

Explanation:

- The **ANDA** is used to **obtain regulatory approval** for **generic drugs**.
- It **does not require preclinical and clinical trial data**; instead, it must **demonstrate bioequivalence** to the reference brand-name drug.

Duration of a Patent:

Generally **20 years** from the filing date (for utility patents).

4. To monitor the safety of the new drug under actual conditions of use in large number of patients has been classified as Clinical trials [GPAT-2021]

(a) Phase III

(b) Phase II

(c) Phase IV

(d) Phase I

4. To monitor the safety of the new drug under actual conditions of use in large number of patients has been classified as Clinical trials [GPAT-2021]

(a) Phase III

(b) Phase II

(c) Phase IV

(d) Phase I

Phase IV clinical trials are conducted to ensure the **long-term safety, effectiveness, and optimal use** of a drug or medical device after it has been approved for public use

5.

Identify phase of clinical trial having following features [GPAT-2020]

[P] Trial is conducted on about 3000 patients

[Q] Purpose of trial is therapeutic confirmation

[R] Safety and tolerability is evaluated on wider scale

[S] Completion of trial is followed by New Drug Application (NDA)

(a) Phase – III

(b) Phase - I

(c) Phase – IV

(d) Phase – II

5.

Identify phase of clinical trial having following features [GPAT-2020]

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(a) Phase – III

(b) Phase - I

(c) Phase – IV

(d) Phase – II

6.

The number of subjects required in a phase 1 clinical trial is (GPAT-2018)

- (a) 20 to 100**
- (b) Up to several hundred**
- (c) 300 to 3,000**
- (d) Several thousands**

6.

The number of subjects required in a phase 1 clinical trial is [GPAT-2018]

(a) 20 to 100

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(c) 300 to 3,000

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7.

Phase 0 studies means (GPAT-2017)

- (a) In vitro studies**
- (b) Part of phase 1 studies of clinical trials**
- (c) First in human micro dosing studies**
- (d) Studies carried out on small number of animals**

7.

Phase 0 studies means (GPAT-2017)

- (a) In vitro studies**
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- (c) First in human micro dosing studies**
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8.

In which of the following phases of clinical trials, healthy normal human volunteers participate [GPAT-2016]

- (a) Phase-I**
- (b) Phase-II**
- (c) Phase-III**
- (d) Phase-IV**

8.

In which of the following phases of clinical trials, healthy normal human volunteers participate [GPAT-2016]

- (a) Phase-I**
- (b) Phase-II**
- (c) Phase-III**
- (d) Phase-IV**

9.

Following are the phases of clinical trials [GPAT-2012]

[P] Human pharmacology

[R] Post marketing trials

[Q] Therapeutic confirmatory trials

[S] Therapeutic exploratory trials

Choose the correct order of phases of clinical trial

(a) P, Q, R, S

(b) P, R, Q, S

(c) P, Q, S, R

(d) P, S, Q, R

9.

Following are the phases of clinical trials [GPAT-2012]

[P] Human pharmacology

[R] Post marketing trials

[Q] Therapeutic confirmatory trials

[S] Therapeutic exploratory trials

Choose the correct order of phases of clinical trial

(a) P, Q, R, S

(b) P, R, Q, S

(c) P, Q, S, R

(d) P, S, Q, R

10.

Geriatric populations should be included in the following phase of clinical trials (GATE-2010)

- (a) Phase I**
- (b) Phase II**
- (c) Phase III**
- (d) Phase IV**

10.

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(a) Phase I

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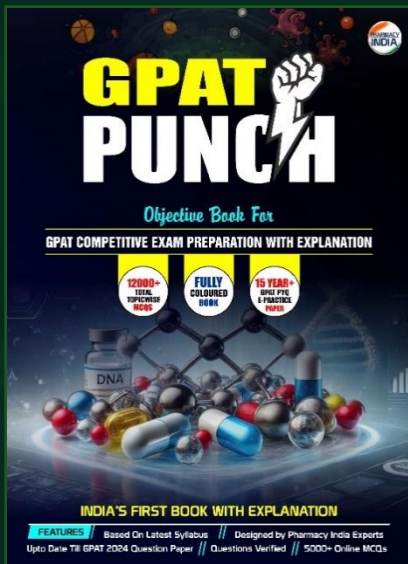
(c) Phase III

(d) Phase IV

Phase	Name	Conducted On	Blinding and Control	Purpose
IV	Post-Marketing Surveillance	Large number of patients treated by practicing physicians	—	<ul style="list-style-type: none">- To know rare and long-term adverse effects- Special groups like children, pregnancy, etc., can be tested

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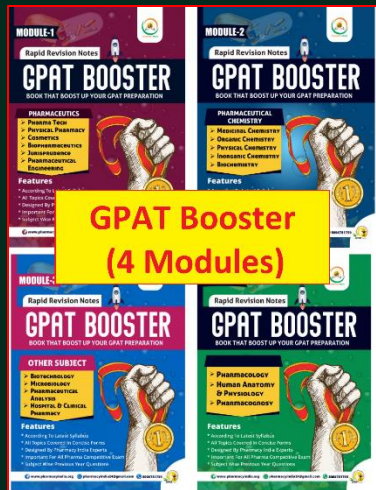
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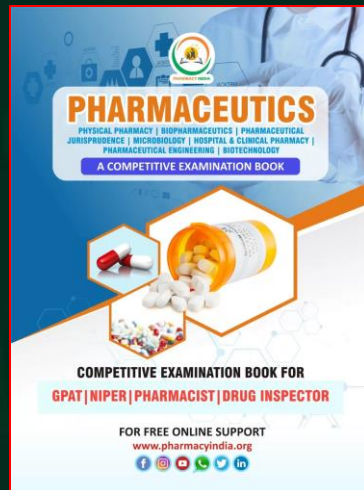
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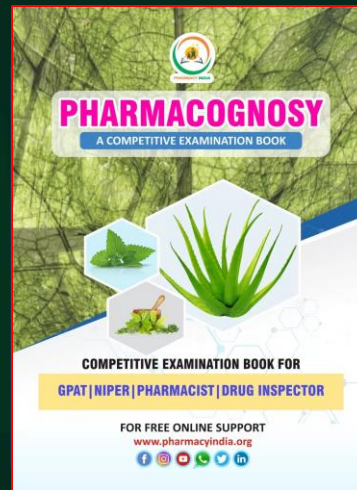


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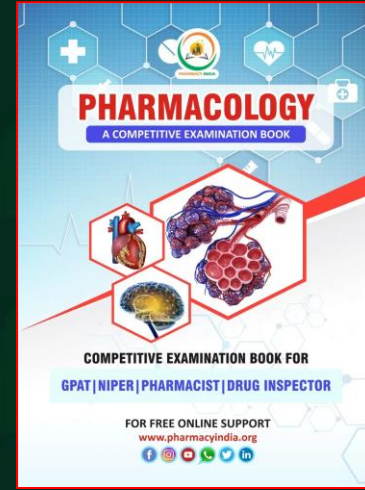
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11.

Phase I clinical studies of a of a drug under development is generally carried out on [GATE-2009]

- (a) At least 10,000 people from different ethnic communities and wide range of age groups**
- (b) A medium sized group of 500-1000 patients suffering from the disease for which the drug is being developed**
- (c) A small group of 20-100 healthy male and female volunteers**
- (d) Reliable in-vitro cell-lines derived from people suffering with the disease**

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12. Pharmacovigilance is done for monitoring

- (a) Drug price**
- (b) Unethical practices**
- (c) Drug safety**
- (d) Pharmacology students**

12. Pharmacovigilance is done for monitoring

- (a) Drug price
- (b) Unethical practices
- (c) Drug safety
- (d) Pharmacology students

Explanation:

Pharmacovigilance

Pharmacovigilance has been defined by the WHO (2002) as the 'science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems.'

13.

What is the main purpose of a titrated dose?

- (a) To maintain minimal side effects while achieving maximal therapeutic effect**
- (b) To standardize drug administration for all patients**
- (c) To achieve a fixed plasma concentration**
- (d) To administer a large initial dose**

13.

What is the main purpose of a titrated dose?

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- (c) To achieve a fixed plasma concentration**
- (d) To administer a large initial dose**

A **titrated dose** refers to a medication dosage that has been carefully adjusted to achieve the desired therapeutic effect while minimizing side effects.

The process of **titration** involves gradually **increasing or decreasing** the dose of a drug based on the patient's response, medical condition, or specific treatment goals.

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14. Which of the following drugs might require a target level dose?

- (a) Antidepressants**
- (b) Antibiotics**
- (c) Antacids**
- (d) Vaccines**

14. Which of the following drugs might require a target level dose?

(a) Antidepressants

(b) Antibiotics

(c) Antacids

(d) Vaccines

A target level dose refers to the specific amount of a medication that aims to achieve a particular therapeutic effect or concentration in the body.

The goal is for the drug level to reach a concentration that is effective for treating the condition, while avoiding side effects or toxicity.

15.

Which of the following is an example of a synergistic drug combination in FDCs?

- (a) Amlodipine + atenolol**
- (b) Sulfamethoxazole + trimethoprim**
- (c) Thiazide + potassium-sparing diuretic**
- (d) Amoxicillin + clavulanic acid**

15.

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Amlodipine + atenolol: These work through different mechanisms to lower blood pressure but **don't have a combined effect greater than their individual actions**. It's more of an additive effect.

Thiazide + potassium-sparing diuretic: **These balance each other out by preventing potassium loss from the thiazide, but they don't enhance each other's actions** beyond their individual roles in diuresis.

Amoxicillin + clavulanic acid: Clavulanic acid inhibits beta-lactamase, allowing amoxicillin to work better, **but it's more of a protective effect** than a true synergy that enhances both drugs' actions together.

16. What is the role of combined formulations in conditions like tuberculosis and falciparum malaria?

- (a) They increase drug costs**
- (b) They improve renal function**
- (c) They reduce therapeutic efficacy**
- (d) They ensure that a single drug is not administered**

16. What is the role of combined formulations in conditions like tuberculosis and falciparum malaria?

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Explanation:

In conditions like **tuberculosis (TB)** and **falciparum malaria**, combined drug formulations are used to prevent **monotherapy** (the use of a single drug), which could lead to:

Drug resistance: By using multiple drugs with different mechanisms of action, the chances of the pathogen developing resistance to one of the drugs are minimized.

Enhanced therapeutic efficacy: Combining drugs with complementary actions can be more effective in killing the pathogen

17. Comparison of efficacy of a new drug B with an existing drug A is done in which phase of clinical trials

- (a) Phase I
- (b) Phase II
- (c) Phase III
- (d) Phase IV

17. Comparison of efficacy of a new drug B with an existing drug A is done in which phase of clinical trials

(a) Phase I

(b) Phase II

(c) Phase III

(d) Phase IV

Explanation:

- Phase III trials are large-scale studies that compare the efficacy and safety of a new drug with standard treatments or placebos.
- Why Not the Others?
 - (a): Phase I focuses on safety and tolerability in healthy volunteers.
 - (b): Phase II evaluates efficacy but does not compare drugs on a large scale.
 - (d): Phase IV monitors post-marketing safety, not efficacy comparison.

18. Good clinical practice (GCP) is not required in

- (a) Preclinical phase**
- (b) Phase I trial**
- (c) Phase II studies**
- (d) Phase IV studies**

18. Good clinical practice (GCP) is not required in

(a) Preclinical phase

(b) Phase I trial

(c) Phase II studies

(d) Phase IV studies

Explanation:

- Good Clinical Practice (**GCP**) applies to **clinical trials** involving **humans**, ensuring ethical and scientific standards.
- Why Not the Others?
 - (b), (c), (d): GCP is mandatory for all phases of clinical trials involving human subjects.
 - The **preclinical phase** involves animal and laboratory studies, adhering to Good Laboratory Practice (**GLP**) instead of GCP.

19.

Why are corticosteroids contraindicated in FDCs?

- (a) They are too costly to produce**
- (b) They cannot be combined with any other drug for internal use**
- (c) They enhance the absorption of other components**
- (d) They are not effective when used in combinations**

19.

Why are corticosteroids contraindicated in FDCs?

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- Corticosteroids are generally **contraindicated in fixed-dose combinations (FDCs)** for the following reasons:
- **Variable response**: Corticosteroids are potent drugs that can have unpredictable effects, and their use in combination with other drugs can make it difficult to manage their precise effects on the body.
- **Side effects**: Long-term use of corticosteroids can cause significant side effects, such as immunosuppression, which may complicate the treatment of other conditions when combined in FDCs.
- **Lack of synergy**: Unlike drugs that can work synergistically, corticosteroids may not enhance the effectiveness of other drugs in an FDC, and they may only contribute to side effects.

20.

Monitoring of plasma drug concentration is required while using [GPAT-2024]

- (a) Antihypertensive drugs**
- (b) Levodopa**
- (c) Lithium carbonate**
- (d) MAO inhibitors**

20.

Monitoring of plasma drug concentration is required while using [GPAT-2024]

(a) Antihypertensive drugs

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Explanation:

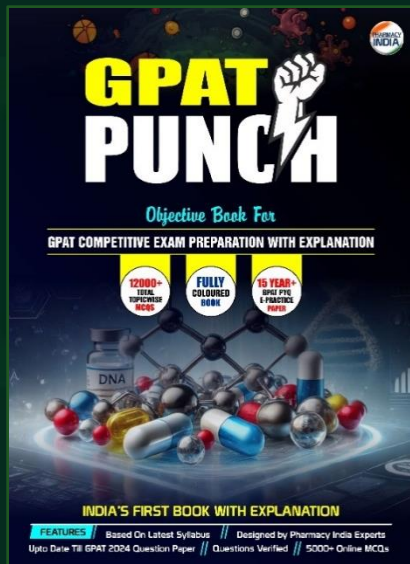
Therapeutic drug monitoring (**TDM**) is particularly useful in the following situations:

1. Drugs with **low safety margin**, e.g. —digoxin, anticonvulsants, antiarrhythmics, theophylline, aminoglycoside antibiotics, lithium, tricyclic antidepressants.
2. If **individual variations are large**, e.g.—anti depressants, lithium.
3. **Potentially toxic drugs** used in the presence of renal failure, e.g. —aminoglycoside antibiotics, vancomycin.

4. In case of **poisoning**.
5. In case of **failure of response** without any apparent reason, e.g. — antimicrobials.
6. To check **patient compliance**, e.g. — psycho pharmacological agents.

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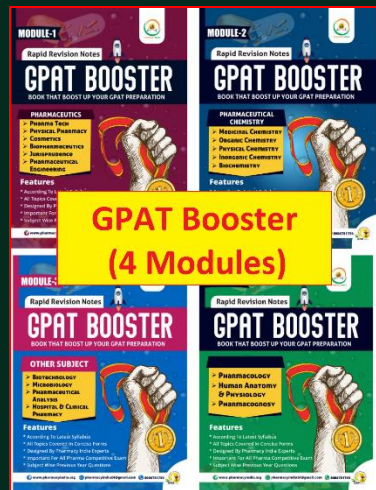
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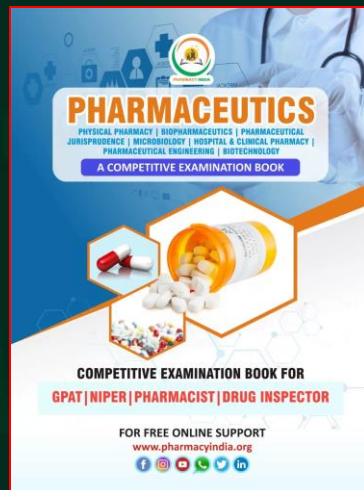
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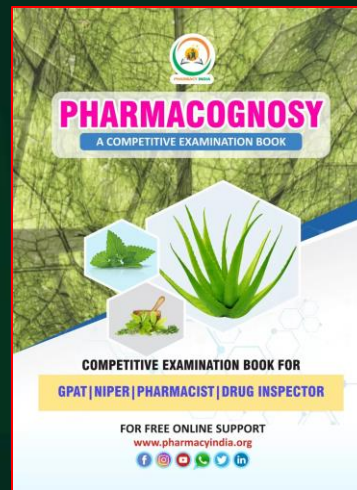


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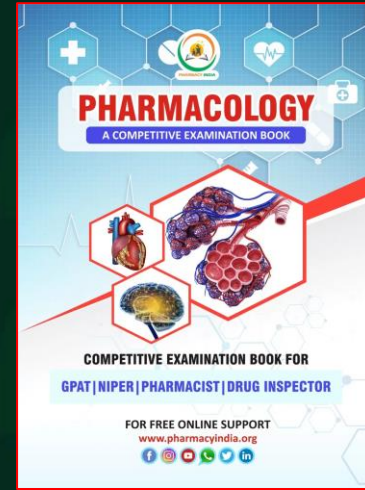
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21.

Match the following cells of immune system List I with their functions List II

[GPAT-2023 SHIFT-I]

List I [Immune system]

1. Mast cell

2. Lymphocytes

3. T-cells

4. Monocytes-Macrophages

List II [Functions]

[P] Master of Immune system

[Q] Allergic reactions

[R] Cell mediated immune reaction

[S] Antigen recognition, Phagocytosis

Choose the CORRECT answer from the options given below

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

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

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

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

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Choose the CORRECT answer from the options given below

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

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

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

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

Explanation:

1. **Mast Cells** → [Q] Allergic Reactions: **Release histamine and mediators** during allergic responses and hypersensitivity.
2. **Lymphocytes** → [P] **Master of Immune System**: Include B and T cells; orchestrate adaptive immune responses.
3. **T-cells** → [R] **Cell-mediated Immune Reaction**: CD8+ T-cells destroy infected cells; CD4+ T-cells regulate immune responses.
4. **Monocytes-Macrophages** → [S] **Antigen Recognition**, Phagocytosis: Perform phagocytosis and present antigens to T-cells.

22. Phocomelia is caused by [GPAT-2023 SHIFT-I]

- (a) Glibenclamide**
- (b) Indapamide**
- (c) Xipamide**
- (d) Thalidomide**

22. Phocomelia is caused by [GPAT-2023 SHIFT-I]

- (a) Glibenclamide
- (b) Indapamide
- (c) Xipamide
- (d) Thalidomide**

Explanation: Human Teratogenic Drugs

Drug	Abnormality
Thalidomide	Phocomelia, multiple defects of internal organs
Anticancer drugs	Cleft palate, hydrocephalus, multiple defects, foetal death
Androgens	Virilization; limb, esophageal, cardiac defects
Progestins	Virilization of female foetus
Stilboestrol	Vaginal carcinoma in teenage female offspring
Tetracyclines	Discolored and deformed teeth, retarded bone growth
Warfarin	Depressed nose; eye and hand defects, growth retardation
Phenytoin	Growth retardation, cleft lip/palate, microcephaly
Phenobarbitone	Various malformations
Carbamazepine	Neural tube defects, assorted abnormalities

Drug	Abnormality
Valproate sodium	Spina bifida and other neural tube defects, heart and limb abnormalities
Alcohol	Low IQ baby, growth retardation, foetal alcohol syndrome
ACE inhibitors	Hypoplasia of organs, growth retardation, foetal loss
Lithium	Foetal goiter, cardiac and other abnormalities
Antithyroid drugs	Foetal goiter and hypothyroidism
Indomethacin/aspirin	Premature closure of ductus arteriosus
Isotretinoin	Craniofacial, heart, and CNS defects, hydrocephalus

23.

Which of the following statements are TRUE with the Adverse Drug Reactions

[A] Any response to a drug which is noxious and unintended

[B] Which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of a disease

[C] Adverse drug event is same as that of Adverse Drug Reaction

[D] Which occurs at normal dose or overdose when used for prophylaxis, diagnosis or therapy of a disease

Choose the CORRECT answer from the options given below [GPAT-2022]

(a) A and B are true while C and D are false

(b) A and C are true while B and D are false

(c) B, C and D are false, Only A is true

(d) A, B and C are false, Only D is true

23.

Which of the following statements are TRUE with the Adverse Drug Reactions

[A] Any response to a drug which is noxious and unintended

[B] Which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of a disease

[C] Adverse drug event is same as that of Adverse Drug Reaction

[D] Which occurs at normal dose or overdose when used for prophylaxis, diagnosis or therapy of a disease

Choose the CORRECT answer from the options given below [GPAT-2022]

(a) A and B are true while C and D are false

(b) A and C are true while B and D are false

(c) B, C and D are false, Only A is true

(d) A, B and C are false, Only D is true

Explanation:

1. [A]: True. ADRs are defined as noxious, unintended drug responses.
2. [B]: True. ADRs occur at therapeutic doses, not due to overdose or misuse.
3. [C]: False.
 - ADR: Noxious response at therapeutic doses.
 - Adverse Drug Event (ADE): Broad term, including errors, overdoses, and ADRs.
4. [D]: False. ADRs do not include responses from overdoses.

24. The management of Type-B adverse drug reaction is [GPAT-2018]

- (a) To reduce the dose**
- (b) To withhold the dose and avoid in future**
- (c) To increase the dose**
- (d) To reintroduce and withdraw slowly**

24. The management of Type-B adverse drug reaction is [GPAT-2018]

- (a) To reduce the dose
- (b) To withhold the dose and avoid in future**
- (c) To increase the dose
- (d) To reintroduce and withdraw slowly

Explanation:

- **Type-B Adverse Drug Reactions (ADRs):**

- These are **idiosyncratic, rare, unpredictable**, and not dose-dependent.
- Often caused by **genetic or immunological** factors.

- **Management:**

- Withhold the drug immediately to prevent further reactions.
- **Avoid the drug in the future** as re-exposure can be life-threatening.

25. Loss of therapeutic efficacy after prolonged/intensive use of drug [GPAT-2016]

- (a) Refractoriness**
- (b) Resistance**
- (c) Tachyphylaxis**
- (d) Idiosyncrasy**

25. Loss of therapeutic efficacy after prolonged/intensive use of drug [GPAT-2016]

(a) Refractoriness

(b) Resistance

(c) Tachyphylaxis

(d) Idiosyncrasy

Explanation:

Tolerance

- It refers to the **requirement of higher dose** of a drug to produce a given response.
- **Loss of therapeutic efficacy** (e.g. of **sulfonylureas** in **type 2 diabetes**, or of **β_2 agonists** in **bronchial asthma**), which is a form of tolerance, is often called 'refractoriness'.

Tolerance is a widely occurring adaptive biological phenomenon. Drug tolerance may be:

1. **Natural** - The species/individual is **inherently less sensitive to the drug**
2. **Acquired** - This occurs by **repeated use of a drug** in an individual who was initially responsive. Body is capable of developing tolerance to most drugs, but the phenomenon is very easily recognized in the case of CNS depressants.
3. **Cross tolerance** - It is **the development of tolerance to pharmacologically related drugs**, e.g. alcoholics are relatively tolerant to barbiturates and general anaesthetics.

26.

A direct way of studying idiosyncratic reactions to the given drug is by [GATE-2004]

- (a) Changing the route of drug administration**
- (b) Change the assay method**
- (c) Pharmacogenomics**
- (d) Structure activity relationship studies of a family of compounds**

26.

A direct way of studying idiosyncratic reactions to the given drug is by [GATE-2004]

- (a) Changing the route of drug administration**
- (b) Change the assay method**
- (c) Pharmacogenomics**
- (d) Structure activity relationship studies of a family of compounds**

Explanation:

- Pharmacogenomics is the use of genetic information to guide the choice of drug and dose on an individual basis.
- It intends to identify individuals who are either more likely or less likely to respond to a drug, as well as those who require altered dose of certain drugs.
- Attempt is made to define the genetic basis of an individual's profile of drug response and to predict the best treatment option for him/her.

27.

One of the following types of adverse drug reactions is NOT believed to be dose related phenomena [GATE-1995]

- (a) Side effects and toxic reactions**
- (b) Toxic reactions and hypersensitivity**
- (c) Side effects and hypersensitivity**
- (d) Hypersensitivity and idiosyncrasy**

27.

One of the following types of adverse drug reactions is NOT believed to be dose related phenomena [GATE-1995]

- (a) Side effects and toxic reactions
- (b) Toxic reactions and hypersensitivity
- (c) Side effects and hypersensitivity**
- (d) Hypersensitivity and idiosyncrasy

Explanation:

- **Dose-Related ADRs:**
 - **Side Effects:** Predictable and dose-dependent.
 - **Toxic Reactions:** Occur when the drug exceeds therapeutic levels.
- **Non-Dose-Related ADRs:**
 - **Hypersensitivity:** Immune-mediated, unpredictable (e.g., anaphylaxis).
 - **Idiosyncrasy:** Genetic, unpredictable, and dose-independent (e.g., G6PD deficiency).

TYPES	SUB-TYPES	DESCRIPTION
Predictable Reactions (Type A or Augmented Reactions)	Side effects	These are the unwanted pharmacological effects of a drug which are seen with therapeutic doses.
	Secondary effects	The primary action of a drug may result in other effects.
	Toxic effects	These are the effects of a drug, which are either due to overdosage or chronic use.

28.

Arthurs reaction is which type of allergic reaction

- (a) Humoral – Type I**
- (b) Humoral – Type II**
- (c) Humoral – Type III**
- (d) Cell Meditated- Type IV**

28.

Arthurs reaction is which type of allergic reaction

- (a) Humoral – Type I
- (b) Humoral – Type II
- (c) Humoral – Type III**
- (d) Cell Meditated- Type IV

Explanation: TYPES OF HYPERSENSITIVITY REACTION

CHARACTERISTIC	TYPE I (Immediate & anaphylactic)	TYPE II (Cytotoxic)	TYPE III (Arthus, serum sickness)	TYPE IV (cell-mediated)
Immune response alters	Humoral	Humoral	Humoral	T CELL Mediated
Immediate or delay	Immediate & anaphylactic	Immediate	Immediate	Delay
Antigen	Soluble	Cell surface	Soluble	Soluble or bound
Mediator	IgE	IgG, IgM	Ag-Ab complex, and IgG	T- cell

29. Following is type B adverse drug reaction

- (a) Side effect**
- (b) Idiosyncrasy**
- (c) Toxic effect**
- (d) Dependence**

29. Following is type B adverse drug reaction

- (a) Side effect
- (b) Idiosyncrasy**
- (c) Toxic effect
- (d) Dependence

TYPES	SUB-TYPES	DESCRIPTION
Unpredictable Reactions (Type B or Bizarre Reactions)		These are non-dose-related unpredictable reactions to a drug. They are not related to the pharmacological actions of the drug
	Drug allergy	It is an abnormal response (local or systemic), mediated by the immune system, to a drug/foreign antigen.
	Idiosyncrasy	It is usually a genetically determined abnormal reaction to drugs, e.g., aplastic anemia caused by chloramphenicol, succinylcholine apnoea, hemolytic anemia seen with primaquine and sulphonamides.

30. All of the following are type A adverse drug reactions except

- (a) Nephrotoxicity
- (b) Phototoxicity
- (c) Allergic reaction
- (d) Hepatotoxicity

30.

All of the following are type A adverse drug reactions except

(a) Nephrotoxicity

(b) Phototoxicity

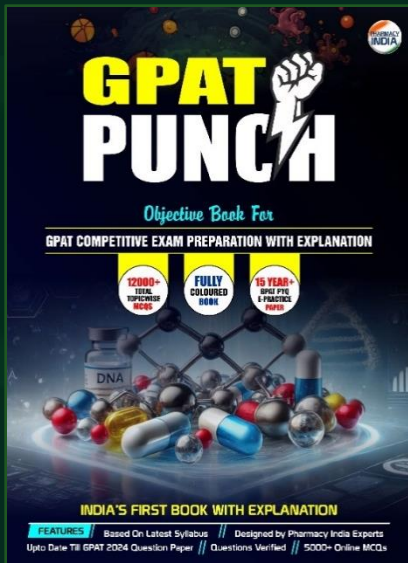
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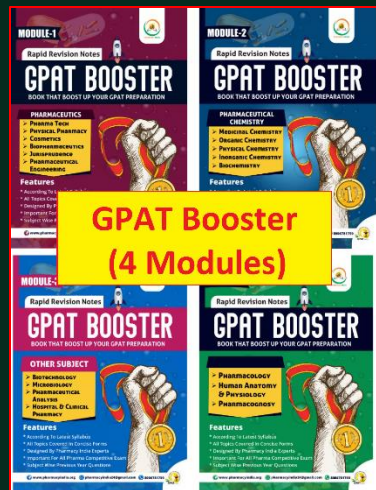
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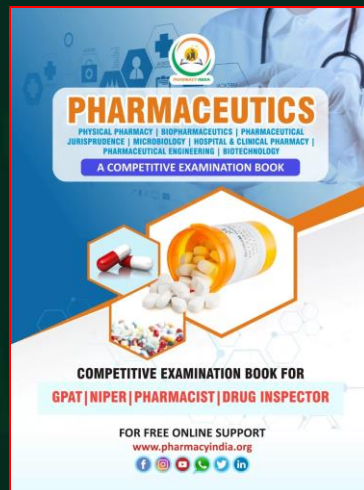
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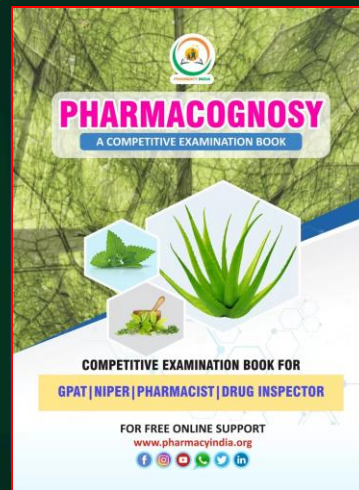


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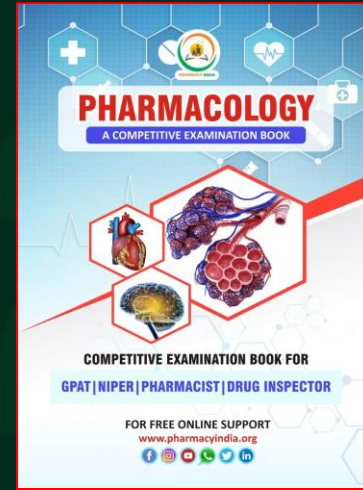
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31. What is the primary goal of rational prescribing?

- (a) To prescribe the cheapest available drug**
- (b) To match all drugs with diseases**
- (c) To ensure the appropriateness of the therapeutic setup and follow-up of the outcome**
- (d) To minimize drug production costs**

31. What is the primary goal of rational prescribing?

- (a) To prescribe the cheapest available drug
- (b) To match all drugs with diseases
- (c) To ensure the appropriateness of the therapeutic setup and follow-up of the outcome
- (d) To minimize drug production costs

Explanation:

Rational prescribing is not just the choice of a correct drug for a disease, or mere matching of drugs with diseases, but also the appropriateness of the whole therapeutic set up along with follow up of the outcome. The criteria to evaluate rational prescribing are:

1. **Appropriate indication:** the reason to prescribe the medicine is based on sound medical considerations.
2. **Appropriate drug in efficacy, tolerability, safety, and suitability** for the patient.

3. **Appropriate dose, route and duration** according to specific features of the patient.
4. **Appropriate patient**: no contraindications exist; drug acceptable to the patient; likelihood of adverse effect is minimal and less than the expected benefit.
5. **Correct dispensing** with appropriate information/instruction to the patient.
6. **Adequate monitoring** of patient's adherence to medication, as well as of anticipated beneficial and untoward effects of the medication

32. What is an example of unnecessary drug combinations?

- (a) Ciprofloxacin + tinidazole for diarrhea**
- (b) Amlodipine + atenolol for hypertension**
- (c) Paracetamol for fever reduction**
- (d) Antacids for acid reflux**

- 32. What is an example of unnecessary drug combinations?**
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33.

Toxic effect is

- (a) Excessive pharmacological action due to over dosage of drug**
- (b) Indirect consequence of primary action of the drug**
- (c) Genetically determined abnormal reaction to a drug**
- (d) Immunological reaction to a drug**

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34. What happens to adrenaline injection (in ampoules) after 1 year of its expiry date?

- (a) It turns solid**
- (b) It becomes cloudy or discolored**
- (c) It retains its potency but loses solubility**
- (d) It decomposes into harmful toxins**

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35. What is the primary aim of evidence-based medicine?

- (a) To replace clinical trials with experience-based decisions**
- (b) To systematically evaluate drugs using clinical research findings**
- (c) To focus solely on patient feedback**
- (d) To prioritize cost over efficacy**

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36. Idiosyncrasy refers to

- (a) Genetically Determined Abnormal Reactivity**
- (b) Quantitatively abnormal drug response at therapeutic doses**
- (c) Abnormal response at large doses**
- (d) Fatal reaction to drugs at large doses**

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(a) Genetically Determined Abnormal Reactivity

(b) Quantitatively abnormal drug response at therapeutic doses

(c) Abnormal response at large doses

(d) Fatal reaction to drugs at large doses

Explanation:

Idiosyncrasy

- It is **genetically determined abnormal reactivity** to a chemical. The drug interacts with some unique feature of the individual, not found in majority of subjects, and produces the **uncharacteristic reaction**. As such, the type of reaction is **restricted to individuals** with a particular genotype. In addition, certain **bizarre drug effects** due to **peculiarities of an individual** (for which no definite genotype has been described) are included among idiosyncratic reactions, e.g.:

37.

Which algorithm is used in India for causality assessment of ADRs?

- (a) Modified Hartwig scale**
- (b) Naranjo algorithm**
- (c) Bradford Hill criteria**
- (d) Algorithm of ADR prediction**

37.

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38.

What monitoring technique is advised for a patient on lithium therapy?

- (a) Prothrombin time**
- (b) White blood cell count**
- (c) Hemoglobin levels**
- (d) Serum drug levels**

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Explanation:

Prevention of adverse effects to drugs

Adverse drug effects can be minimized but not altogether eliminated by observing the following practices:

1. Avoid all inappropriate use of drugs in the context of patient's clinical condition.
2. Use appropriate dose, route and frequency of drug administration based on patient's specific variables.
3. Elicit and take into consideration previous history of drug reactions.

4. Elicit history of **allergic diseases and exercise caution** (drug allergy is more common in patients with allergic diseases).
5. **Rule out possibility of drug interactions** when more than one drug is prescribed.
6. **Adopt correct drug administration technique** (e.g. intravenous injection of vancomycin must be slow).
7. **Carry out appropriate laboratory monitoring** (e.g. prothrombin time with warfarin, serum drug levels with lithium).

39. The following agent produce both physical and psychological dependence except

- (a) Alcohol**
- (b) Amphetamines**
- (c) Morphine**
- (d) Triprolidine**

39. The following agent produce both physical and psychological dependence except

- (a) Alcohol
- (b) Amphetamines
- (c) Morphine
- (d) Triprolidine

Explanation:

Physical dependence

- It is an **altered physio logical state** produced by repeated administration of a drug which necessitates the continued presence of the drug to maintain physiological equilibrium. **Discontinuation of the drug results** in a characteristic withdrawal (abstinence) syn drome.
- **Drugs producing physical dependence** are— opioids, barbiturates and other depressants including alcohol and benzodiazepines.

- **Stimulant drugs**, e.g. **amphetamines**, cocaine produce little or no physical dependence.

Psychological dependence

- It is said to have **developed when the individual believes that optimal state of wellbeing is achieved only through the actions of the drug.** The subject feels emotionally distressed if the drug is not taken.

40. Appearance of characteristic withdrawal syndrome on discontinuation of a drug is called

- (a) Drug addiction**
- (b) Drug abuse**
- (c) Psychological dependence**
- (d) Physical dependence**

40.

Appearance of characteristic withdrawal syndrome on discontinuation of a drug is called

- (a) Drug addiction**
- (b) Drug abuse**
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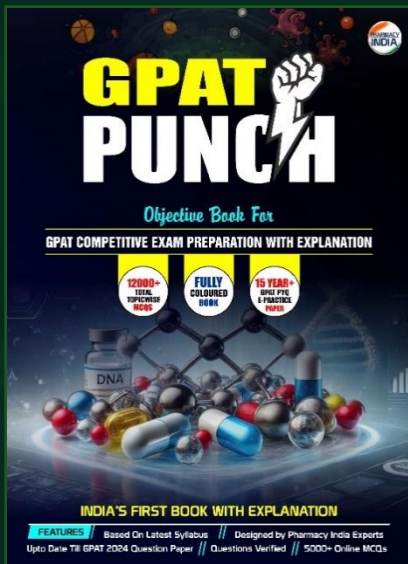
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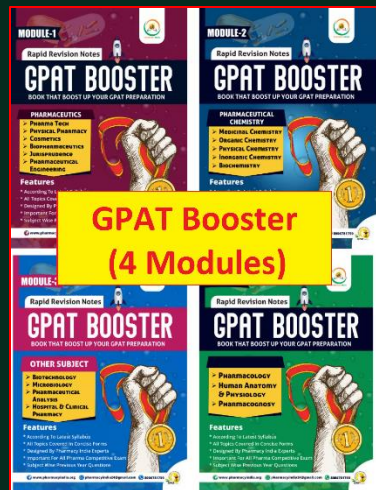
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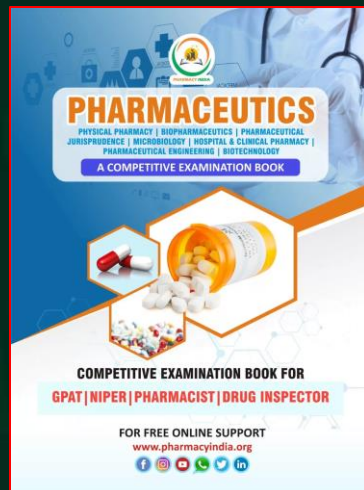
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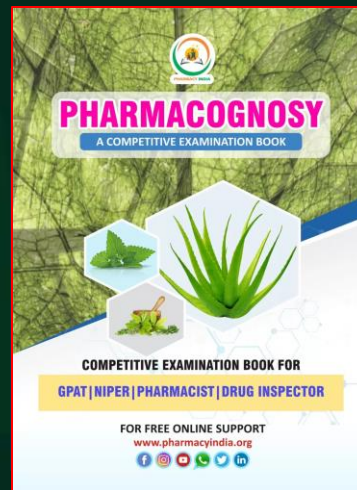


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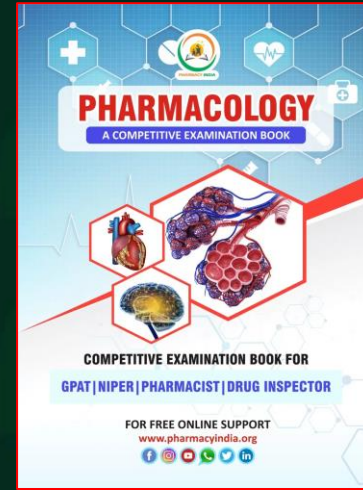
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41. Abrupt withdrawal of therapy is not recommended for following agents except

- (a) Propranolol**
- (b) Prednisolone**
- (c) Omeprazole**
- (d) Phenytoin**

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- (a) Propranolol
- (b) Prednisolone
- (c) Omeprazole**
- (d) Phenytoin

Explanation:

- **Abrupt Withdrawal Risks:**

- **Propranolol:** Can cause **rebound hypertension** and **tachycardia**. Gradual tapering is required.
- **Prednisolone:** Can **cause adrenal insufficiency**. Corticosteroids must be tapered off gradually.
- **Phenytoin:** Sudden **cessation can trigger seizures**. Tapering is essential.
- **Omeprazole:** A **proton pump inhibitor** that can be stopped abruptly without significant **withdrawal symptoms**, as it does not cause physical dependence.

42.

All of the following Agents are teratogenic drug except

- (a) Tetracycline**
- (b) Methotrexate**
- (c) Penicillin**
- (d) Valproic acid**

42.

All of the following Agents are teratogenic drug except

- (a) Tetracycline
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- (c) Penicillin
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Explanation: Human Teratogenic Drugs

Drug	Abnormality
Tetracyclines	Discolored and deformed teeth, retarded bone growth
Methotrexate	A strong teratogen, causing severe birth defects by disrupting cell division.
Valproate sodium	Spina bifida and other neural tube defects, heart and limb abnormalities

43. Which of the following substances cannot be absorbed by activated charcoal?

- (a) Caustics and hydrocarbons**
- (b) Pesticides and alkaloids**
- (c) Strong acids and barbiturates**
- (d) Organic solvents and heavy metals**

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Explanation:

Prevention of absorption of ingested poison

- A suspension of 20–40 g (1g/kg) of activated charcoal, which has large surface area and can adsorb many chemicals, should be administered in 200 ml of water.
- However, strong acids and alkalies, metallic salts, iodine, cyanide, caustics, alcohol, hydrocarbons and other organic solvents are not adsorbed by charcoal.
- Charcoal should not be administered if there is paralytic ileus or intestinal obstruction or when the patient reports > 2 hours after ingesting the poison.

44. Toxic effect of the drug leading to abnormalities of genetic material (genes, chromosomes) is known as

- (a) Mutagenic effect**
- (b) Teratogenic effect**
- (c) Pharmacogenetics**
- (d) Idiosyncrasy**

44.

Toxic effect of the drug leading to abnormalities of genetic material (genes, chromosomes) is known as

(a) Mutagenic effect

(b) Teratogenic effect

(c) Pharmacogenetics

(d) Idiosyncrasy

Explanation:

Mutagenicity and Carcinogenicity

- It refers to **capacity of a drug to cause genetic defects** and cancer respectively.
- Usually oxidation of the drug results in the production of reactive intermediates which affect genes and may cause **structural changes in the chromosomes**.
- **Covalent interaction with DNA** can modify it to induce mutations, which may manifest as heritable defects in the next generation.

45. Which of the following is safe drug for nursing mother

- (a) Chloramphenicol**
- (b) Digoxin**
- (c) Lithium**
- (d) Amphetamines**

45. Which of the following is safe drug for nursing mother

(a) Chloramphenicol

(b) Digoxin

(c) Lithium

(d) Amphetamines

Explanation:

- **Digoxin:** Safe for breastfeeding mothers due to low milk transfer and minimal infant exposure.
- **Chloramphenicol:** Contraindicated as it can pass into milk and cause serious effects like gray baby syndrome or bone marrow suppression.

- **Lithium:** Contraindicated as it can transfer to breast milk in significant amounts, causing toxicity in infants.
 - **Amphetamines:** Unsafe due to potential stimulant effects on infants, such as irritability and poor feeding.
- Thus, **digoxin** is the safest option for breastfeeding mothers.

46. Drug contraindicated during breast feeding period

- (a) Morphine**
- (b) Propranolol**
- (c) Diuretics**
- (d) Bromocriptine**

46. Drug contraindicated during breast feeding period

(a) Morphine

(b) Propranolol

(c) Diuretics

(d) Bromocriptine

Explanation:

- **Bromocriptine:** Contraindicated during breastfeeding as it inhibits prolactin secretion, reducing milk production. It acts as an antigalactopoietic agent by activating dopaminergic receptors.
- **Morphine:** Although not ideal, it may be used cautiously at low doses under supervision.
- **Propranolol:** Safe for breastfeeding; negligible transfer to breast milk.
- **Diuretics:** May reduce milk supply but are not strictly contraindicated. Thus, **bromocriptine** is contraindicated as it strongly inhibits lactation.

47. Which drug intolerance can cause ataxia in some people?

- (a) Trifluoperazine**
- (b) Carbamazepine**
- (c) Chloroquine**
- (d) Quinine**

47.

Which drug intolerance can cause ataxia in some people?

(a) Trifluoperazine

(b) Carbamazepine

(c) Chloroquine

(d) Quinine

Explanation:

Intolerance

- It is the **appearance of characteristic toxic effects** of a drug in an individual at therapeutic doses.
- It is the **converse of tolerance** and **indicates a low threshold of the individual to the action of a drug**. These are individuals who fall on the extreme left side of the Gaussian frequency distribution curve for sensitivity to the drug.

Examples are:

- A single dose of triflupromazine induces muscular dystonias in some individuals, specially children.
- Only few doses of carbamazepine may cause ataxia in some people.
- One tablet of chloroquine may cause vomiting and abdominal pain in an occasional patient.

48.

What is the mechanism of Type-I (anaphylactic) reactions?

- (a) Production of IgE antibodies that bind to mast cells, causing histamine release**
- (b) Cytotoxicity caused by IgG and complement activation**
- (c) Formation of antigen-antibody complexes that precipitate on vascular endothelium**
- (d) Sensitized T-lymphocytes attacking specific tissues**

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- (c) Formation of antigen-antibody complexes that precipitate on vascular endothelium**
- (d) Sensitized T-lymphocytes attacking specific tissues**

Explanation:

Type-I (anaphylactic) reactions

- Reaginic antibodies (IgE) are produced which get fixed to the mast cells.
- On exposure to the drug, AG: AB reaction takes place on the mast cell surface releasing mediators like histamine, 5-HT, leukotrienes (especially LT-C4 and D4), prostaglandins, PAF, etc. resulting in urticaria, itching, angioedema, bronchospasm, rhinitis or anaphylactic shock.

- **Anaphylaxis** is usually **heralded by paresthesia**, flushing, swelling of lips, generalized itching, wheezing, palpitation followed by **syncope**.
- The **manifestations occur quickly** after challenge and are called immediate hypersensitivity.
- **Antihistaminic drugs** are beneficial in some of these reactions.

49. Which of the following is an example of a Type-II (cytotoxic) reaction?

- (a) Thrombocytopenia and hemolysis**
- (b) Stevens-Johnson syndrome**
- (c) Contact dermatitis**
- (d) Anaphylaxis**

49. Which of the following is an example of a Type-II (cytotoxic) reaction?

(a) Thrombocytopenia and hemolysis

(b) Stevens-Johnson syndrome

(c) Contact dermatitis

(d) Anaphylaxis

Explanation:

Type-II (cytolytic) reactions

- Drug + component of a specific tissue cell act as AG.
- The resulting antibodies (IgG, IgM) bind to the target cells; on reexposure AG: AB reaction takes place on the surface of these cells, complement is activated and cytolysis occurs, e.g. thrombocytopenia, agranulocytosis, aplastic anaemia, haemolysis, organ damage (liver, kidney, muscle), systemic lupus erythematosus.

50.

Which of the following is NOT associated with Type-III reactions?

- (a) Rashes and severe sickness**
- (b) Stevens-Johnson syndrome**
- (c) Agranulocytosis**
- (d) Polyarteritis nodosa**
inflammation of medium-sized arteries

50.

Which of the following is NOT associated with Type-III reactions?

- (a) Rashes and severe sickness**
- (b) Stevens-Johnson syndrome**
- (c) Agranulocytosis**
- (d) Polyarteritis nodosa**

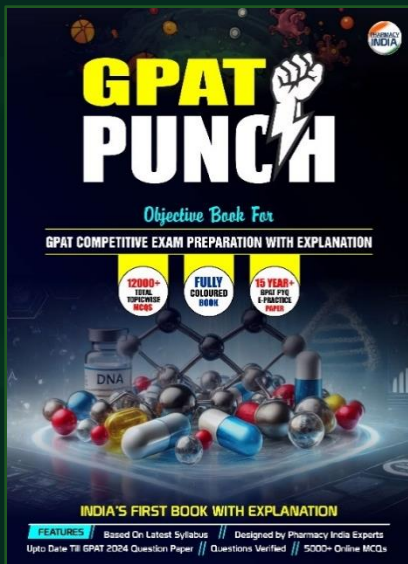
Explanation:

Type-III (retarded, Arthus) reactions

- These are mediated by **circulating antibodies** (predominantly IgG, mopping AB).
- **AG: AB complexes** bind complement and precipitate on vascular **endothelium** giving rise to a destructive inflammatory response.
- Manifestations are **rashes, serum sick ness** (fever, arthralgia, lymphadenopathy), **polyarteritis nodosa, Stevens-Johnson syndrome** (erythema multiforme, arthritis, nephritis, myocarditis, mental symptoms).
- The reaction usually **subsides in 1–2 weeks**.

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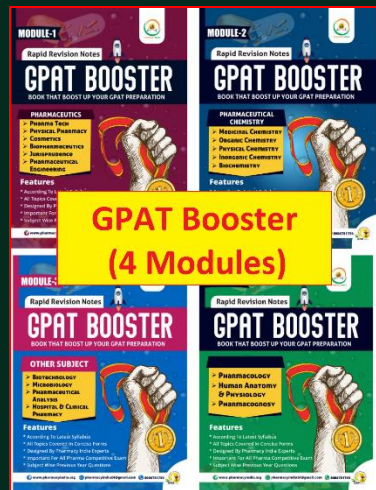
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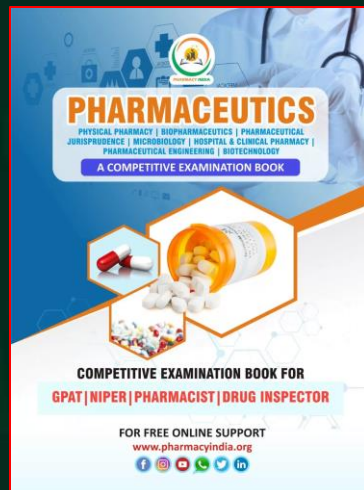
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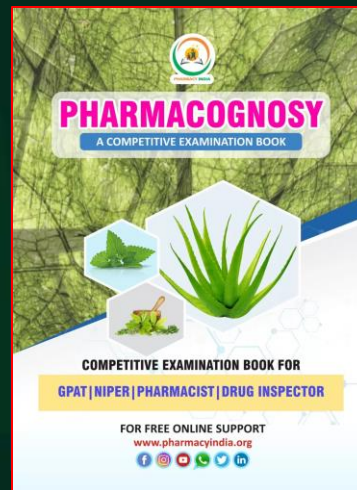


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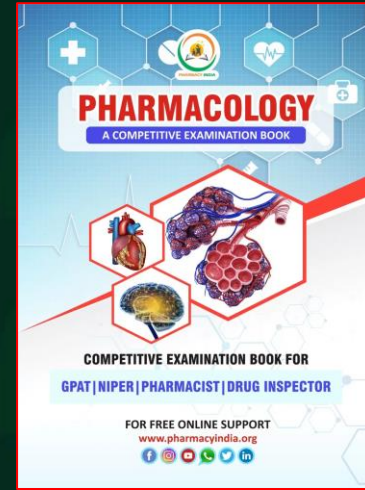
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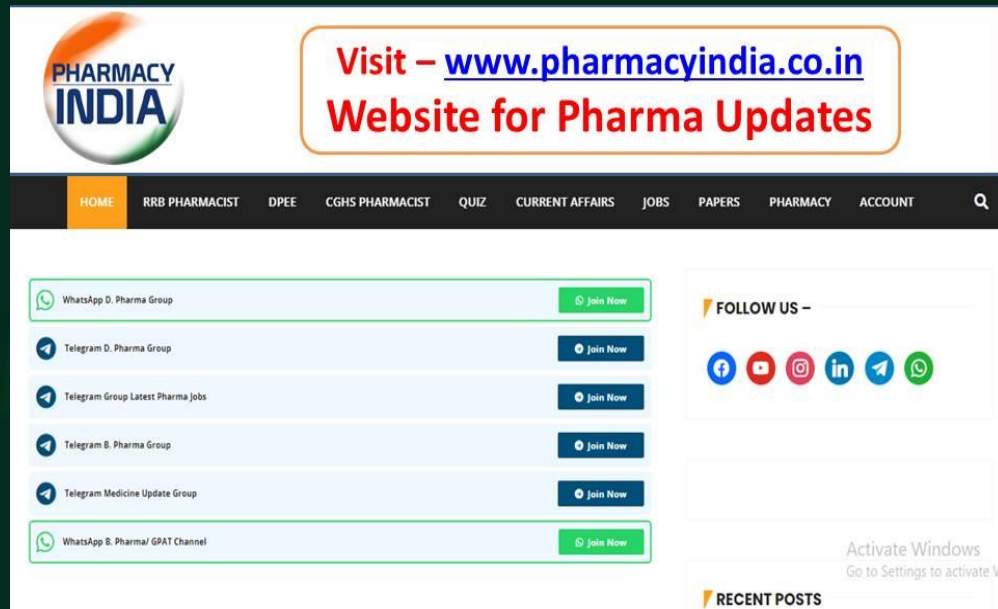


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