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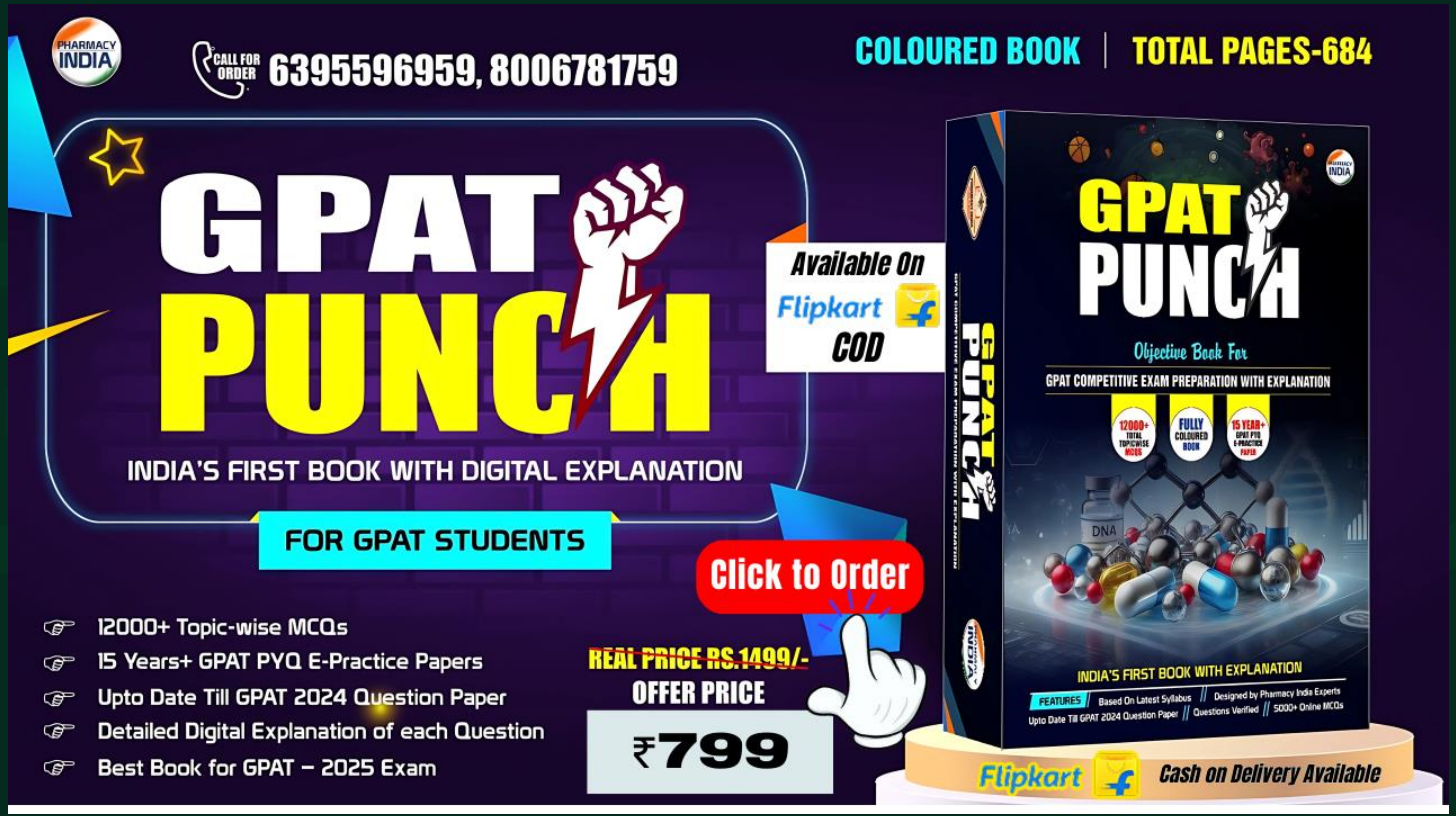

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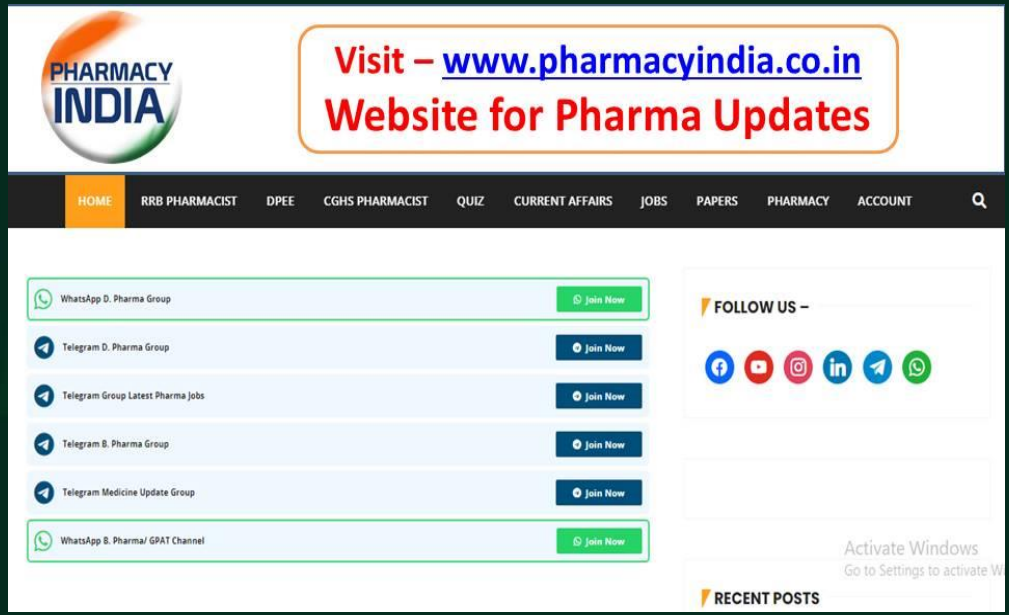

SUPPOSITORIES

1. **Sarong SpA semiautomatic equipment is used for the [GPAT – 2023 SHIFT – II]**

(a) Filling and packaging line for topical pharmaceutical aerosols

(b) Filling of hard gelatin capsule

(c) Production of suppositories

(d) Inserting rubber closure in vials

1. **Sarong SpA semiautomatic equipment is used for the [GPAT – 2023 SHIFT – II]**

(a) Filling and packaging line for topical pharmaceutical aerosols

(b) Filling of hard gelatin capsule

(c) Production of suppositories

(d) Inserting rubber closure in vials

- **Explanation:**

Sarong SpA is known for manufacturing semi-automatic and automatic equipment specifically designed for the production and filling of suppositories. This equipment is used to handle the precise filling and cooling processes required in suppository production.

2. Given below are two statements, one is labelled as Assertion [A] and the other is labelled as

Reason [R]

Assertion [A]: In the manufacturing of glycero-gelatin suppositories, overfilling of mould is necessary

Reason [R]: Glycero-gelatin bases contract very little on cooling and the excess cannot be neatly removed

2. **In light of the above statements, choose the correct answer from the options given below [GPAT – 2022]**

(a) Both [A] and [R] are true and [R] is the correct explanation of [A]

(b) Both [A] and [R] are true and [R] is the correct explanation of [A]

(c) [A] is true but [R] is false

(d) [A] is false but [R] is true

2. **In light of the above statements, choose the correct answer from the options given below [GPAT – 2022]**

(a) Both [A] and [R] are true and [R] is the correct explanation of [A]

(b) Both [A] and [R] are true and [R] is the correct explanation of [A]

(c) [A] is true but [R] is false

(d) [A] is false but [R] is true

- **Explanation:**

- **Assertion [A]:** In the manufacturing of **glycero-gelatin suppositories**, overfilling the mold is **not necessarily required**. While it's true that these bases contract very little upon cooling, the key reason for overfilling is not because excess material cannot be removed neatly, but to compensate for any minimal shrinkage. However, careful molding is usually used to avoid excess.
- **Reason [R]:** **Glycero-gelatin bases contract very little on cooling**, and this statement is true. These bases indeed have very minimal contraction, so there is less need for overfilling, but if overfilling is done, the excess can be removed with minimal issues.

The **assertion** is **false** because overfilling is not strictly necessary, while the **reason** is true, making option **(d)** correct.

3. When six suppositories containing 20 percent of morphine hydrochloride in Theobroma oil are to be prepared, which of the following statement is correct (Given: Displacement value of morphine hydrochloride is 1.5, weight of each suppository is 1g) GP 2010 [GPAT – 2020]

(a) The displacement value of morphine hydrochloride is to be considered

(b) The displacement values of both morphine hydrochloride and Theobroma oil are to be considered

(c) The displacement value of morphine hydrochloride is to be ignored

(d) The displacement value of Theobroma oil is to be considered

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(a) The displacement value of morphine hydrochloride is to be considered

(b) The displacement values of both morphine hydrochloride and Theobroma oil are to be considered

(c) The displacement value of morphine hydrochloride is to be ignored

(d) The displacement value of Theobroma oil is to be considered

- **Explanation:**

- When preparing **suppositories** containing **morphine hydrochloride** and **Theobroma oil**, the **displacement value** of the **active ingredient** **(morphine hydrochloride)** is **ignored** in this context.
- **Displacement value** is used to account for the volume displacement caused by the active ingredient. In the case of suppositories, it helps adjust the base material (here, **Theobroma oil**) to account for the volume that will be occupied by the active ingredient.

- However, since the question states that **Theobroma oil** is used as the base, and no specific information is given about considering the volume displacement of Theobroma oil or another excipient, it is typical to **ignore the displacement value of morphine hydrochloride** because Theobroma oil will accommodate it directly.
- Therefore, the focus is on **preparing** the required amount of **Theobroma oil** and ensuring it forms a proper base, without adjustments for the displacement of morphine hydrochloride.

4. **In case of suppositories base, SFI stands for [GPAT – 2019]**

(a) Solidified Fatty acid Indices

(b) Solid Fluid Indices

(c) Solidified Fatty acid Incline

(d) Solid Fat Index

4. **In case of suppositories base, SFI stands for [GPAT – 2019]**

(a) Solidified Fatty acid Indices

(b) Solid Fluid Indices

(c) Solidified Fatty acid Incline

(d) Solid Fat Index

- **Explanation:**

Solid-fat index (SFI):

- One can determine the solidification and melting ranges of fatty bases as well as the molding character, surface feel and hardness of the bases.
- The solid content at room temperature could determine suppository hardness. Since skin temperature is about 32° C, one can predict that would be dry to touch from a solid content over 30% at that temperature.

5. **The displacement value is defined as [GPAT – 2016]**

(a) Quantity of drug which displace one part of the base

(b) Quantity of base which displace one part of the drug

(c) Quantity of drug which displace one part of the acid

(d) Quantity of base which displace one part of the acid

5. **The displacement value is defined as [GPAT – 2016]**

(a) Quantity of drug which displace one part of the base

(b) Quantity of base which displace one part of the drug

(c) Quantity of drug which displace one part of the acid

(d) Quantity of base which displace one part of the acid

- **Explanation:**

Displacement value. A drug property which should be considered during the formulation of suspension

suppositories, where the drug is dispersed in the molten base, is the displacement value. The displacement value is the mass of drug that displaces 1 g of base, and it allows calculation of the required amount of base in the suppository formulation.

6. **Bougies are [GPAT – 2015]**

(a) Rectal suppository

(b) Urethral suppository

(c) Hydrogel suppository

(d) None of these

6. **Bougies are [GPAT – 2015]**

(a) Rectal suppository

(b) Urethral suppository

(c) Hydrogel suppository

(d) None of these

Explanation: TYPES OF SUPPOSITORIES

Types of Suppositories	Size of Suppository	Shape of Suppository
Rectal Suppositories	Adult- 2gm, Children – 1 gm	Torpedo shape
Vaginal Suppositories (Pessaries)	Vaginal tablets & Capsules 3 to 5 gm	Conical shape
Urethral Suppositories (Bogies)	Male -4gm, Female 2gm, length 60-75 mm	Pencil shaped
Nasal Suppositories	Weight 1 gm, length 9-10 cm	Cylindrical shape
Ear Cones (Aurinaries)	Weight 1 gm	Bullet shape

7. **The ideal saponification value for suppository base is [GPAT – 2014]**

(a) 50-100

(b) 100-150

(c) 150-200

(d) 200-500

7. **The ideal saponification value for suppository base is [GPAT – 2014]**

(a) 50-100

(b) 100-150

(c) 150-200

(d) 200-500

Explanation:

IDEAL PROPERTIES

- Should be completely non-toxic & non-irritant.
- Should be compatible with a broad variety of drugs.
- Should be non-sensitizing.
- Should have wetting & emulsifying properties.
- Should be stable on the storage i.e., does not change color, odor or drug release pattern.
- Should have **acid value below 0.2.**

- Should have **iodine value less than 7.**
- Should have “saponification value" ranges from **200 to 245.**
- The water no. is high i.e., high percentage of water can be incorporated in it.

8. Match the following terms and their examples [GPAT – 2006]

Group-1 (Term)	Group-II (Example)
1. Hydrophilic suppository Base	[P] Nitrocellulose
2. Polymorphism	[Q] Titanium dioxide
3. Film former used in the Formation	[R] Cocoa butter of nail lacquer
4. Opaquant extender	[S] Polyethylene glycol

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

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

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

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

8. Match the following terms and their examples [GPAT – 2006]

Group-1 (Term)	Group-II (Example)
1. Hydrophilic suppository Base	[P] Nitrocellulose
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(a) 1-[P], 2-[Q], 3-[R], 4-[S]

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

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

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

Explanation:

Hydrophilic suppositories base	Gelatin, polyethylene glycol
Polymorphism	Cocoa Butter
Film former used in the formation of nail lacquer	Nitro cellulose, ethyl cellulose, vinyl polymers
Opaquant extender	Titanium oxide

EXAMPLES OF SUPPOSITORY BASE

SUPPOSITORY BASE	EXAMPLE
Oleaginous (Fatty) Base	Cocoa Butter (Theobroma oil), Synthetic Fats, Hydrogenated palm kernel oil
Aqueous Base	Glycerinated gelatin (14 % Gelatin + 70% glycerine + Water) Soap glycerine, Polyethylene glycol (Macrogol)
Emulsifying Base	Massa esterinum, Witepsol, Massupol

DIFFERENT POLYMORPHOUS FORM OF COCA BUTTER

POLYMORPH	M.P.°C	DESCRIPTION
α - form	24	Obtained by suddenly cooling melted coca butter at 0°C
β - form	28-31	Crystallizes out from liquified coca butter on stirring at 18-23°C
β - form	34-35	Most stable from for making suppositories
γ - form	18	Obtained by rapid cooling to liquefied cocoa butter at refrigeration temperature

9. **Which of the following is NOT an ideal property of bases**

(a) Shall be non-irritant

(b) Shall not interfere in release

(c) Shall be compatible with drugs

(d) None of the above

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Explanation:

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- Should be completely non-toxic & non-irritant.
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- Should be non-sensitizing.
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- Should have “saponification value" ranges from **200 to 245.**
- The water no. is high i.e., high percentage of water can be incorporated in it.

10. **Which of the following is an example of Hydrophilic bases**

(a) Hydrogenated oils

(b) Emulsified cocoa butter

(c) Glycero-gelatin base

(d) None of the above

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Explanation:

TYPES OF SUPPOSITORY BASE

Oleaginous (fatty) base	Cocoa butter (Theobroma oil), Synthetic fats, Hydrogenated palm kernel oil
Aqueous base	Glycerinated gelatin (14% gelatin + 70% glycerine + Water), Soap glycerine, Polyethylene glycol (Macrogol).
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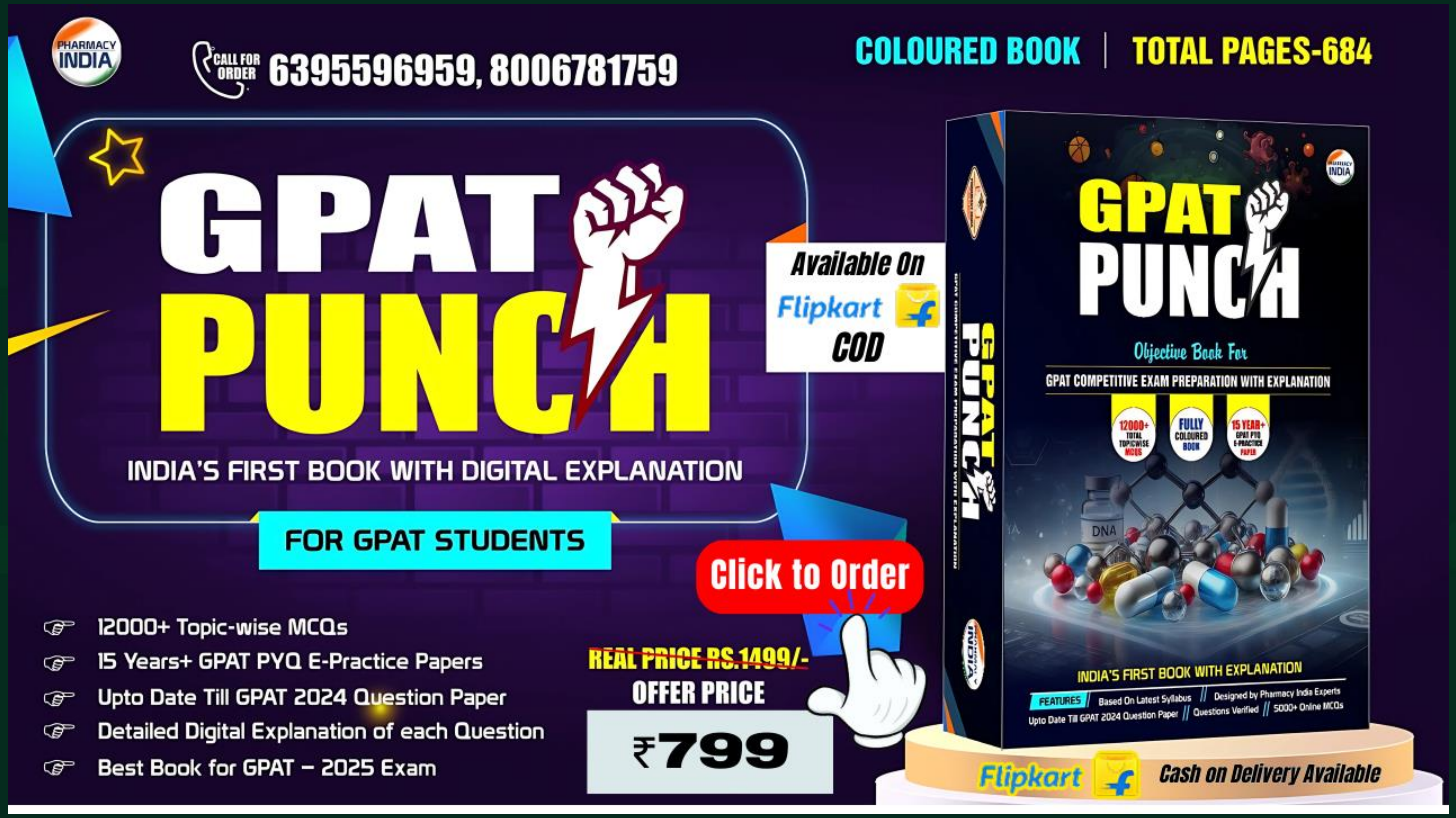

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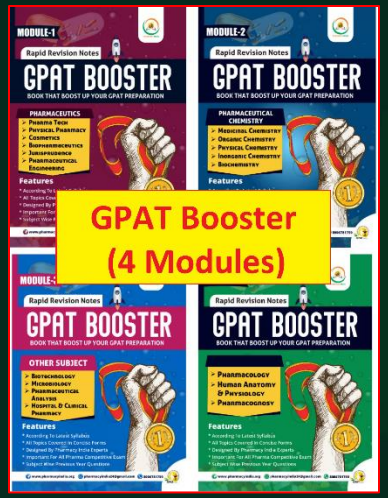

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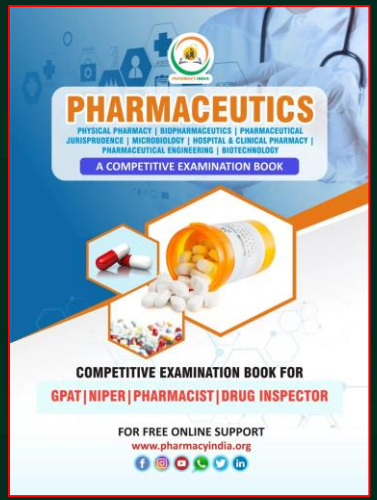

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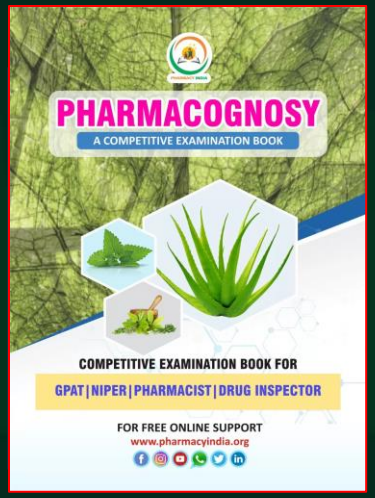

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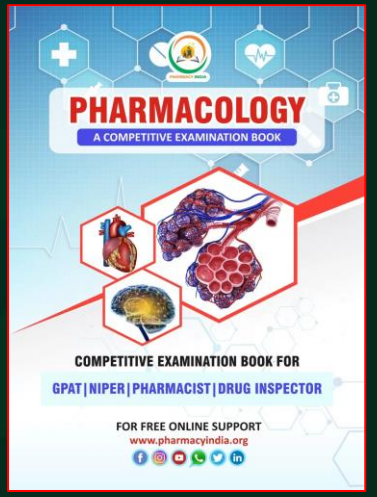

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11. **Which of the following is an example of oily bases**

(a) Witespol

(b) Emulsified cocoa butter

(c) Glycero-gelatin base

(d) Massupol

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(b) Emulsified cocoa butter

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Explanation:

TYPES OF SUPPOSITORY BASE

Oleaginous (fatty) base	Cocoa butter (Theobroma oil), Synthetic fats, Hydrogenated palm kernel oil
Aqueous base	Glycerinated gelatin (14% gelatin + 70% glycerine + Water), Soap glycerine, Polyethylene glycol (Macrogol).
Emulsifying base	Massa esterinum, Witepsol, Massupol

12. **Which of the following is NOT an example of Hydrophilic bases**

(a) Soap-glycerin base

(b) Emulsified cocoa butter

(c) Glycero-gelatin base

(d) None of the above

12. **Which of the following is NOT an example of Hydrophilic bases**

(a) Soap-glycerin base

(b) Emulsified cocoa butter

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Explanation:

TYPES OF SUPPOSITORY BASE

Oleaginous (fatty) base	Cocoa butter (Theobroma oil), Synthetic fats, Hydrogenated palm kernel oil
Aqueous base	Glycerinated gelatin (14% gelatin + 70% glycerine + Water), Soap glycerine, Polyethylene glycol (Macrogol).
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13. **Which of the following is substitute for Theobroma oil**

(a) Hydrogenated oils

(b) Emulsified cocoa

(c) Polyethylene-Glycol

(d) Nonez

13. **Which of the following is substitute for Theobroma oil**

(a) Hydrogenated oils

(b) Emulsified cocoa

(c) Polyethylene-Glycol

(d) Nonez

Explanation:

Theobroma oil (also known as cocoa butter) – once a very commonly used base – is no longer used because of its many disadvantages, such as its polymorphic behaviour, insufficient contraction during cooling, low softening point, chemical instability, poor water absorptive power and high cost.

14. **Which of the following is an Obsolete method of suppositories**

(a) Hand Rolling

(b) Fusion method

(c) Cold compression

(d) None of the above

14. **Which of the following is an Obsolete method of suppositories**

(a) Hand Rolling

(b) Fusion method

(c) Cold compression

(d) None of the above

Explanation:

- **Hand Rolling (a): Hand rolling** is an obsolete method of preparing suppositories where the suppository base and drug are manually rolled into a cylindrical shape. This method is no longer widely used due to its inefficiency and lack of precision in shaping suppositories.
- **Fusion method (b):** The **fusion method** is still a commonly used method for preparing suppositories. It involves melting the suppository base, mixing in the drug, and then cooling the mixture in molds to form the suppositories.

- **Cold compression (c):** The **cold compression method** is also still in use. In this method, the drug and base are mixed and then compressed into molds at room temperature, which is particularly useful for bases that do not require heat to melt.

15. **Which of the following bases are more brittle**

(a) Synthetic fat bases with high stearate concentrations

(b) Those that are highly hydrogenated

(c) Both (a) and (b)

(d) None of the above

15. **Which of the following bases are more brittle**

(a) Synthetic fat bases with high stearate concentrations

(b) Those that are highly hydrogenated

(c) Both (a) and (b)

(d) None of the above

Explanation:

Synthetic fat bases with a high degree of hydrogenation and high stearate contents, and therefore a higher solid content at room temperature, are usually more brittle. Fracturing of the suppository made with such bases is often induced by rapid chilling (shock cooling) of the melted bases in an extremely cold mold.

16. **Which of the following is second step in fusion method**

(a) Melting the suppository base

(b) Allowing the melt to congeal

(c) Removing the formed suppositories from the mould

(d) Dispersing or dissolving the drug in the melted base

16. **Which of the following is second step in fusion method**

(a) Melting the suppository base

(b) Allowing the melt to congeal

(c) Removing the formed suppositories from the mould

(d) Dispersing or dissolving the drug in the melted base

Explanation:

- In the **fusion method** for preparing suppositories, the general steps are as follows:
  1. **Melting the suppository base**.
  2. **Dispersing or dissolving the drug in the melted base** (second step).
  3. Pouring the mixture into molds.
  4. Allowing the melt to congeal.
  5. Removing the formed suppositories from the mold.
- Therefore, the correct answer is **(d) Dispersing or dissolving the drug in the melted base**.

17. **Vaginal suppositories also called as**

(a) Pessaries

(b) Simple suppositories

(c) Bougies

(d) None of the above

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(a) Pessaries

(b) Simple suppositories

(c) Bougies

(d) None of the above

Explanation: TYPES OF SUPPOSITORIES

Types of Suppositories	Size of Suppository	Shape of Suppository
Rectal Suppositories	Adult- 2gm, Children – 1 gm	Torpedo shape
Vaginal Suppositories (Pessaries)	Vaginal tablets & Capsules 3 to 5 gm	Conical shape
Urethral Suppositories (Bogies)	Male -4gm, Female 2gm, length 60-75 mm	Pencil shaped
Nasal Suppositories	Weight 1 gm, length 9-10 cm	Cylindrical shape
Ear Cones (Aurinaries)	Weight 1 gm	Bullet shape

18. “Oleum theobromae” was first recommended by

(a) A.B. Taylor

(b) Griffin

(c) Stocks’s

(d) None of the above

18. “Oleum theobromae” was first recommended by

(a) A.B. Taylor

(b) Griffin

(c) Stocks’s

(d) None of the above

Explanation:

- Oleum Theobromae, also known as theobroma oil or cocoa butter, was introduced to American pharmacists by A.B. Taylor in 1852 as a suitable base for suppositories.
- Its recommendation was based on its unique properties, which made it an ideal medium for delivering medications in this form.
- Cocoa butter is a natural fat derived from cocoa beans, possessing a solid consistency at room temperature and melting at body temperature, which allows for the easy release of the active ingredient once inside the body.

19. **Weight of rectal suppository for adults is**

(a) 1g

(b) 5g

(c) 2g

(d) 0.25g

19. **Weight of rectal suppository for adults is**

(a) 1g

(b) 5g

(c) 2g

(d) 0.25g

Explanation: TYPES OF SUPPOSITORIES

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Ear Cones (Aurinaries)	Weight 1 gm	Bullet shape

20. **Urethral suppositories also called as**

(a) Pessaries

(b) Bougies

(c) Both (a) and (b)

(d) None of the above

20. **Urethral suppositories also called as**

(a) Pessaries

(b) Bougies

(c) Both (a) and (b)

(d) None of the above

Explanation:

- Urethral suppositories, sometimes called bougies, are pencil-shaped and pointed at one extremity.
- Urethral suppositories intended for males weigh about 4 g each and are 100 to 150 mm long; for females, they are 2 g each and usually 60 to 75 mm in length.

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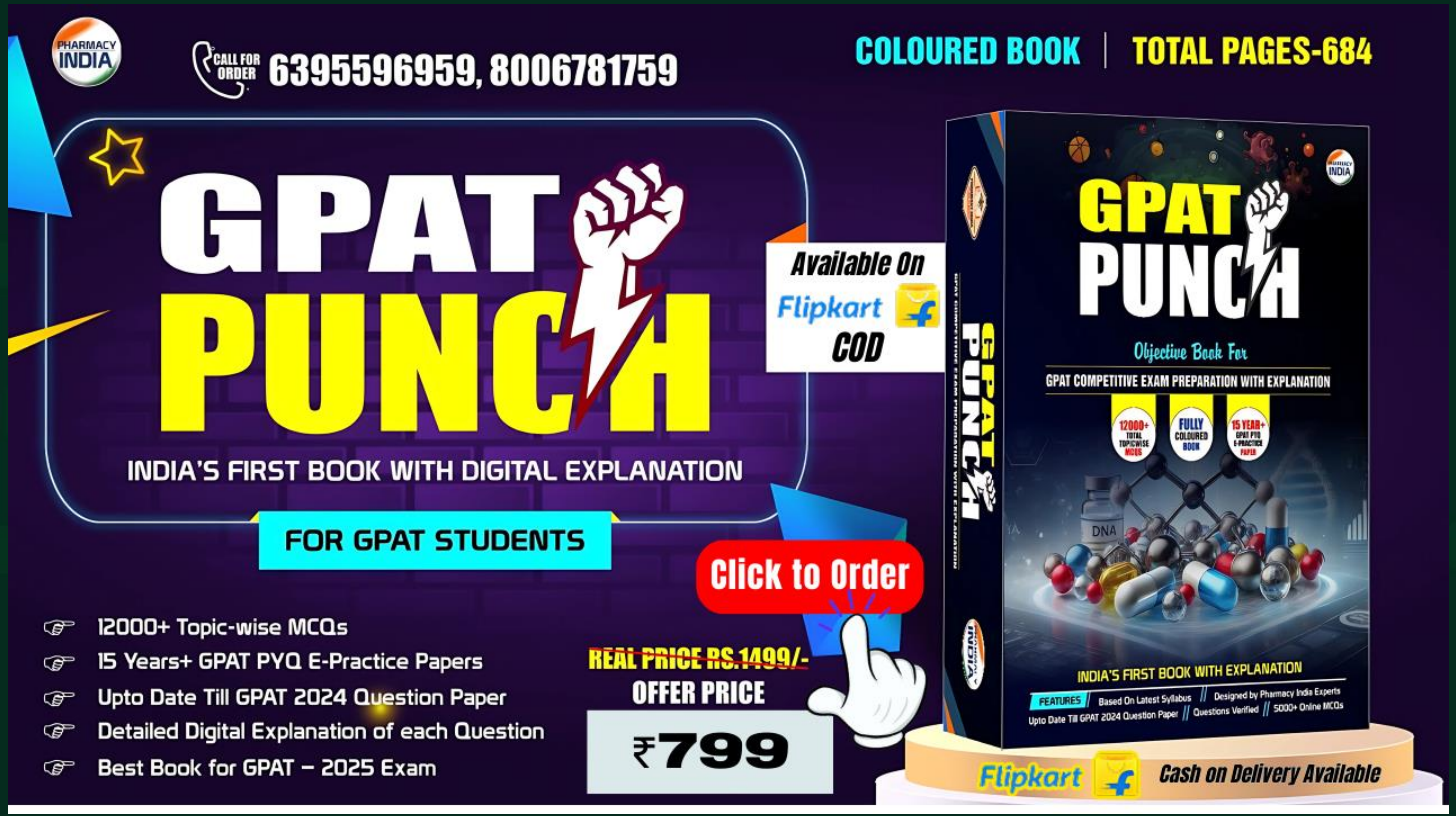

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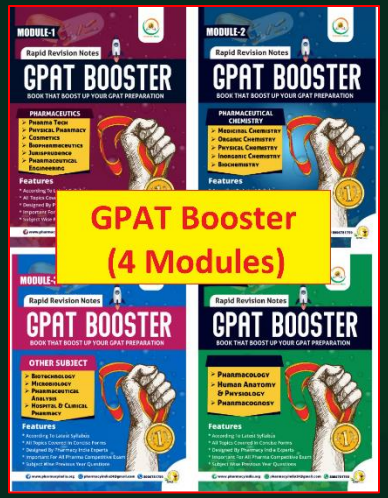

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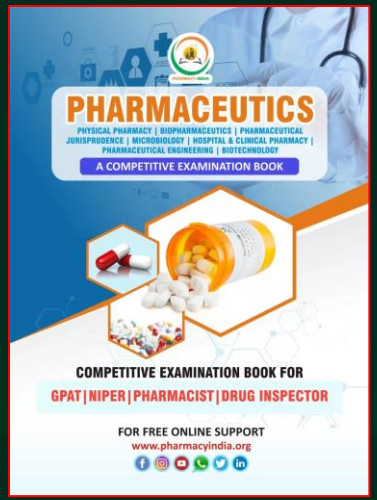

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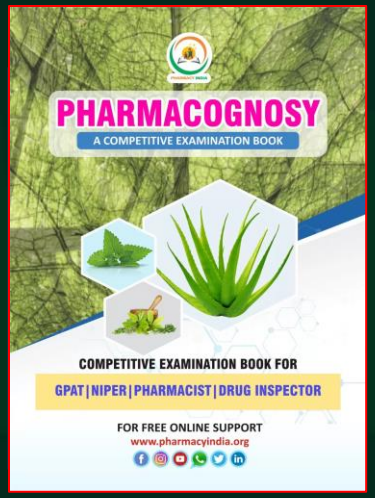

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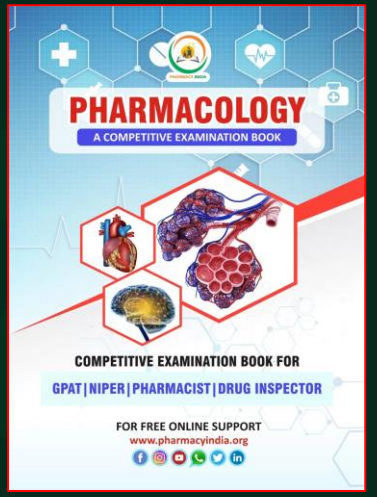

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21. **The number of milligrams of KOH required neutralizing free acids & saponify the esters contained in 1 g of fat is known as**

(a) Iodine value

(b) Saponification value

(c) Water number

(d) Acid value

21. The number of milligrams of KOH required neutralizing free acids & saponify the esters contained in 1 g of fat is known as

(a) Iodine value

(b) Saponification value

(c) Water number

(d) Acid value

Explanation:

Saponification Value:

- "The number of milligrams of KOH (Potassium hydroxide) required to neutralize the free fatty acids and saponify the ester contained in 1 g of a fat."
- From saponification value we can know the type of glyceride present (mono-, di- or tri-) and also amount present.

22. **The number of grams of iodine that reacts with 100 g of fat is known as**

(a) Iodine value

(b) Saponification value

(c) Water number

(d) Acid value

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(a) Iodine value

(b) Saponification value

(c) Water number

(d) Acid value

Explanation:

Iodine value:

- It is the number of grams of Iodine that reacts with l00 g of fat or other unsaturated material.
- The possibility of decomposition by moisture, acids, oxygen (which leads to rancidity of fats) increases with higher iodine value.

23. **The number of milligrams of KOH required neutralizing free acids in I g of fat is known as**

(a) Iodine value

(b) Saponification value

(c) Hydroxyl value

(d) Acid value

23. **The number of milligrams of KOH required neutralizing free acids in I g of fat is known as**

(a) Iodine value

(b) Saponification value

(c) Hydroxyl value

(d) Acid value

Explanation:

Acid value:

- It is the number of milligrams of KOH (Potassium hydroxide) required neutralizing the free fatty acids in I g substance (fat).
- Low acid value or absence of acid value is important for good suppository bases.

24. **Cocoa butter available in following forms**

(a) α-form

(b) β-form

(c) γ-form

(d) All of the above

24. **Cocoa butter available in following forms**

(a) α-form

(b) β-form

(c) γ-form

(d) All of the above

Explanation:

Cocoa butter or Theobroma Oil

- Cocoa butter is fat obtained from the roasted seed of Theobroma cocoa.
- Chemically, it is a triglyceride (combination of glycerin and one or different fatty acids) primarily of oleopalmitostearin and oleodistearine.
- It melts at 30 - 35^0C,
- Iodine value – 34 to 38.
- Acid value is not higher than 4.

DIFFERENT POLYMORPHOUS FORM OF COCA BUTTER

POLYMORPH	M.P.°C	DESCRIPTION
α - form	24	Obtained by suddenly cooling melted coca butter at 0°C
β - form	28-31	Crystallizes out from liquified coca butter on stirring at 18-23°C
β - form	34-35	Most stable from for making suppositories
γ - form	18	Obtained by rapid cooling to liquefied cocoa butter at refrigeration temperature

25. The solidification point of cocoa butter lies between

(a) 12-13°

(b) 20-30°

(c) 5-10°

(d) 20-25°

25. The solidification point of cocoa butter lies between

(a) 12-13°

(b) 20-30°

(c) 5-10°

(d) 20-25°

Explanation:

- Cocoa butter exhibits marked polymorphism (the property of existing in different crystalline forms), a phenomenon probably attributable to the high proportion of unsaturated triglycerides.
- Each of the different forms of cocoa butter has different melting points, as well as different drug release rates.
- When cocoa butter is heated above its melting temperature (about 36°C) and chilled to its solidification point (below 15°C), immediately after returning to room temperature this cocoa butter has a melting point of about 24°C, approximately 12° below its original state.
- A knowledge of these polymorphic states is essential for an understand.

26. **Which route showed similar effectiveness to intravenous administration in the study of theophylline derivatives?**

(a) Oral administration

(b) Enema retention

(c) Rectal administration

(d) Timed disintegrating tablets

26. **Which route showed similar effectiveness to intravenous administration in the study of theophylline derivatives?**

(a) Oral administration

(b) Enema retention

(c) Rectal administration

(d) Timed disintegrating tablets

Explanation:

- Rudolfo et al. reported blood levels resulting from the oral, rectal, and intravenous administration of theophylline derivatives.
- Rectal retention enemas and intravenous injections showed that these two routes are similarly effective if allowance is made for the approximately 30 min delay required for drug absorption from the rectum.

27. **Which drug's absorption is slower by the rectal route than oral administration?**

(a) Morphine

(b) Sodium iodide

(c) Sodium salicylate

(d) Methylene blue

27. **Which drug's absorption is slower by the rectal route than oral administration?**

(a) Morphine

(b) Sodium iodide

(c) Sodium salicylate

(d) Methylene blue

Explanation:

- Enesco and coworkers made a comparative study on the absorption time of six drugs, namely sodium salicylate, chloral hydrate, methylene blue, atropine, morphine, and sodium iodide.
- The first five drugs are absorbed rectally more quickly and at therapeutically more effective levels than with oral administration.
- Absorption of sodium iodide is slower by the rectal route than by the oral route, but varies considerably from one individual to another.

28. **What is the melting point range of cocoa butter?**

(a) 15°C to 20°C

(b) 18°C to 23°C

(c) 30°C to 35°C

(d) 36°C to 40°C

28. What is the melting point range of cocoa butter?

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(c) 30°C to 35°C

(d) 36°C to 40°C

Explanation:

Cocoa butter or Theobroma Oil

- Cocoa butter is fat obtained from the roasted seed of Theobroma cocoa.
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29. **What happens to cocoa butter when it is overheated and then returned to room temperature?**

(a) It solidifies with the same melting point.

(b) Its melting point decreases to about 24°C.

(c) It loses its crystalline structure permanently.

(d) It becomes chemically reactive.

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Explanation:

- When cocoa butter is heated above its melting temperature (about 36°C) and chilled to its solidification point (below 15°C), immediately after returning to room temperature this cocoa butter has a melting point of about 24°C, approximately 12° below its original state.
- A knowledge of these polymorphic states is essential for an understanding of how uniform drug release patterns can be obtained from suppository bases consisting primarily of cocoa butter.

30. **Which crystalline form of cocoa butter has a melting point between 34°C and 35°C?**

(a) The α form

(b) The β' form

(c) The β form

(d) The γ form

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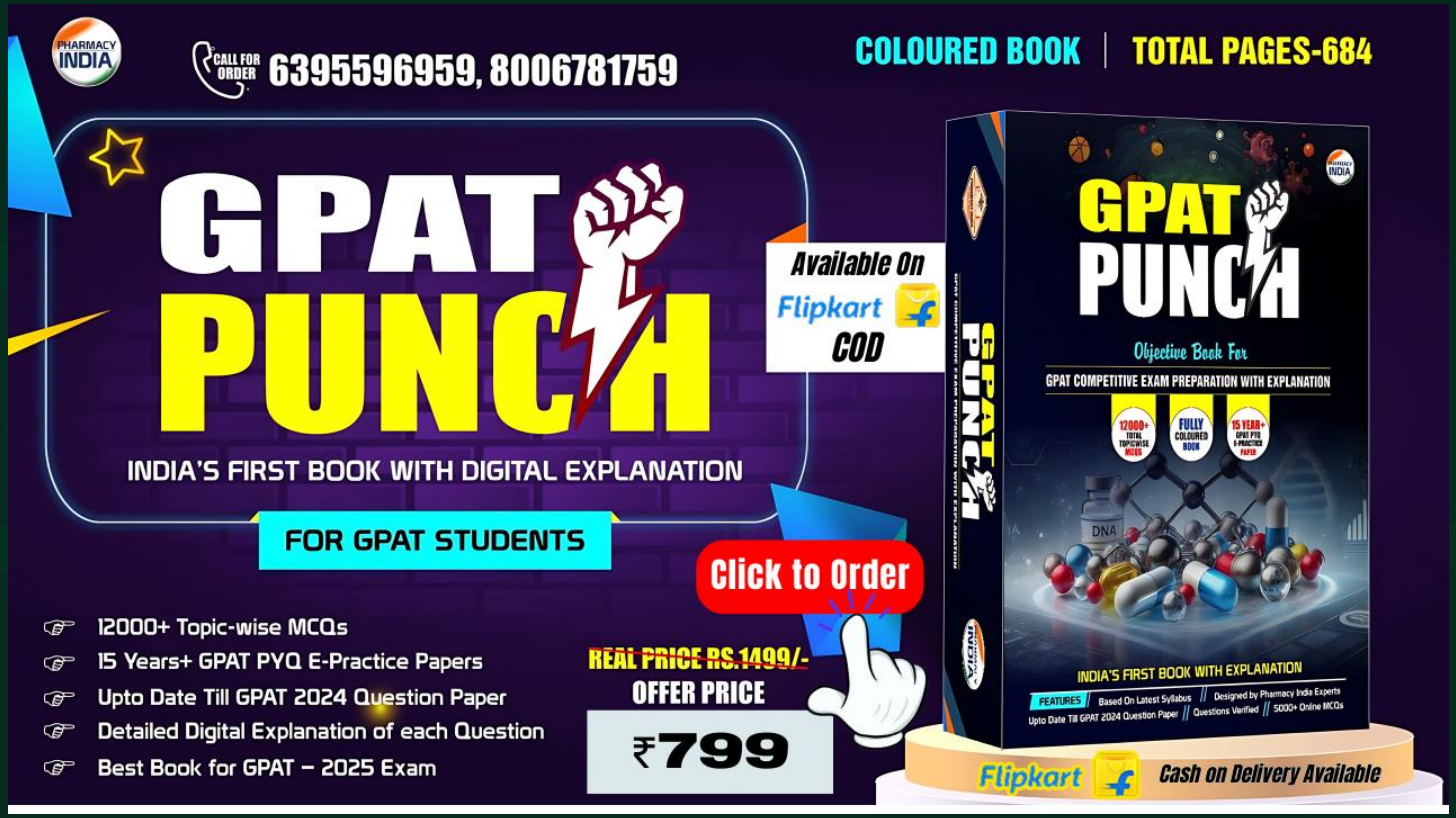

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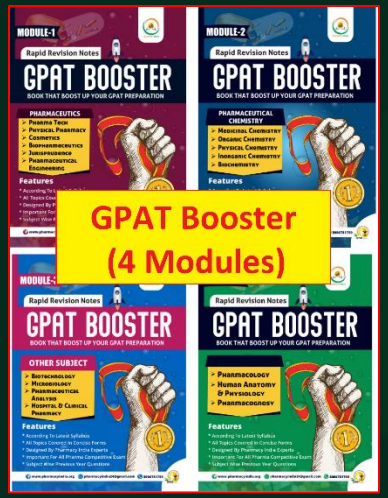

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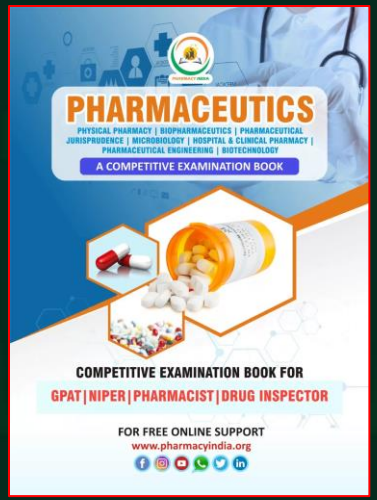

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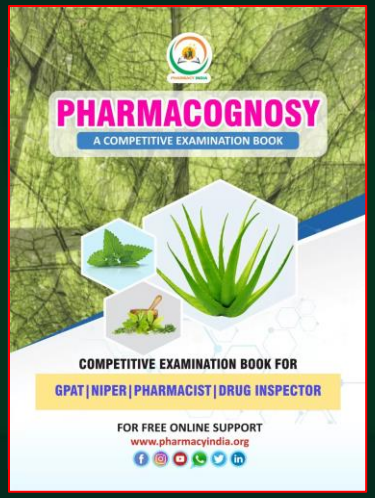

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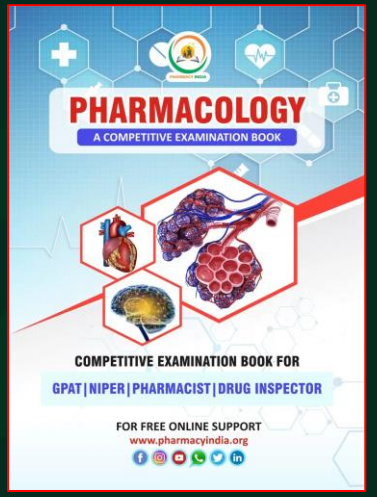

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31. **Which process helps in accelerating the change from unstable to stable crystals in cocoa butter?**

(a) Melting at low temperatures

(b) Freezing the cocoa butter immediately

(c) Adding small amounts of stable crystals to the melted mass

(d) Avoiding the use of molds during solidification

31. **Which process helps in accelerating the change from unstable to stable crystals in cocoa butter?**

(a) Melting at low temperatures

(b) Freezing the cocoa butter immediately

(c) Adding small amounts of stable crystals to the melted mass

(d) Avoiding the use of molds during solidification

- **Explanation**:

The formation of the unstable forms can be avoided by various methods

(1)If the mass is not completely melted, the remaining crystals prevent the formation of the unstable form.

(2)Small amounts of stable crystals added to the melted cocoa butter accelerate the change from the unstable to the stable form; this process is called "seeding."

(3)The solidified melt is tempered at temperatures between 28 and 32°C for hours or days, causing a comparatively quick change from the unstable to the stable form.

32. **What is the process of adding stable crystals to melted cocoa butter called?**

(a) Tempering

(b) Crystallizing

(c) Solidifying

(d) Seeding

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33. What is the primary advantage of hydrogenating corn oil?

(a) Reducing the cost of production

(b) Increasing the percentage of solid triglycerides at room temperature

(c) Lowering its melting point drastically

(d) Enhancing its liquid consistency

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Explanation:

- Fat-type suppository bases are produced from a variety of materials, either synthetic or natural in origin.
- For example, such vegetable oils as coconut or palm kernel oil are modified by esterification, hydrogenation, and fractionation at different melting ranges to obtain the desired product.
- An inexpensive method involves hydrogenation of corn oil to reduce unsaturation and so increase the percentage of solid triglycerides at room temperature.
- The triglycerides with lower melting points are then removed by solvent extraction or by pressing. Manufacturers of fats and oils refer to this type of product as a "hard butter."

34. **What is the purpose of glycerinated gelatin suppositories?**

(a) To dissolve quickly at body temperature

(b) To serve as a cathartic

(c) To deliver antimicrobial agents locally

(d) To protect from environmental moisture

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Explanation:

Glycerin Suppositories

- The glycerin is heated in a suitable container to about 120°C.
- The sodium stearate is dissolved, with gentle stirring, in the heated glycerin, after which the purified water is added and mixed, and the hot mixture is immediately poured into a suitable mold.

- In addition to the above official preparation, USP XX also provided an unofficial formula for glycerated gelatin suppositories:

  Drug and purified water 10 g

  Gelatin 20 g

  Glycerin 70 g

- This formula is most often used in vaginal suppositories, where local application of antimicrobial agents is intended.

35. **Which component in glycerinated gelatin suppositories helps to regulate solution time?**

(a) Sodium stearate

(b) Gelatin/glycerin/water ratio

(c) Environmental moisture content

(d) Reaction of gelatin with the drug

35. **Which component in glycerinated gelatin suppositories helps to regulate solution time?**

(a) Sodium stearate

(b) Gelatin/glycerin/water ratio

(c) Environmental moisture content

(d) Reaction of gelatin with the drug

Explanation:

- Glycerinated gelatin suppositories do not melt at body temperature, but rather dissolve in the secretions of the body cavity in which they are inserted.
- Solution time is regulated by the proportion of gelatin/glycerin/water used, the nature of the gelatin used, and the chemical reaction of the drug with gelatin.

36. When does absorption from water-containing suppositories improve?

(a) When an oil-in-water emulsion contains more than 50% water in the external phase.

(b) When the water content is below 10%.

(c) When water evaporates after the preparation.

(d) When water is used without emulsification.

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(c) When water evaporates after the preparation.

(d) When water is used without emulsification.

Explanation:

Water in Suppositories

- Use of water as a solvent for incorporating substances in suppository bases should be avoided for the following reasons:
- Water accelerates the oxidation of fats.
- If the water evaporates, the dissolved substances crystallize out.
- Unless the water is present at a level significantly higher than that required for dissolving the drug, the water has little value in facilitating drug absorption.

- Absorption from water-containing suppositories is enhanced only if an oil-in-water emulsion exists with more than 50% of the water in the external phase.
- Reactions between ingredients contained in suppositories are more likely to occur in the presence of water.
- Sometimes, anhydrous chemicals are used to avoid this possibility.
- The incorporation of water or other substances that might be contaminated with bacterial or fungal growth necessitates the addition of bacteriostatic agents such as the parabens.

37. **How does molecular weight affect the hygroscopicity of polyethylene glycol bases?**

(a) Higher molecular weight increases hygroscopicity.

(b) Higher molecular weight decreases hygroscopicity.

(c) Molecular weight has no effect.

(d) Lower molecular weight decreases hygroscopicity.

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(c) Molecular weight has no effect.

(d) Lower molecular weight decreases hygroscopicity.

Explanation:

Hygroscopicity

- Glycerinated gelatin suppositories lose moisture by evaporation in dry climates and absorb moisture under conditions of high humidity.
- Polyethylene glycol bases are also hygroscopic. The rate of moisture change in polyethylene glycol bases depends not only on humidity and temperature, but also on the chain length of the molecule.
- As the molecular weight of these, ethylene oxide polymers increases, the hygroscopicity decreases, with a significant drop for the 4000 and the 6000 series.

38. **Which of the following is incompatible with polyethylene glycol bases?**

(a) Salicylic acid

(b) Sodium stearate

(c) Parabens

(d) Gelatin

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(a) Salicylic acid

(b) Sodium stearate

(c) Parabens

(d) Gelatin

Explanation:

Incompatibilities

- Polyethylene glycol bases were found to be incompatible with silver salts, tannic acid, aminopyrine, quinine, ichthammol, aspirin, benzocaine, iodochlorhydroxyquin, and sulfonamides.
- Many chemicals have a tendency to crystallize out of polyethylene glycol, e.g. sodium barbital, salicylic acid, and camphor.
- Higher concentrations of salicylic acid soften polyethylene glycol to an ointment-like consistency, and aspirin complexes with it.
- Penicillin G, although stable in cocoa butter and other fatty bases, was found to decompose in polyethylene glycol bases. Fatty bases with significant hydroxyl values may react with acidic ingredients.

39. **What can be added to increase the viscosity of a suppository base?**

(a) Sodium stearate

(b) Aluminum monostearate

(c) Glycerin

(d) Parabens

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(a) Sodium stearate

(b) Aluminum monostearate

(c) Glycerin

(d) Parabens

Explanation:

The following approaches may be taken to overcome the problems caused by use of low viscosity bases:

- Use a base with a more narrow melting range that is closer to body temperature.
- The inclusion of approximately 2% aluminum monostearate not only increases the viscosity of the fat base considerably, but also aids in maintaining a homogeneous suspension of insoluble materials. Cetyl, stearyl, or myristyl alcohols or stearic acid are added to improve the consistency of suppositories.

40. **What is a common cause of brittleness in synthetic fat-based suppositories?**

(a) Low hydrogenation levels

(b) High glycerin content

(c) High solid content at room temperature

(d) Rapid warming of melted bases

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(c) High solid content at room temperature

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Explanation:

Brittleness

- Suppositories made from cocoa butter are quite elastic and do not fracture readily.
- Synthetic fat bases with a high degree of hydrogenation and high stearate contents, and therefore a higher solid content at room temperature, are usually more brittle. Fracturing of the suppository made with such bases is often induced by rapid chilling (shock cooling) of the melted bases in an extremely cold mold.

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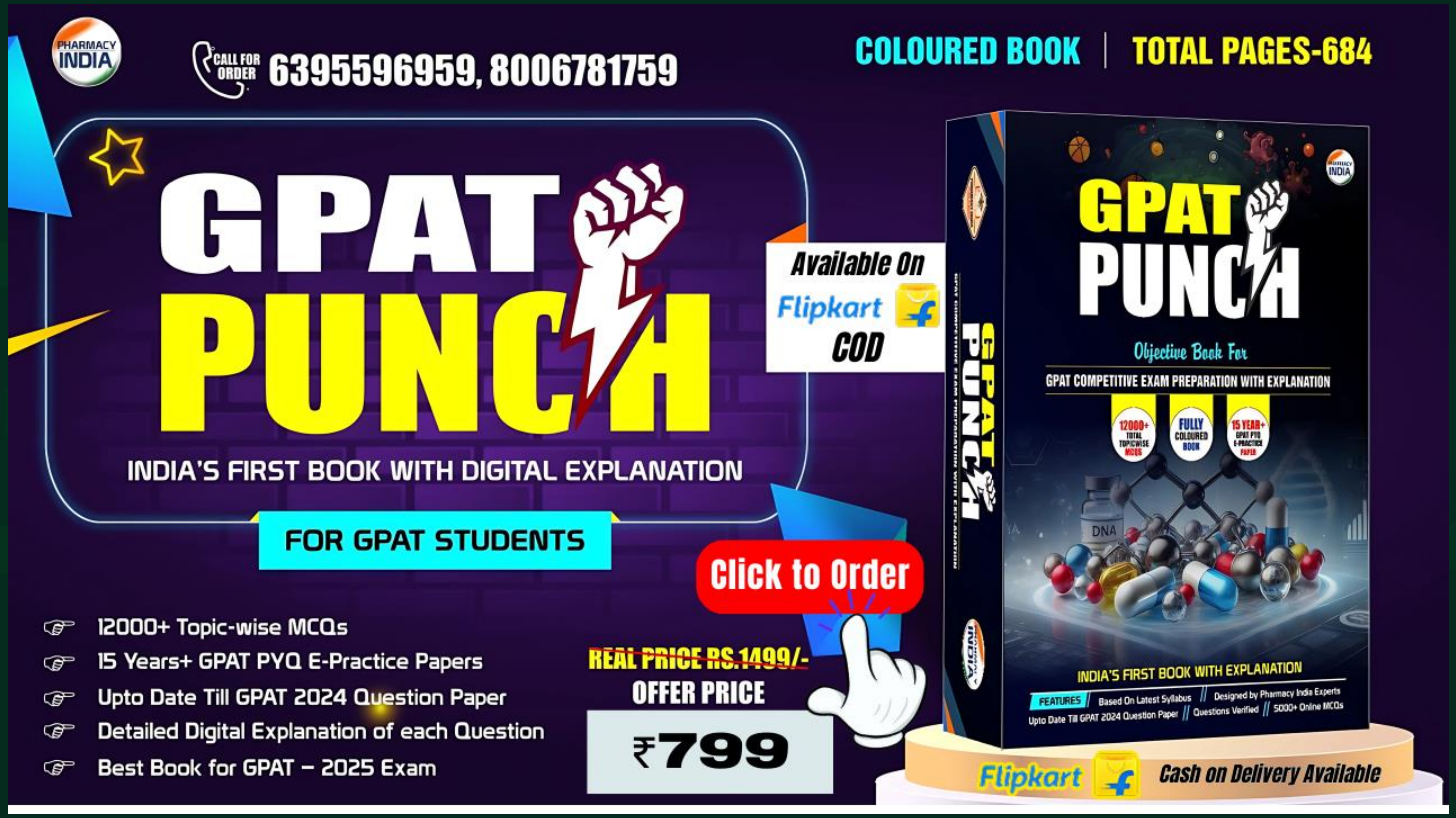

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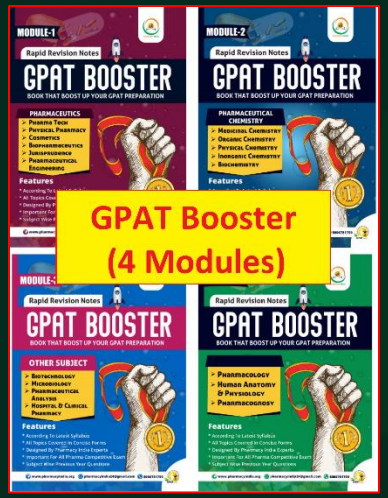

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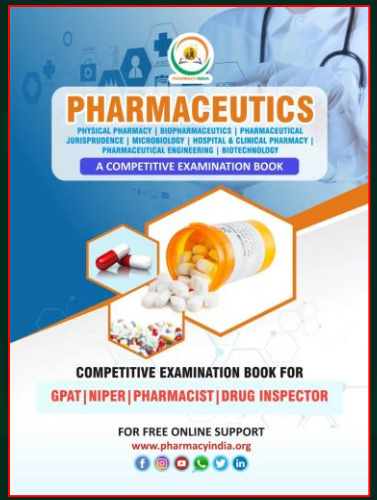

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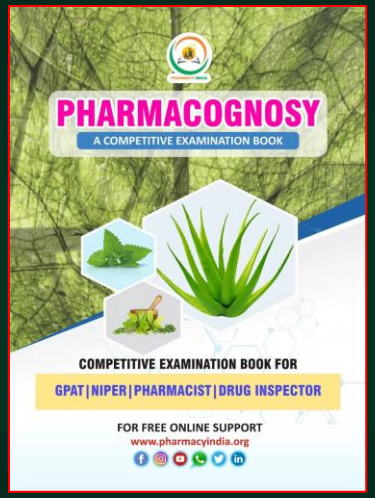

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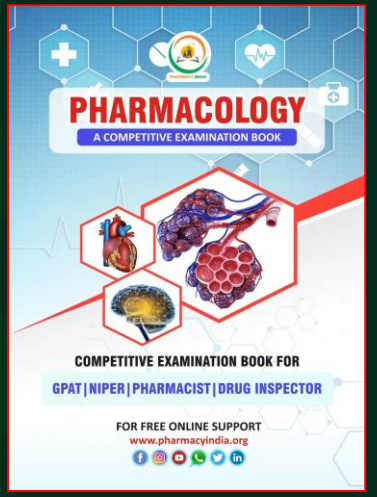

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- Brittle suppositories are troublesome not only in manufacturing, but also in the subsequent handling, wrapping, and use.
- To overcome this difficulty, the temperature differential between melted base and mold should be as small as possible. Addition of a small amount of Tween 80, Tween 85, fatty acid monoglycerides, castor oil, glycerin, or propylene glycol imparts plasticity to a fat and renders it less brittle.

41. Why is density important in suppository formulation?

(a) It determines the rate of drug absorption.

(b) It is required to calculate the amount of drug per suppository.

(c) It ensures the suppository does not fracture during handling.

(d) It helps prevent brittleness in the base.

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Explanation:

Density

- To calculate the amount of drug per suppository, the density of the base must be known. The volume of the mold cavity is fixed, and therefore, the weight of the individual suppository depends on the density of the mass.
- Knowledge of the suppository weight can be obtained from a given mold and density of the chosen base; the active ingredients can then be added to the bulk base in such an amount that the exact quantity of drug is present in each molded suppository.

- If volume contraction occurs in the mold during cooling, additional compensation must be made to obtain the proper suppository weight. Thus, density alone cannot be the sole criterion for calculating suppository weight per fixed volume mold.

42. **Which of the following is an example of a mold release agent?**

(a) Salicylic acid

(b) Tincture of green soap

(c) Sodium stearate

(d) Tween 80

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(c) Sodium stearate

(d) Tween 80

Explanation:

Lubricants or Mold Release Agents

- Cocoa butter adheres to suppository molds because of its low volume contraction. These suppositories are difficult to remove from the molds, and various mold lubricants or release agents must be used to overcome this difficulty.
- Mineral oil, an aqueous solution of sodium lauryl sulfate, various silicones, alcohol, and tincture of green soap are examples of agents employed for this purpose.
- They are applied by wiping, brushing, or spraying. The release of suppositories from damaged molds was improved by coating the cavities with polytetrafluoroethylene (Teflon).

43. **What is the formula for calculating the dosage replacement factor fff?**

(a) $f = \frac{100(E-G)}{(G)(X)} + 1$

(b) $f = \frac{E+G}{100} \times X$

(c) $f = \frac{100(E+G)}{(G)(X)} - 1$

(d) $f = \frac{(G)(X)}{100(E+G)} + 1$

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(d) $f = \frac{(G)(X)}{100(E+G)} + 1$

Explanation:

Dosage Replacement Factor

The amount of base that is replaced by active ingredients in the suppository formulation can be calculated. The replacement factor, f, is derived from the following equation:

$$f = \frac{100(E-G)}{(G)(X)} + 1$$

where, E is weight of pure base suppositories, G is weight of suppositories with X% active ingredient.

44. What is the phenomenon called when cocoa butter suppositories form a white powdery deposit on the surface?

(a) Hardening

(b) Bloom

(c) Crystallization

(d) Degradation

44. What is the phenomenon called when cocoa butter suppositories form a white powdery deposit on the surface?

(a) Hardening

(b) Bloom

(c) Crystallization

(d) Degradation

Explanation:

Cocoa butter suppositories in storage sometimes "bloom", i.e. form a white powdery deposit on the surface. This is unsightly and usually can be avoided if the suppositories are wrapped in foil, and stored at uniform cool or refrigerator temperatures.

45.

45. What causes fat base suppositories to harden over time?

(a) Reaction with moisture

(b) Crystallization to more stable polymorphic forms

(c) Interaction with active ingredients

(d) Exposure to UV light

45.

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(a) Reaction with moisture

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Explanation:

- Fat base suppositories have been shown to harden for a period of time after manufacture.
- This upward shift in melting range is due to slow crystallization to the more stable polymorphic forms of the base.
- Depending on the initial melting range and the formula of the suppository, this phenomenon may affect the melting of the suppository and subsequent drug absorption rates.

46. **Which test is used as a stability-indicating method to predict changes in melting range?**

(a) Hardness test

(b) Softening time test

(c) Differential scanning calorimetry

(d) Moisture absorption test

46. **Which test is used as a stability-indicating method to predict changes in melting range?**

(a) Hardness test

(b) Softening time test

(c) Differential scanning calorimetry

(d) Moisture absorption test

Explanation:

- The softening time test and differential scanning calorimetry can be used as stability-indicating test methods to predict problems of this sort.
- Storage immediately after manufacture at an elevated temperature below the melting range speeds up the aging process. Since the hardening phenomenon is a finite process, this tempering approach can minimize further changes in melting range, which may be worth the addition to manufacturing cycle time.

47. **Which apparatus is used for the melting range test?**

(a) PM 30 Penetration Tester

(b) Graduated tube with a water jacket

(c) Glass U-tube

(d) Conical flask with a thermostat

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(b) Graduated tube with a water jacket

(c) Glass U-tube

(d) Conical flask with a thermostat

Explanation:

Melting Range Test

- This test is also called the macromelting range test and is a measure of the time it takes for the entire suppository to melt when immersed in a constant temperature (37°C) water bath.
- In contrast, the micromelting range test is the melting range measured in capillary tubes for the fat base only.
- The suppository melting point apparatus by ERWEKA® consists of a graduated tube like glass test chamber.

48. **At what temperature range is the softening time test conducted?**

(a) 30°C to 32°C

(b) 35.5°C to 37°C

(c) 40°C to 45°C

(d) Below 25°C

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Explanation:

Softening Time Tests of Suppositories

- Softening time test apparatus consists of a U-tube partially submersed in a constant-temperature water bath.
- A constriction on one side holds the suppository in place in the tube.
- A glass rod is placed on top of the suppository, and the time for the rod to pass through to the constriction is recorded as the “softening time”.
- This can be carried out at various temperatures from 35.5 to 37°C, as a quality control check and can also be studied as a measure of physical stability over time.

49. **At what interval are weights added during the breaking test?**

(a) Every 30 seconds

(b) Every 2 minutes

(c) Every 1 minute

(d) Every 5 minutes

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(a) Every 30 seconds

(b) Every 2 minutes

(c) Every 1 minute

(d) Every 5 minutes

Explanation:

Breaking Test

- The breaking test is designed as a method for measuring the fragility or brittleness of suppositories.
- The apparatus used for the test consists of a double-wall chamber in which the test suppository is placed.
- Water at 37°C is pumped through the double walls of the chamber, and the suppository, contained in the dry inner chamber, supports a disc to which a rod is attached.

- The other end of the rod consists of another disc to which weights are applied. The test is conducted by placing 600 g on the platform.
- At 1 min intervals, 200 g weights are added, and the weight at which the suppository collapses is the breaking point, or the force that determines the fragility or brittleness characteristics of the suppository.

50. **Which base characteristic results in slow drug release with poor escaping tendency?**

(a) Oil-soluble drug in an oily base

(b) Oil-soluble drug in a water-miscible base

(c) Water-soluble drug in an oily base

(d) Water-soluble drug in a water-miscible base

50. **Which base characteristic results in slow drug release with poor escaping tendency?**

(a) Oil-soluble drug in an oily base

(b) Oil-soluble drug in a water-miscible base

(c) Water-soluble drug in an oily base

(d) Water-soluble drug in a water-miscible base

Explanation:

Drug Release Rates

General approximate drug release rates as they relate to the drug and base characteristics are summarized as follows:

Drug:Base Characteristics	Approximate Drug Release Rate
Oil-soluble drug: Oily base	Slow release; poor escaping tendency
Water-soluble drug: Oily base	Rapid release
Oil-soluble drug: Water-miscible base	Moderate release
Water-miscible drug: Water-miscible base	Moderate release; based on diffusion; all water soluble

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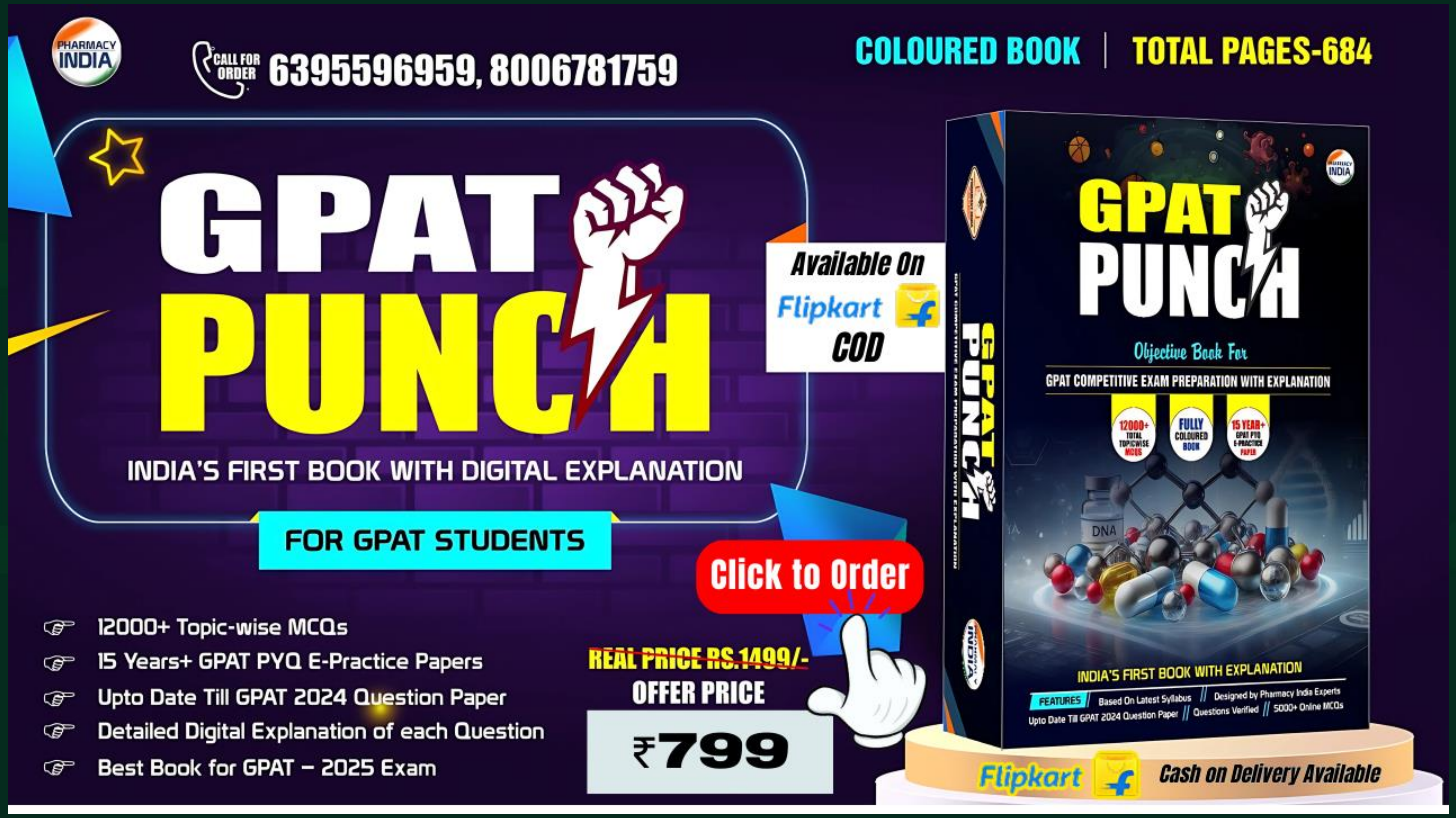

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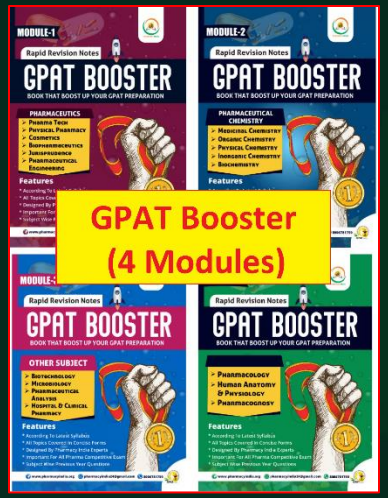

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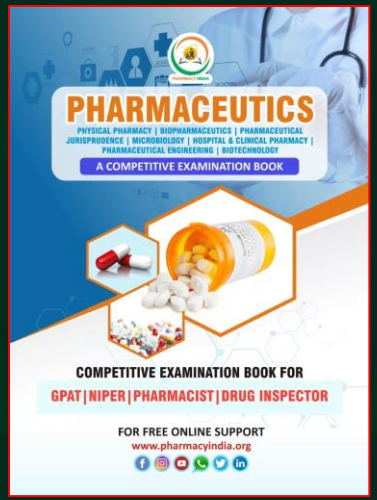

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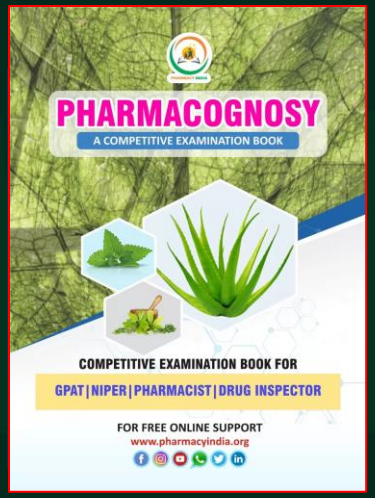

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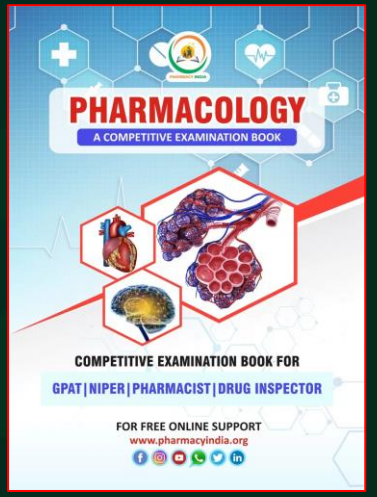

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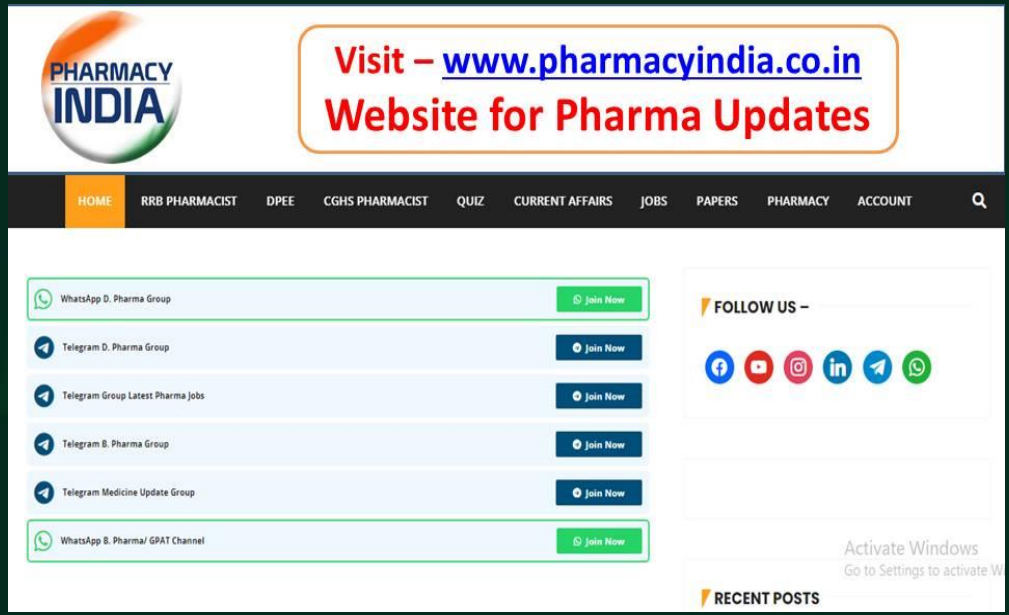

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