IMHS
INSTITUTE OF MEDICINE AND HEALTH SCIENCES

Paper Discussion with

(for 2024 SLMC Examination)

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IMHS
INSTITUTE OF MEDICINE AND HEALTH SCIENCES

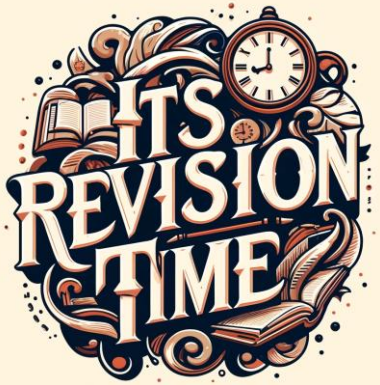
For CEYLON MEDICAL COLLEGE COUNCIL

PHARMACIST EXAMINATION

(EXTERNAL)

2024

Model Exam Paper 01



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01. Examples of inhaled corticosteroids, T/F?

a. Beclomethasone
b. Budesonide
c. Fluticasone
d. Prednisone
e. Triamcinolone

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a. T
b. T
c. T
d. F
e. T

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a. **True** - Beclomethasone is an inhaled corticosteroid commonly used in the management of asthma and chronic obstructive pulmonary disease (COPD).
b. **True** - Budesonide is another inhaled corticosteroid used to reduce inflammation in the airways in asthma and COPD.
c. **True** - Fluticasone is a widely used inhaled corticosteroid for controlling symptoms of asthma and COPD.
d. **False** - Prednisone is an oral corticosteroid, not typically used in inhaled form.
e. **True** - Triamcinolone can be administered as an inhaled corticosteroid, though it is less commonly used compared to the others like budesonide or fluticasone.

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02. Structure found inside a synovial include T/F?

a. Hyaline cartilage
b. Nerve endings
c. Synovial membrane
d. Joint fluids
e. Articular capsule

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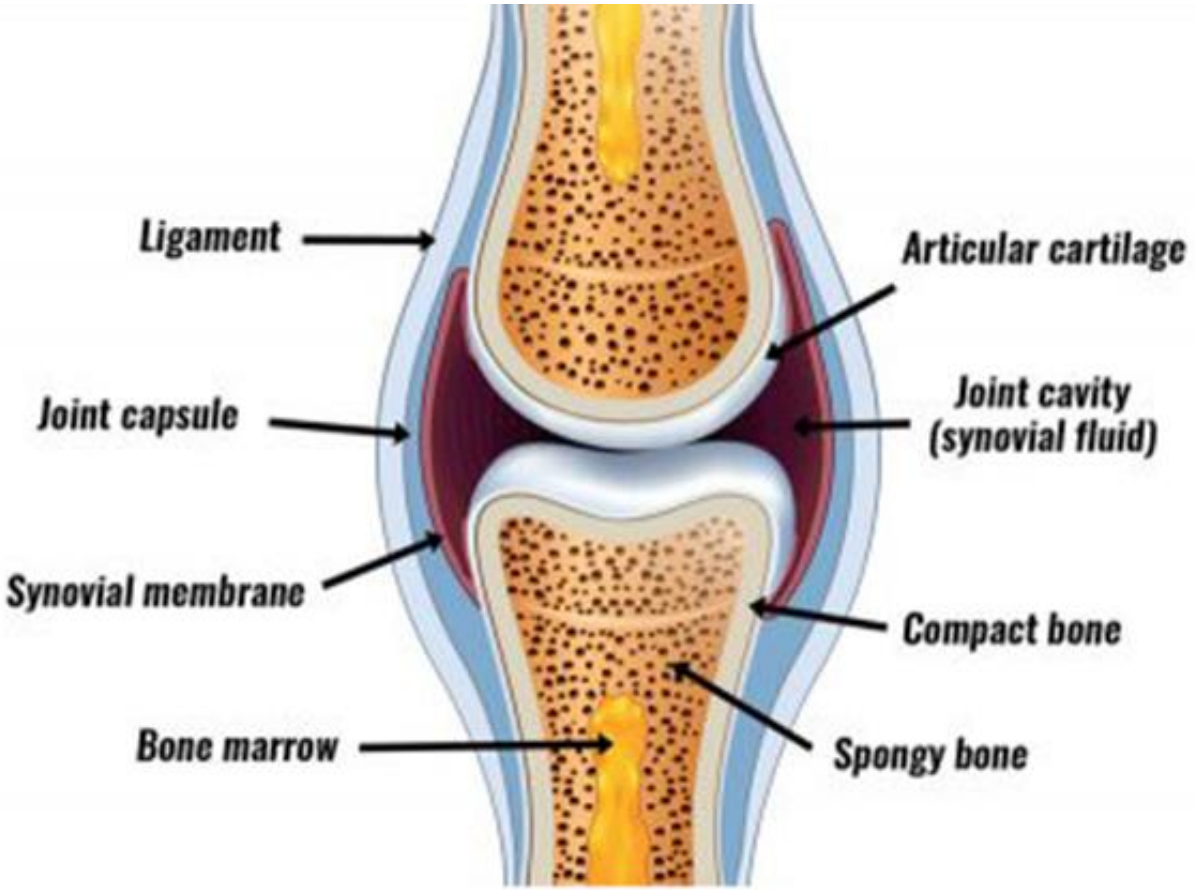

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a. **True –** Hyaline cartilage is commonly found on the articular surfaces of synovial joints.
b. **True –** Synovial joints have nerve endings, especially for pain and proprioception.
c. **True–** The synovial membrane lines the inner surface of the joint capsule and secretes synovial fluid.
d. **True –** Synovial fluid is present in synovial joints, providing lubrication.
e. **True–** The articular capsule surrounds the joint and encloses the synovial cavity.

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03. The following are examples of inactivated vaccines:

a. Influenza vaccine (injectable)
b. Tetanus toxoid vaccine
c. Inactivated Polio vaccine (IPV)
d. Rabies vaccine
e. Yellow fever vaccine

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a. **True** - The injectable **influenza vaccine** is an inactivated vaccine, containing killed viruses.
b. **False** - The **tetanus toxoid vaccine** is not an inactivated vaccine but rather a **toxoid vaccine**, which uses an inactivated toxin produced by the bacteria.
c. **True** - The **Inactivated polio vaccine** (IPV) is an inactivated vaccine, containing killed poliovirus.
d. **True** - The **rabies vaccine** is an inactivated vaccine, containing killed rabies virus.
e. **False** - The **yellow fever vaccine** is a **live-attenuated vaccine**, not an inactivated one.

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04. True or false regarding following facts?

a. Suppositories should be stored in a cool freezer in a refrigerator
b. Vaginal delivery exert systemic effects through absorption via the mucosal membrane in addition to providing localized action at the site of administration.
c. Sucrose is used as a sweetener
d. Antibacterial tablets frequently incorporate methylparaben as a preservative due to its broad-spectrum antimicrobial properties
e. EDTA can be given in heavy metal poisoning

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a) **False:** Suppositories should be stored in a refrigerator (2–8°C), but not in a freezer. Freezing them can alter their consistency and effectiveness.

b) **True:** Vaginal delivery systems can provide both localized action at the site of administration and systemic effects through absorption via the mucosal membrane.

c) **True:** Sucrose is typically used as a sweetener.

d) **False:** Antibiotic tablets generally do not need preservatives like methylparaben, as the active ingredients have antimicrobial properties.

e) **True:** EDTA can be used in cases of heavy metal poisoning. It acts as a chelating agent to bind heavy metals like lead and mercury for elimination from the body.

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05. True or false about the strength of drugs and their formulations?

a. The concentration of paracetamol in syrup form (250 mg/5 ml) results in compared to paracetamol drops (150 mg/ml).
b. The efficacy of chlorine-based disinfectants is quantified in terms of parts per million (ppm).
c. Vitamin A’s potency is conventionally measured in International Units (IU), a standard used to quantify the biological activity or effect of fat-soluble vitamins in humans.
d. A hydrogen peroxide solution labeled as "20-volume" refers to its ability to release 20 times its own volume of oxygen, which is commonly used for disinfecting and bleaching purposes.
e. The therapeutic dose of chloroquine base varies between chloroquine phosphate and chloroquine sulfate, due to the molecular weight differences between the salt forms.

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a. **False.** Paracetamol drops are more concentrated per milliliter, so the dosage per volume is generally higher in the drops.
b. **True.** The efficacy of chlorine-based disinfectants is commonly quantified in terms of parts per million (ppm), which is a standard measurement for disinfectant strength
c. **True.** Vitamin A's potency is conventionally measured in International Units (IU), which is a standard used to quantify the biological activity or effect of fat-soluble vitamins in humans
d. **True.** A hydrogen peroxide solution labeled as "20-volume" refers to its ability to release 20 times its own volume of oxygen, which is commonly used for disinfecting and bleaching purposes.
e. **True.** The therapeutic dose of chloroquine base varies between chloroquine phosphate and chloroquine sulfate due to the molecular weight differences between the salt forms.

06. The following statements about diuretics are true:

a. Loop diuretics are more potent than thiazide diuretics.
b. Spironolactone acts by Inhibiting aldosterone.
c. Loop diuretics act on the thick ascending limb of the loop of Henle.
d. Potassium-sparing diuretics can cause hyperkalemia.
e. Diuretics are commonly used in patients with heart failure.

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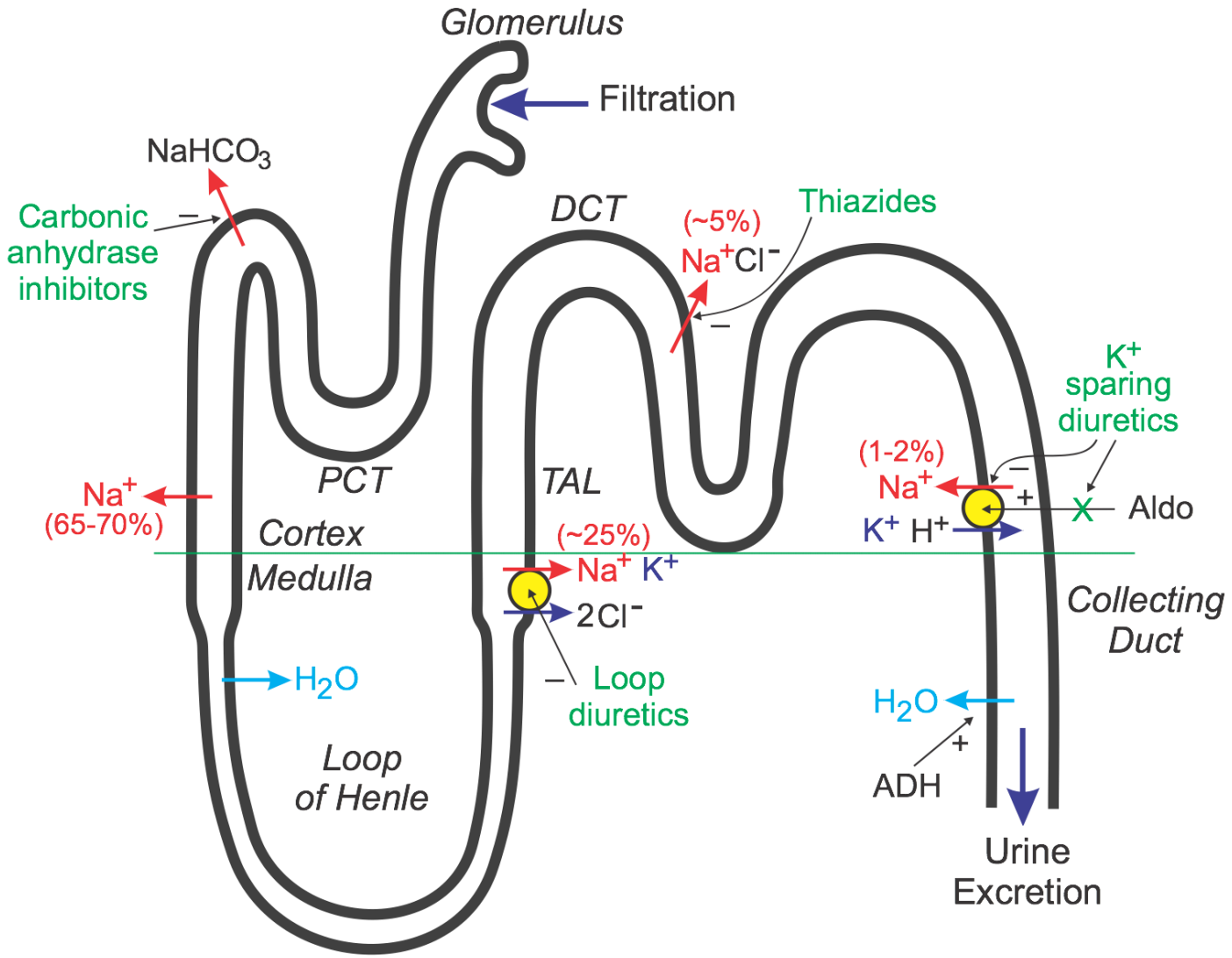

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a. **True** - Loop diuretics are more potent than thiazide diuretics because they act on the loop of Henle, which reabsorbs a larger proportion of filtered sodium.
b. **True** - Spironolactone is a potassium-sparing diuretic that acts by inhibiting aldosterone, reducing sodium reabsorption and potassium excretion.
c. **True** - Loop diuretics act on the thick ascending limb of the loop of Henle, inhibiting sodium, potassium, and chloride reabsorption.
d. **True** - Potassium-sparing diuretics, such as spironolactone, can cause hyperkalemia (high potassium levels) as they reduce potassium excretion.
e. **True** - Diuretics are commonly used in heart failure.

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07. True or false about disinfectants, antiseptics, and preservatives?

a. Benzalkonium is a preservative in ophthalmic preparations.
b. Povidone-iodine, though effective as a skin disinfectant, is not commonly recommended for environmental surface disinfection such as toilets.
c. Hydrogen peroxide at low concentrations is not recommended for open wound care due to the potential for tissue damage.
d. Iodine-based antiseptics, such as povidone-iodine, are commonly used for skin disinfection before surgical procedures.
e. Glutaraldehyde is considered a high-level disinfectant and is frequently used for sterilizing medical equipment, including endoscopes, due to its effectiveness against a wide range of microorganisms.

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a. **True.** Benzalkonium is indeed used as a preservative in ophthalmic preparations to maintain sterility of the product.
b. **True.** Povidone-iodine, while effective as a skin disinfectant, is not typically recommended for environmental surface disinfection, such as for cleaning toilets.
c. **False.** Hydrogen peroxide at low concentrations (typically 3%) is actually used for wound care, especially for cleaning minor cuts and abrasions, because it helps in removing debris and killing bacteria..
d. **True.** Iodine-based antiseptics, such as povidone-iodine, are commonly used for skin disinfection prior to surgical procedures due to their broad-spectrum antimicrobial activity.
e. **True.** Glutaraldehyde is effective in disinfecting medical equipment like endoscopes.

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08. Which of the following medications used in the treatment of gout?

a. Indomethacin
b. Diclofenac
c. Piroxicam
d. Aspirin
e. Ibuprofen

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b. T

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a. **True:** Indomethacin, a nonsteroidal anti-inflammatory drug (NSAID), is commonly used to treat the acute pain and inflammation associated with gout attacks.
b. **True:** Diclofenac is another NSAID that can be used to manage pain and inflammation in acute gout attacks, although it's not as commonly used as indomethacin.
c. **True:** Colchicine is a specific medication used in the treatment of gout, particularly for acute attacks and to prevent recurrent episodes. It works by reducing inflammation caused by uric acid crystals.
d. **False:** Aspirin is generally not used in the treatment of gout because it can alter uric acid levels in a way that may worsen gout by inhibiting uric acid excretion at low doses.
e. **True:** Ibuprofen, an NSAID, is used to treat pain and inflammation in acute gout attacks, although it may not be as commonly used as indomethacin or diclofenac.

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09. Theophylline levels can be increased by concomitant administration of which drugs, T/F?

a. Cimetidine
b. Rifampicine
c. Carbamazepine
d. Erythromycin
e. Phenobarbital

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b. F

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a. **True**. Cimetidine is a known inhibitor of the cytochrome P450 enzymes that metabolize theophylline, leading to increased theophylline levels.

b. **False.** Rifampin is an inducer of cytochrome P450 enzymes, which would decrease theophylline levels by increasing its metabolism.

c. **False.** Carbamazepine is also an inducer of cytochrome P450 enzymes, leading to decreased theophylline levels.

d. **True.** Erythromycin is an inhibitor of cytochrome P450 enzymes and can increase theophylline levels by decreasing its metabolism.

e. **False.** Phenobarbital is an inducer of cytochrome P450 enzymes, leading to decreased theophylline levels.

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ENZYME INHIBITORS	ENZYME INDUCERS
Cimetidine	Phenobarbitone
Chloramphenicol	Rifampicine
Fluoxetine	Carbamazepine
Isoniazid	Phenytoin
Ketoconazole	Griseofulvin
Sodium valproate	
ciprofloxacin	

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10 .True or false the correct matching of excipients?

a. Dextrose is used as a tonicity adjusting agent in parenteral solutions, helping to maintain osmotic balance with physiological fluids
b. Hydroxypropyl methylcellulose (HPMC) is widely used as a viscosity-enhancing agent in liquid formulations
c. Cetrimide functions as a cationic surfactant in pharmaceutical formulations
d. Sodium lauryl sulfate acts as an emulsifying agent, enabling the formation of stable oil-in-water emulsions by reducing surface tension
e. Povidone (polyvinylpyrrolidone) is used as a binder in tablet formulations, facilitating the adhesion of powder particles during granulation and improving the mechanical strength of tablets

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b. T
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a. **True** - Dextrose is used as a tonicity-adjusting agent in parenteral solutions, helping to maintain osmotic balance with physiological fluids.

b. **True** - Hydroxypropyl methylcellulose (HPMC) is widely used as a viscosity-enhancing agent in liquid formulations, especially in eye drops and oral suspensions.

c. **True** - Cetrimide functions as a cationic surfactant in pharmaceutical formulations, commonly used for its antiseptic and preservative properties.

d. **True** - Sodium lauryl sulfate acts as an emulsifying agent, reducing surface tension to form stable oil-in-water emulsions in various pharmaceutical preparations.

e. **True** - Povidone (polyvinylpyrrolidone) is used as a binder in tablet formulations. It helps in binding particles during granulation and improves the mechanical strength of the tablets.

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External Pharmacist Examination 2024

11. True or false regarding enteric coated tablets?

a. Enteric coating primarily functions to protect the active pharmaceutical ingredient (API) from degradation in the acidic pH of the stomach
b. A polymer barrier, typically composed of pH-sensitive materials, is applied to the tablet to prevent premature drug dissolution in the stomach
c. The release of the active ingredient from an enteric-coated tablet is designed to occur primarily in the small intestine.
d. Hydroxypropyl methylcellulose phthalate (HPMCP) is one of the commonly used polymers in enteric coatings.
e. Crushing of enteric coated tablets is leading to premature drug release in the stomach.

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b. T
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e. T

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a. **True** - Enteric coating primarily functions to protect the active pharmaceutical ingredient (API) from degradation in the acidic pH of the stomach, ensuring the drug reaches the intestines for absorption.

b. **True** - A polymer barrier, typically composed of pH-sensitive materials, is applied to the tablet to prevent premature drug dissolution in the stomach, allowing release in the intestine.

c. **True** - The release of the active ingredient from an enteric-coated tablet is indeed designed to occur primarily in the small intestine, where the pH is higher.

d. **True** - Hydroxypropyl methylcellulose phthalate (HPMCP) is a common polymer used in enteric coatings to provide protection against acidic gastric pH and to ensure dissolution in the small intestine.

e. **True** - Crushing enteric-coated tablets can lead to premature drug release in the stomach, defeating the purpose of the coating and potentially causing irritation or reduced efficacy.

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12. Which of the following statements True or false regarding the side effects of cytotoxic drugs?

a. Vomiting is a common adverse effect due to damage to rapidly dividing cells in the gastrointestinal tract.
b. Hypertrichosis (excessive hair growth) is a more frequent adverse effect of cytotoxic drugs compared to alopecia, which occurs due to the destruction of hair follicle cells.
c. Bone marrow suppression, including neutropenia, anemia, and thrombocytopenia, is a dose-limiting toxicity of many cytotoxic drugs.
d. Weight loss is most common.
e. Loss of appetite (anorexia) is a common side effect of cytotoxic drugs, often exacerbated by chemotherapy-induced taste changes (dysgeusia) and nausea, leading to significant nutritional deficits in patients undergoing treatment.

a. T
b. F
c. T
d. T
e. T

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a. **True:** Vomiting is indeed a common adverse effect due to damage to rapidly dividing cells in the gastrointestinal tract.

b. **False:** Alopecia (hair loss) is a more frequent adverse effect of cytotoxic drugs compared to hypertrichosis (excessive hair growth). Hair follicle cells, being rapidly dividing, are more susceptible to damage, leading to hair loss.

c. **True:** Bone marrow suppression, which can manifest as neutropenia, anemia, and thrombocytopenia, is a dose-limiting toxicity of many cytotoxic drugs and is a critical adverse effect in cancer therapy.

d. **True:** Weight loss is common caused by cytotoxic drugs.

e. **True:** Loss of appetite (anorexia) is indeed a common side effect of cytotoxic drugs, often exacerbated by chemotherapy-induced taste changes (dysgeusia) and nausea, leading to significant nutritional deficits in patients undergoing treatment.

13. True or false regarding antihypertensive medications?

a. Hydrochlorothiazide, in higher doses, poses a risk of electrolyte imbalances, and high-dose usage is no longer favored for hypertension treatment.

b. First-dose ACE inhibitors can cause significant hypotension, especially in patients with elevated renin activity, due to their potent vasodilatory effects.

c. Nifedipine extended-release is preferred for chronic hypertension management to avoid reflex tachycardia linked to immediate-release forms.

d. Furosemide is primarily used in hypertension associated with heart failure, rather than for essential hypertension.

e. Losartan is an angiotensin II receptor blocker (ARB), not an alpha-1 receptor blocker, used to cause vasodilation.

a. T
b. T
c. T
d. T
e. T

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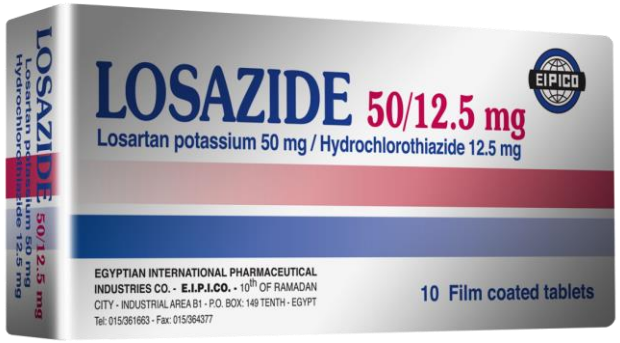
a. **True**
Hydrochlorothiazide, in higher doses, poses a risk of electrolyte imbalances (such as low potassium and sodium levels), and high-dose usage is no longer favored for hypertension treatment due to these risks.

b. **True**
First-dose ACE inhibitors can cause significant hypotension, particularly in patients with elevated renin activity, due to their potent vasodilatory effects.

c. **True**
Nifedipine extended-release is preferred for chronic hypertension management as it avoids the reflex tachycardia commonly associated with the immediate-release form.

d. **True**
Furosemide is primarily used in the management of hypertension associated with heart failure. It is a potent diuretic, and its use is less common in essential hypertension, where thiazide diuretics are usually preferred.

e. **True**
Losartan is an angiotensin II receptor blocker (ARB), not an alpha-1 receptor blocker. It is used to cause vasodilation and lower blood pressure by blocking the effects of angiotensin II.



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External Pharmacist Examination 2024

14. True or false regarding the drugs classification to hazardous because of their potential to cause significant adverse health consequences true or false?

a. Antineoplastic agents, commonly used in chemotherapy, are classified as hazardous due to their cytotoxic properties
b. Certain antiviral agents, particularly those with mutagenic or teratogenic properties (e.g., nucleoside analogs) are classified as hazardous
c. Biologic agents, particularly those used in immunotherapy (e.g., monoclonal antibodies), are typically classified as hazardous
d. Drugs with a high risk of hepatotoxicity, including certain anti-tuberculosis medications (e.g., isoniazid and rifampicin), are classified as hazardous
e. Radioactive isotopes, used in diagnostic imaging (e.g., iodine-131 for thyroid scans), are considered hazardous

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e. T

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a. **True.** Antineoplastic agents, commonly used in chemotherapy, are classified as hazardous due to their cytotoxic properties, which can cause significant health risks such as mutagenicity and carcinogenicity.
b. **True.** Certain antiviral agents with mutagenic properties are considered hazardous because they can cause genetic mutations and other serious health effects.
c. **False.** Biologic agents, particularly those used in immunotherapy (e.g., monoclonal antibodies), are not typically classified as hazardous.
d. **True.** Drugs with a high risk of hepatotoxicity are considered hazardous because they can cause severe liver damage, which can be life-threatening.
e. **True.** Radioactive isotopes used in diagnostic imaging are hazardous due to their radiation, which can lead to cancer and other serious health effects.

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15. Which of the following methods are commonly used for the preservation of pharmaceutical products , T/F?

a. Refrigeration
b. Freezing
c. Lyophilization
d. Pasteurization
e. Irradiation

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b. T
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a. **True. Refrigeration**: Used to preserve temperature-sensitive pharmaceuticals by slowing down degradation processes.
b. **True. Freezing:** Used for long-term storage of certain pharmaceuticals to prevent chemical reactions and microbial growth.
c. **True. Lyophilization**: Also known as freeze-drying, it is used to preserve pharmaceuticals by removing water content, thereby increasing stability.
d. **False. Pasteurization**: Not commonly used for pharmaceuticals; it is a process used primarily in food and beverage preservation.
e. **True. Irradiation**: Used to sterilize pharmaceuticals by exposing them to ionizing radiation, which kills microorganisms and prolongs shelf life.

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16. Amoxicillin is,

a. A narrow spectrum penicillin.
b. A bactericidal agent.
c. Not inactivated by penicillinase enzyme produced by staphylococcus aureus.
d. Poorly absorbed when there is food in the stomach.
e. Included in the triple therapy used in Helicobacter pylori eradication.

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a) F

b) T

c) F

d) F

e) T

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a. **False** - Amoxicillin is a broad-spectrum penicillin.

b. **True** - Amoxicillin is bactericidal, killing bacteria by inhibiting cell wall synthesis.

c. **False** - Amoxicillin can be inactivated by penicillinase produced by bacteria like Staphylococcus aureus.

d. **False** - Amoxicillin is well absorbed even when there is food in the stomach.

e. **True** - Amoxicillin is included in the triple therapy used in Helicobacter pylori eradication.

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17. Important aspects of the emergency treatment of poisoning according to the provided content , true or false?

a. Identification of common poisons and their mechanisms
b. Use of antidotes and specific treatment protocols
c. Methods for preventing absorption and enhancing elimination of poisons
d. Management of acute and chronic poisoning scenarios
e. Understanding the legal and ethical considerations in poisoning cases

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a. **True.** Identification of common poisons and their mechanisms is crucial in the emergency treatment of poisoning to understand the toxic effects and appropriate treatment.
b. **True.** The use of antidotes and specific treatment protocols is a fundamental aspect of managing poisoning cases to counteract the effects of the poison.
c. **True.** Methods for preventing absorption and enhancing elimination of poisons, such as activated charcoal or gastric lavage, are key strategies in treating poisonings.
d. **True.** Management of acute and chronic poisoning scenarios involves different approaches, making it essential to address both in emergency treatment plans.
e. **True.** Understanding the legal and ethical considerations in poisoning cases is important to ensure proper documentation, patient consent, and adherence to legal protocols.

18. Low molecular weight heparins (LMWHs), T/F?

a. Enoxaparin
b. Warfarin
c. Dalteparin
d. Reviparin
e. Unfractionated heparin

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b. F
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a. **True** - Enoxaparin is a low molecular weight heparin (LMWH) used for anticoagulation, especially in the treatment and prevention of deep vein thrombosis (DVT) and pulmonary embolism (PE).
b. **False** - Warfarin is not a low molecular weight heparin; it is an oral anticoagulant that works as a vitamin K antagonist.
c. **True** - Dalteparin is a low molecular weight heparin (LMWH) used for anticoagulation in conditions such as DVT and PE.
d. **True** - Reviparin is a low molecular weight heparin (LMWH) used for the prevention and treatment of thromboembolic disorders.
e. **False** - Unfractionated heparin is not a low molecular weight heparin; it is a different form of heparin with a broader range of molecular weights.

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19). In the context of pharmacy and pharmaceuticals, "pH" stands for "potential of hydrogen" and is a measure of the acidity or alkalinity of a solution. T/F?

a. The pH of a pharmaceutical formulation affects the stability of the active pharmaceutical ingredients (APIs).
b. Certain drugs are more soluble in specific pH ranges
c. The pH level affects the compatibility of ingredients in a formulation.
d. Different body parts have varying pH levels, affecting how drugs are absorbed and distributed
e. pH testing is a standard quality control measure

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a. **True** - The pH of a formulation affects the stability of the active pharmaceutical ingredients

b. **True -** Certain drugs are indeed more soluble in specific pH ranges. For example, weakly acidic drugs are more soluble in alkaline environments, while weakly basic drugs are more soluble in acidic environments.

c. **True -** pH levels affect the compatibility of ingredients in a formulation.

d. **True -** Different body parts (e.g., the stomach vs. the intestines) have varying pH levels, which affects how drugs are absorbed and distributed.

e. **True -** pH testing is a standard quality control measure in pharmaceutical manufacturing. Ensuring the correct pH is critical for the stability, solubility, and efficacy of the product.

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20. Regarding insulin and hypoglycemic medications for diabetes mellitus (DM) , True or False?

a. Oral administration of insulin is not effective for glycemic control due to degradation by gastrointestinal enzymes, necessitating parenteral routes such as subcutaneous injection for therapeutic efficacy.
b. Metformin, as a first-line treatment for type 2 diabetes, reduces hepatic gluconeogenesis and enhances peripheral insulin sensitivity by activating AMP-activated protein kinase (AMPK).
c. Sulfonylureas act by binding to ATP-sensitive potassium channels on pancreatic beta cells, promoting insulin secretion, making them effective in patients with residual beta-cell function.
d. Insulin glargine provides a rapid-acting effect suitable for postprandial glucose control.
e. Thiazolidinediones (TZDs) enhance insulin sensitivity by binding to peroxisome proliferator-activated receptor-gamma (PPAR-gamma), influencing gene expression related to glucose and lipid metabolism.

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a. **True -** Oral administration of insulin is not effective for glycemic control due to degradation by gastrointestinal enzymes, which necessitates parenteral routes such as subcutaneous injection for therapeutic efficacy.

b. **True-** Metformin, as a first-line treatment for type 2 diabetes, reduces hepatic gluconeogenesis and enhances peripheral insulin sensitivity by activating AMP-activated protein kinase (AMPK), which helps lower blood sugar levels.

c. **True -** Sulfonylureas act by binding to ATP-sensitive potassium channels on pancreatic beta cells, promoting insulin secretion. This makes them effective in patients with residual beta-cell function.

d. **False -** Insulin glargine provides long-acting glucose control and is not suitable for postprandial glucose control. Rapid-acting insulins (e.g., insulin lispro or insulin aspart) are typically used for postprandial control.

e. **True -** Thiazolidinediones (TZDs) enhance insulin sensitivity by binding to peroxisome proliferator-activated receptor-gamma (PPAR-gamma), influencing gene expression related to glucose and lipid metabolism, which helps improve blood sugar control

21. Anticoagulant medications , T/F?

a. Warfarin is a vitamin K antagonist used for long-term anticoagulation.
b. Direct oral anticoagulants (DOACs) like rivaroxaban are used to prevent stroke in atrial fibrillation.
c. Heparin is used for immediate anticoagulation and can be monitored using the aPTT.
d. Enoxaparin is a low molecular weight heparin used for both treatment and prevention of thromboembolic events.
e. Anticoagulants are contraindicated in patients with active bleeding or a high risk of bleeding.

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a) **True-** Warfarin inhibits the synthesis of vitamin K-dependent clotting factors, providing long-term anticoagulation.

b) **True -** DOACs, including rivaroxaban, are used to reduce the risk of stroke in patients with atrial fibrillation by preventing clot formation.

c) **True-** Heparin provides immediate anticoagulation and is monitored by measuring the activated partial thromboplastin time (aPTT).

d) **True-** Enoxaparin, a low molecular weight heparin, is used for prophylaxis and treatment of thromboembolic disorders.

e) **True -** Anticoagulants increase the risk of bleeding and are contraindicated in patients with active bleeding or high bleeding risk.

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22. Regarding controlled release of medication, T/F?

a) Controlled release (CR) formulations are designed to release the active ingredient at a predetermined rate
b) Reduced dosing frequency enhances patient adherence to the medication regimen and it will Improve Compliance
c) Maintains a more consistent therapeutic drug level, reducing the peaks
d) Minimized fluctuation in drug levels can lead to fewer side effects and better tolerability.
e) Often used in the management of psychiatric disorders to provide stable drug levels

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a. **True.** Controlled release (CR) formulations are designed to release the active ingredient at a predetermined rate, location, and duration.

b. True. Reduced dosing frequency enhances patient adherence to the medication regimen and improves compliance.

c. True. CR formulations maintain a more consistent therapeutic drug level, reducing peaks and troughs in drug concentration.

d. True. Minimized fluctuation in drug levels can lead to fewer side effects and better tolerability.

e. True. CR formulations are often used in the management of psychiatric disorders to provide stable drug levels.

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23. Which of the following statements about medications used for asthma, COPD, and allergic disorders are TRUE?

a. Salbutamol is a short-acting beta-agonist used to relieve symptoms of asthma and COPD.
b. Inhaled corticosteroids like fluticasone are used for long-term control of asthma and COPD.
c. Montelukast is a leukotriene receptor antagonist used to manage asthma and allergic rhinitis.
d. Antihistamines like cetirizine are commonly used to treat allergic disorders.
e. Tiotropium is a long-acting muscarinic antagonist used to manage COPD.

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a. **True -** Salbutamol (albuterol) is a short-acting beta-agonist that provides quick relief from asthma and COPD symptoms by relaxing the airway muscles.
b. **True** - Inhaled corticosteroids reduce inflammation in the airways and are used for long-term control of asthma and COPD.
c. **True-** Montelukast blocks leukotriene receptors, reducing inflammation and bronchoconstriction in asthma and allergic rhinitis.
d. **True-** Antihistamines block the action of histamine and are widely used to treat allergic conditions like hay fever and urticaria.
e. **True) -** Tiotropium is a long-acting muscarinic antagonist that helps open the airways and reduce symptoms in COPD patients.

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24. Regarding medications used for diarrhea are True or false?

a. Loperamide is an antidiarrheal that slows bowel movements.
b. Bismuth subsalicylate has antimicrobial properties and reduces inflammation in the intestines.
c. Oral rehydration salts (ORS) help to replace lost fluids and electrolytes during diarrhea.
d. Probiotics can help restore healthy gut flora during and after diarrhea.
e. Diphenoxylate is used with atropine to reduce bowel movements and alleviate diarrhea symptoms.

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a. **True -** Loperamide slows down gut movement, increasing the absorption of fluids and reducing the frequency of diarrhea.
b. **True -** Bismuth subsalicylate helps reduce intestinal inflammation and has antimicrobial effects that can treat the cause of diarrhea.
c. **True -** ORS contain a balanced mixture of salts and sugar, which help to replace lost fluids and electrolytes during episodes of diarrhea.
d. **True -** Probiotics help to replenish the good bacteria in the gut, which can be beneficial during and after diarrhea.
e. **True -** Diphenoxylate is an opioid used to treat diarrhea. It is often combined with atropine to reduce bowel movements.

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25. True or false?

a. A 1000 ml solution of “0.9% w/v Normal Saline” contains 9 grams of NaCl in total, meaning 100 ml of the solution contains 0.9 grams of NaCl, consistent with the isotonic concentration of saline used in clinical settings.
b. The sum of 1000 milligrams + 100 mg + 10 mg + 1 mg + 1 g + 10 g + 100 g equals exactly 111.111 grams, converting all units to the base unit of grams for accurate addition
c. One thousand microliters (µL) is equivalent to exactly 1 milliliter (mL).
d. Three tablespoonfuls, with each tablespoonful typically measured as 15 ml, are equal to 45 ml in total.
e. A teaspoon of paracetamol syrup (120 mg/5 ml) contains 120 mg of paracetamol, which is less than 1/4 of a 500 mg paracetamol tablet

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a. **True.** 1000 ml of 0.9% w/v Normal Saline solution contains 0.9% NaCl, so 100 ml contains 0.9 g NaCl.

b. **False.** 1 g + 0.1 g + 0.01 g + 0.001 g + 1 g + 10 g + 100 g = 112.111 grams (not 111.111 grams).

c. **True.**

d. **True.** Three tablespoonfuls, with each tablespoonful typically measured as 15 mL, equal 45 mL in total

e. **True.** A teaspoon of paracetamol syrup (120 mg/5 mL) contains 120 mg of paracetamol, which is less than 1/4 of a 500 mg paracetamol tablet (as 1/4 of a 500 mg tablet would be 125 mg).

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26. Determine if the following statements about drugs acting on the autonomic nervous system are true or false.

a. Beta-blockers, such as propranolol, are used to manage hypertension and anxiety.
b. Alpha-adrenergic agonists, like clonidine, can be used to treat high blood pressure.
c. Anticholinergics, such as atropine, are used to reduce saliva production during surgery.
d. Sympathomimetic drugs mimic the effects of the sympathetic nervous system.
e. Parasympathomimetic drugs stimulate the parasympathetic nervous system and can be used to treat dry mouth.

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a. **True -** Beta-blockers are commonly used for these conditions.
b. **True -** Clonidine is an alpha-adrenergic agonist used for hypertension.
c. **True -** Anticholinergics like atropine reduce saliva production.
d. **True -** These drugs stimulate the sympathetic nervous system.
e. **True -** Parasympathomimetics stimulate the parasympathetic system and treat conditions like dry mouth.

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27. Drug delivery systems refer to the methods or technologies used to administer pharmaceutical compounds into the body effectively. True or false?

a. **Controlled Release Systems**; Reduce dosing frequency and Minimize side effects by maintaining steady drug levels.
b. **Parenteral Delivery**; Bypasses the gastrointestinal tract for faster action.
c. **Oral Delivery**; Most convenient and widely used route.
d. **Implantable Devices**; Provide continuous drug release over long periods
e. **Transdermal Patches**; Provide steady drug delivery through the skin.

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a) T

b) T

c) T

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a. **True -** Controlled-release systems reduce dosing frequency and minimize side effects by maintaining steady drug levels.

b. **True -** Parenteral delivery bypasses the gastrointestinal tract for faster action.

c. **True -** Oral delivery is the most convenient and widely used route for drug administration.

d. **True** - Implantable devices provide continuous drug release over long periods.

e. **True -** Transdermal patches provide steady drug delivery through the skin.

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28. Bioavailability & Bioequivalance, T/F?

a. Bioavailability is the proportion of a drug dose that reaches systemic circulation for therapeutic effect.
b. Route of administration, formulation, and first-pass metabolism affect bioavailability
c. Blood level measurements show how much of a drug enters circulation over time.
d. Bioequivalence means two drugs have no significant difference in absorption rate and extent.
e. AUC, Cmax, and Tmax are used to assess bioequivalence

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e) T

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a. **True** - Bioavailability is the proportion of a drug dose that reaches systemic circulation for therapeutic effect. It reflects the rate and extent to which the active ingredient is absorbed.

b. **True -** The route of administration, formulation, and first-pass metabolism significantly affect bioavailability. For example, oral drugs undergo first-pass metabolism in the liver, which can reduce bioavailability.

c. **True** - Blood level measurements are used to determine how much of a drug enters the systemic circulation over time, often through pharmacokinetic parameters such as AUC (area under the curve).

d. **True -** Bioequivalence means that two drugs have no significant difference in absorption rate and extent when administered at the same dose and under similar conditions.

e. **True -** AUC (Area Under the Curve), Cmax (maximum concentration), and Tmax (time to reach maximum concentration) are standard parameters used to assess bioequivalence between drugs.

29. Assess the truthfulness of these statements about the application of filtration in pharmacy (True/False):

a. All liquid pharmaceuticals improve in quality when subjected to filtration.
b. Decantation is a form of crude filtration.
c. Gases cannot be subjected to filtration.
d. Sterile filtration is carried out with membrane filters with 10 micrometers opening.
e. Reverse osmosis is a form of filtration.

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a. **False :** Not all liquid pharmaceuticals benefit from filtration; it depends on the nature of the preparation and the contaminants.
b. **True :** Decantation is a basic method of separating liquids from solids or immiscible liquids.
c. **False :** Gases can be filtered using appropriate filters to remove particulate matter or microorganisms.
d. **False :** Sterile filtration typically uses membrane filters with pore sizes of 0.22 micrometers or smaller.
e. **True:** Reverse osmosis is a filtration process that removes particles and dissolved ions from water.

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30 . True or false regarding the medication storage :

a. Rubella (MMR) vaccine must be stored between 2°C and 8°C, with light protection, and can remain stable for up to 8 hours once reconstituted under these conditions.

b. Vaccines should not be stored on refrigerator door shelves due to temperature fluctuations from frequent opening, which may compromise their stability

c. Storing eye drops in a personal pocket for immediate access in emergencies can lead to thermal degradation, affecting their sterility and efficacy

d. Nitroglycerin (GTN) tablets should not be stored in a home refrigerator, as the low temperature and moisture could cause degradation; they require storage at room temperature in a tightly sealed container.

e. Unopened insulin should be stored in the main compartment of the refrigerator at 2°C to 8°C

a. T
b. T
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31 . Which of the following are primary purposes of Good Manufacturing Practices (GMP) true or false?

a. Ensuring product quality
b. Preventing contamination
c. Ensuring regulatory compliance
d. Enhancing safety and efficacy
e. Minimizing risks

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a. **True. Ensuring product quality**: GMP aims to produce pharmaceutical products of high quality by following strict manufacturing processes.

b. **True. Preventing contamination**: GMP involves measures to prevent contamination and ensure that products are safe for use.

c. **True. Ensuring regulatory compliance**: GMP ensures that manufacturing processes comply with national and international regulatory requirements.

d. **True. Enhancing safety and efficacy**: GMP practices help ensure that products are safe to use and effective in their intended purposes.

e. **True. Minimizing risks:** GMP minimizes risks associated with pharmaceutical production, including cross-contamination, mix-ups, and errors in manufacturing.

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32. The following practices align with Good Distribution Practice (GDP) for pharmaceuticals, Are the statements true or false?

a. Using tracking systems to monitor the movement of products.
b. Conducting regular audits to ensure compliance with GDP standards.
c. Ensuring proper packaging to protect products during transit.
d. Providing training for all personnel on GDP requirements.
e. Mixing pharmaceutical products with non-pharmaceutical goods during transport.

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a. **True:** GDP guidelines emphasize the use of tracking systems to ensure the integrity and traceability of pharmaceutical products throughout the distribution process.
b. **True:** Regular audits are conducted to ensure that all distribution practices comply with GDP standards, maintaining the quality and safety of pharmaceutical products.
c. **True:** Proper packaging is essential to protect pharmaceutical products from damage, contamination, and degradation during transit.
d. **True:** Training personnel on GDP requirements ensures that everyone involved in the distribution process understands and adheres to the necessary standards.
e. **False:** Mixing pharmaceutical products with non-pharmaceutical goods during transport is against GDP guidelines as it can

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33. True or false regarding bacteria, bacterial infections, and anti-bacterial medications

a. Antibiotics are used to treat bacterial infections by targeting specific bacterial structures or functions.
b. Antibiotic resistance occurs when bacteria acquire mutations that enable them to survive antibiotic treatment.
c. Broad-spectrum antibiotics are effective against a wide range of both Gram-positive and Gram-negative bacteria.
d. Narrow-spectrum antibiotics specifically target either Gram-positive or Gram-negative bacteria.
e. Overuse and misuse of antibiotics contribute significantly to the development of antibiotic-resistant bacteria.

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a. **True:** Antibiotics are used to treat bacterial infections by targeting specific bacterial structures or functions, such as cell wall synthesis, protein synthesis, or DNA replication.

b. **True:** Antibiotic resistance occurs when bacteria acquire mutations or gain resistance genes that enable them to survive antibiotic treatment, rendering the antibiotic ineffective.

c. **True:** Broad-spectrum antibiotics are effective against a wide range of both Gram-positive and Gram-negative bacteria, making them useful in treating infections where the causative organism is not known.

d. **True:** Narrow-spectrum antibiotics specifically target either Gram-positive or Gram-negative bacteria, which makes them useful when the infecting organism has been identified.

e. **True:** Overuse and misuse of antibiotics contribute significantly to the development of antibiotic-resistant bacteria. This includes taking antibiotics for viral infections, not completing prescribed courses, or using antibiotics in agriculture

34. Verify whether the following statements about medications used for anxiety and insomnia are true or false

a. Benzodiazepines are commonly used to treat anxiety and insomnia.
b. SSRIs are prescribed for long-term management of anxiety disorders.
c. Buspirone is an anxiolytic that does not cause sedation or dependency.
d. Antihistamines are sometimes used for short-term treatment of insomnia.
e. Beta-blockers can be used to manage physical symptoms of anxiety, such as tachycardia.

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a. **True**
Benzodiazepines are commonly used to treat anxiety and insomnia, especially in the short term, due to their sedative and anxiolytic properties.

b. **True**
Selective serotonin reuptake inhibitors (SSRIs) are prescribed for the long-term management of anxiety disorders as they help regulate serotonin levels in the brain.

c. **True**
Buspirone is an anxiolytic that does not cause sedation or dependency, making it a safer option for long-term anxiety management compared to benzodiazepines.

d. **True**
Antihistamines, such as diphenhydramine, are sometimes used for short-term treatment of insomnia due to their sedative effects.

e. **True**
Beta-blockers can be used to manage the physical symptoms of anxiety, such as tachycardia (rapid heartbeat), by blocking the effects of adrenaline on the heart.

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35. About contraception and contraceptives, true or false?

a. Combined oral contraceptives (COCs) contain both estrogen and progestin and are taken daily to prevent ovulation, thicken cervical mucus, and thin the endometrial lining to prevent pregnancy.
b. Progestin-only pills (POPs) contain only progestin and are suitable for women who cannot take estrogen. They primarily work by thickening cervical mucus and sometimes by inhibiting ovulation.
c. Intrauterine devices (IUDs) are small, T-shaped devices inserted into the uterus. Copper IUDs release copper ions that are toxic to sperm, while hormonal IUDs release progestin to thicken cervical mucus and inhibit sperm movement.
d. Implantable contraceptives are small rods placed under the skin of the upper arm that release progestin to prevent ovulation.
e. Emergency contraceptive pills can be used after unprotected intercourse to prevent pregnancy

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a. **True -** COCs contain estrogen and progestin, which prevent ovulation, thicken cervical mucus, and thin the endometrium to prevent pregnancy.
b. **True -** POPs contain only progestin and are suitable for those who cannot take estrogen, working mainly by thickening cervical mucus and inhibiting ovulation.
c. **True -** IUDs can be copper or hormonal, with copper IUDs releasing ions toxic to sperm and hormonal IUDs releasing progestin to inhibit sperm movement.
d. **True -** Implantable contraceptives are small rods that release progestin to prevent ovulation, providing long-term contraception.
e. **True -** Emergency contraceptive pills can prevent pregnancy if taken shortly after unprotected intercourse by delaying ovulation or preventing fertilization.

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36. True or false?

a. Potassium chloride is hygroscopic, readily absorbing moisture under normal conditions
b. Erythromycin stearate, an ester of erythromycin and a fatty acid, enhances the stability of the antibiotic
c. Povidone is water-soluble, which makes it an effective binder in tablet formulations
d. Soaps are sodium salts of fatty acids, produced via saponification of fats and oils
e. Cardamom oil has carminative effects, traditionally used to alleviate flatulence and gastrointestinal discomfort.

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a. **True**
Potassium chloride is hygroscopic, meaning it readily absorbs moisture from the environment under normal conditions.

b. **True**
Erythromycin stearate, an ester of erythromycin and a fatty acid, enhances the stability of the antibiotic and improves its absorption when taken orally.

c. **True**
Povidone is water-soluble, which makes it an effective binder in tablet formulations as it helps to hold the components of the tablet together.

d. **True**
Soaps are sodium salts of fatty acids, produced through the process of saponification, which involves the reaction of fats and oils with an alkali.

e. **True**
Cardamom oil has carminative effects, meaning it is traditionally used to alleviate flatulence and gastrointestinal discomfort by reducing gas and bloating.

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37. Following facts are related to the Medical ordinance: True or false

a. President of medical council is elected from among the members
b. Registrar of medical council can only act as the secretary of the medical council
c. Part VII is associated with pharmacists in the medical ordinance
d. Medical practitioners can not register as pharmacists
e. If registered person changed the residence registrar will erase the name from the register

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a. T
b. F
c. F
d. T
e. F

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a. **True -** The President of the medical council is elected from among the members of the council.
b. **False -** The Registrar of the medical council not only acts as the secretary but also has other administrative responsibilities, including maintaining the register of practitioners.
c. **False -** Part VII of the Medical Ordinance is associated with midwives, not pharmacists. Part VIII is associated with pharmacists..
d. **True -** Medical practitioners are not eligible to register as pharmacists under the Medical Ordinance, as these are separate professions with distinct regulatory frameworks.
e. **False -** If a registered person changes residence, the registrar does not erase the name from the register. The person is required to notify the registrar of the change, if fails to inform the registrar or respond to inquiries, their name can be erased from the register.

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38. Evaluate the accuracy of these statements regarding pharmaceutical compounds and excipients true or false?

a. Citric acid is used as an antioxidant in formulations, preventing oxidative degradation by neutralizing free radicals.
b. Calamine lotion includes zinc oxide as an active ingredient, providing soothing effects for skin irritations.
c. Glycerin and glycerol are chemically distinct, with unique pharmaceutical applications.
d. Benzoic acid acts as a preservative by inhibiting microbial growth, extending product shelf life.
e. Lanolin (wool fat) contains cholesterol, contributing to its emollient properties in skin-care products.

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a. F
b. T
c. F
d. T
e. T

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a. **False**
Citric acid is not typically used as an antioxidant in formulations. It is more commonly used as a pH adjuster and chelating agent. Antioxidants such as vitamin E or ascorbic acid are more commonly used to neutralize free radicals.

b. **True**
Calamine lotion includes zinc oxide as an active ingredient, providing soothing and anti-inflammatory effects for skin irritations.

c. **False**
Glycerin and glycerol are the same compound (glycerol is the chemical name, and glycerin is the common name).

d. **True**
Benzoic acid acts as a preservative by inhibiting microbial growth, thereby extending the shelf life of products.

e. **True**
Lanolin (wool fat) contains cholesterol, which contributes to its emollient properties, making it a valuable ingredient in skin-care products to soften and moisturize the skin.

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39 . Which of the following are true regarding the sale, distribution, and possession of dangerous drugs under the Poisons, Opium, and Dangerous Drugs Ordinance?

a. A pharmacist may only dispense dangerous drugs on the prescription of a medical practitioner, dentist, or veterinary surgeon.
b. A prescription for a dangerous drug must always be given in writing, and no dangerous drug can be prescribed for the prescriber's own use.
c. The possession of a dangerous drug by an individual is lawful only if it has been prescribed by a medical practitioner or pharmacist.
d. Dangerous drugs dispensed for immediate use do not need to be entered into the **Sale of Poisons Book** if a prescription is provided.
e. The sale of dangerous drugs to unknown individuals is strictly prohibited unless they are introduced by someone known to the vendor or they present a valid prescription.

a. T
b. T
c. F
d. F
e. T

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a. **True** – A pharmacist may only dispense dangerous drugs based on a prescription issued by a licensed medical practitioner, dentist, or veterinary surgeon. This ensures that dangerous drugs are handled appropriately and only provided under professional supervision.

b. **True** – A prescription for a dangerous drug must always be given in writing, and it is illegal for a medical practitioner to prescribe dangerous drugs for their own use. This regulation aims to prevent misuse and self-prescription of dangerous drugs.

c. **False** – While possession of a dangerous drug is lawful if prescribed by a medical practitioner, a pharmacist alone cannot prescribe these drugs. The pharmacist's role is to dispense, not prescribe. Only licensed medical practitioners can prescribe.

d. **False** – Dangerous drugs must be meticulously recorded, including entries into the **Sale of Poisons Book**, even if they are dispensed for immediate use with a valid prescription. Record-keeping is a critical component of legal compliance.

e. **True** – The sale of dangerous drugs to unknown individuals is indeed prohibited unless they present a valid prescription or are introduced by someone known to the vendor, ensuring traceability and preventing unauthorized sales.

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40. True or false regarding the pricing of medicines, under National Medicines Regulatory Authority Act, No 5 of 2015 and regulations?

a. The Authority appoints the Pricing Committee.
b. The International Reference Prices are considered determine the introductory price of medicines.
c. Current market prices of similar products are considered determine the introductory price of medicines.
d. When determining the price of a new medical entity, the benefit of the new product and the cost effectiveness are being considered.
e. The provisions of the Consumer Affairs Authority Act, No. 9 of 2003 is taken into consideration when prescribing a pricing mechanism for medicines.

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a. F
b. T
c. T
d. T
e. T

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a. **False –** By minister.

b. **True –** International Reference Prices (IRP) are taken into account when determining the introductory price of medicines, ensuring prices are aligned with international standards.

c. **True –** The pricing committee considers the current market prices of similar products available in the local market when determining the introductory price of a new medicine.

d. **True** – The NMRA Act and regulations state that cost-effectiveness and the potential benefits of the new medical entity are critical factors in determining its pricing.

e. **True –** The Consumer Affairs Authority Act is considered when prescribing a pricing mechanism, ensuring consumer protection and affordability in the pricing structure for medicines.

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STRUCTURED ESSAY QUESTIONS

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01). According to NMRA act,

1.1). Write 03 main objectives of the NMRA Act?

1.2). Regarding borderline products,

a. Briefly define borderline products?
b. Write down five responsibilities of NMRA pertaining to borderline products?
c. State five common product types of borderline products?

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1.1. Main objectives of the NMRA Act?

AN ACT TO PROVIDE FOR THE ESTABLISHMENT OF A REGULATORY AUTHORITY TO BE KNOWN AS THE NATIONAL MEDICINES REGULATORY AUTHORITY WHICH SHALL BE RESPONSIBLE FOR THE REGULATION AND CONTROL OF, REGISTRATION, LICENSING, MANUFACTURE, IMPORTATION AND ALL OTHER ASPECTS PERTAINING TO MEDICINES, MEDICAL DEVICES, BOARDERLINE PRODUCTS AND FOR THE CONDUCTING OF CLINICAL TRIALS IN A MANNER COMPATIBLE WITH THE NATIONAL MEDICINES POLICY; TO PROVIDE FOR THE ESTABLISHMENT OF DIVISIONS OF THE NATIONAL MEDICINES REGULATORY AUTHORITY INCLUDING THE MEDICINES REGULATORY DIVISION, MEDICAL DEVICES REGULATORY DIVISION, BORDERLINE PRODUCTS REGULATORY DIVISION AND CLINICAL TRIALS REGULATORY DIVISION; TO ESTABLISH A NATIONAL ADVISORY BODY; TO REPEAL THE COSMETICS, DEVICES AND DRUGS ACT, NO. 27 OF 1980; AND FOR MATTERS CONNECTED THEREWITH OR INCIDENTAL THERETO.

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- Establishment of National Medicinal Regulatory Authority

- Establish a National Advisory Body / National Advisory Committee

- Regulation and Control of
  - Registration
  - Licensing
  - Manufacturing
  - Importation, and
  - All other activities,

  of Medicines, Medical Devices and Boarderline products

- Conducting of clinical trials

- Establishment of Regulatory Divisions of;
  - Medical regulatory division
  - Medical devices regulatory division
  - Boarderline products regulatory division
  - Clinical trials regulatory division

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1.2
a. Briefly define borderline products?

- Boarderline products are products having combined characteristics of medicine along with foods, medical devices or cosmetics

OR

- Products having combined characteristics of medicines and foods, medicines and medical devices or medicines and cosmetics

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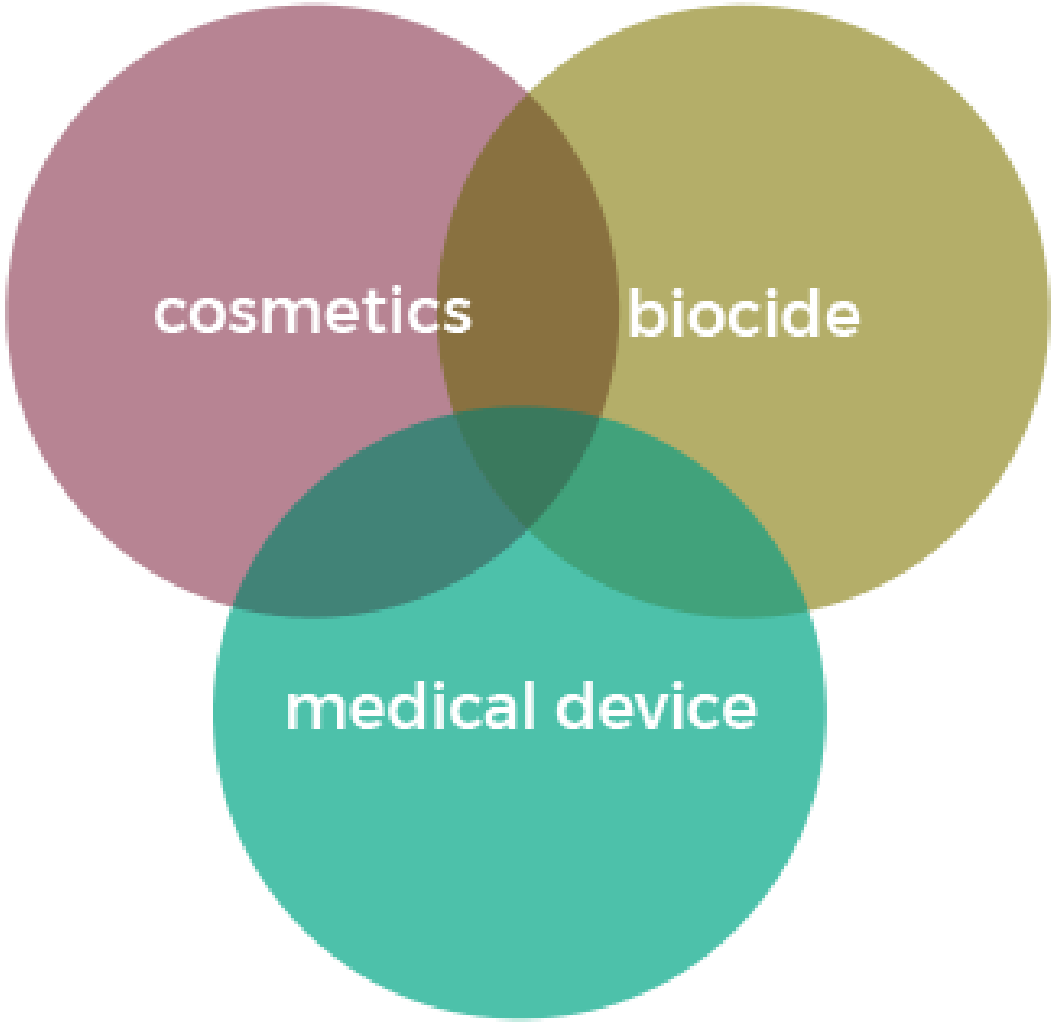

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b. Write down five responsibilities of NMRA pertaining to borderline products?

National Medicines Regulatory Authority shall be responsible for the regulation and control of,

- Registration
- Licensing
- Manufacture
- Importation
- Sale
- Distribution
- Handling of quality failures

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c. Common product types of borderline products

- Multi vitamins & multi minerals
- Multivitamins
- Glucosamine only products
- Glucosamine combinations
- Probiotics & Prebiotics

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- Coenzyme Q10 products
- Glutathione containing products (oral dosage forms)
- Enzyme containing products
- Sun protection creams (SPF value > 30)
- Fish oil products

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- Herbal & multivitamin combinations
- Medicated toothpastes (Special toothpastes containing Potassium Nitrate and other salts)
- Amino acid containing products
- Preparation containing collagen peptides, cartilages, bone particles, etc

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02. Answer the following questions on dosage forms

a.

I. Write 3 differences between film coated and enteric coated tablets

II. What are the requirements to be fulfilled in manufacturing of parenteral preparation

b.

I. Write 3 antiseptic products available in pharmacy

II. Write 5 characteristics should be in an ideal antiseptic

III. How to dilute KMnO4 use as an antiseptic

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02.

a.

I. Differences between film-coated and enteric-coated tablets:

- Film-coated: Thin polymer layer that dissolves quickly after swallowing.
- Enteric-coated: Designed to resist stomach acid and dissolve in the intestines.

- Film-coated: Provides taste masking or protects the drug from light.
- Enteric-coated: Protects the drug from stomach acid or prevents gastric irritation.

- Film-coated: Typically dissolves in the stomach.
- Enteric-coated: Delays release until reaching the intestines.

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Characteristic	Film-coated Tablets	Enteric-coated Tablets
Coating Type	Thin polymer layer	Acid-resistant polymer layer
Dissolution Location	Dissolves quickly in the stomach	Resists stomach acid, dissolves in the intestines
Purpose	Taste masking, appearance, protection from light or moisture	Protects drug from stomach acid, prevents gastric irritation
Gastric Resistance	Not resistant to stomach acid	Resistant to stomach acid
Drug Release	Releases active ingredient in the stomach	Delays release until the intestines

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II. Requirements for manufacturing parenteral preparations:

- **Sterility:** Must be free from microorganisms.
- **Isotonicity:** The solution must match the osmotic pressure of body fluids.
- **Purity:** Must be free from particulates, pyrogens, and toxins.
- **Aseptic conditions:** Must be manufactured in clean environments to avoid contamination.
- **Stability:** Should remain stable over time and not degrade.

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b.

I. Antiseptic products available in a pharmacy:

- Chlorhexidine
- Povidone-iodine
- Hydrogen peroxide

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II. Characteristics of an ideal antiseptic:

- **Broad-spectrum antimicrobial activity** – effective against bacteria, viruses, fungi, and other pathogens.
- **Non-toxic to human tissues** – safe for use on skin, wounds, and mucous membranes without causing irritation or damage.
- **Rapid onset of action** – begins to act quickly to reduce microbial load.
- **Sustained effect** – provides prolonged protection against microbial contamination after application.
- **Stable and easy to use** – should remain effective for a reasonable time period and be simple to apply or use.

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III.

$KMnO_4$ is frequently used as a topical antiseptic in very dilute solutions, particularly for treating skin conditions, wounds, and as a disinfectant soak.

- **The 1:10,000 dilution (0.01%) is a standard concentration used in many healthcare practices to ensure that the solution is safe for skin contact while still maintaining its antiseptic properties.**

- **1:10,000 dilution means dissolving 1 gram of $KMnO_4$ in 10 liters of water, or 0.1 grams in 1 liter.**

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Questions

03). Pharmaceuticals degradation is the process of degrading of pharmaceuticals and, become lower quality, safety and efficacies product.

Due to the "Pharmaceutical products degradation", it is made unwanted chemicals and that can affect the efficacy of pharmaceutical products.

I. List 02 environmental related factors affecting to the process of pharmaceuticals degradation?
II. State 02 visual changes of the oral solution due to degradation?
III. What are the two types of stability studies & shortly explain?
IV. Write one preservatives for each category mentioned below?
    I. Cream
    II. Eye drop

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03.

i. Environmental factors affecting pharmaceuticals degradation

- **Temperature**: High temperatures can accelerate the chemical reactions that lead to the degradation of drugs. Some pharmaceuticals are sensitive to heat and must be stored in cool conditions.

- **Humidity**: Moisture can cause hydrolysis, which is a major degradation pathway for many drugs, especially for tablets and capsules, leading to loss of potency.

- **Light (Photodegradation)**: Exposure to light, particularly UV light, can cause photochemical reactions, resulting in the breakdown of sensitive pharmaceuticals like vitamins and antibiotics.

- **Oxygen (Oxidation)**: Oxygen can lead to the oxidation of drugs, especially those containing unsaturated bonds, such as fats and oils. This is common in solutions and emulsions.

- **pH**: Changes in pH can alter the stability of pharmaceuticals, leading to hydrolysis or degradation of drugs that are pH-sensitive, such as protein-based drugs.

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ii. Visual changes of the oral solution due to degradation

- **Color Change**: The solution may darken, fade, or develop a different color, indicating chemical reactions such as oxidation or photodegradation.
- **Precipitation**: Solid particles may appear in the solution, suggesting that the drug or excipients have broken down and are no longer fully dissolved.
- **Cloudiness**: The solution may become turbid or cloudy, indicating microbial contamination or chemical instability.
- **Separation**: Layering or phase separation may occur, especially in emulsions or suspensions, suggesting that the formulation has broken down.

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iii. Types of Stability Studies for the pharmaceuticals

1. Real time stability studies
2. Accelerated stability studies

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Real-Time Stability Testing

This form of stability testing is conducted on drugs for the same duration as the recommended shelf life.

In real-time stability testing, a product is stored at recommended storage conditions and monitored until it fails the specification.

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Accelerated Stability Studies

In accelerated stability tests, a product is stored at elevated stress conditions (such as temperature, humidity, and pH).

- Accelerated Stability Testing is done to determine the shelf life of finished products.

- As per the result, the expiry date of a particular product is fixed.

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iv. Preservatives

- Chemical substances used to improve or amplify shelf life of drugs by reducing microbial production.

- **Cream: Methylparaben** – commonly used in topical formulations to prevent microbial growth.

- **Eye drop: Benzalkonium chloride** – widely used in ophthalmic solutions to inhibit microbial contamination.

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Preservatives used in Pharmaceutical Preparations

Preparation	Preservative	Conc. (% w.v)
Injections	Phenol	0.5
	Cresol	0.3
	Chlorocresol	0.1
Eye drops	Chlorhexidine acetate	0.01
	Benzalkonium chloride	0.01
Mixtures	Benzoic acid	0.1
	Methyl paraben	0.1
	Alcohol	12-20
Creams	Parabens	0.1-0.2
	Chlorocresol	0.10
Tablets	Methylparaben	0.1

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Questions

04. Regarding the management of Diabetes Mellitus with a focus on insulin and antidiabetic medications

a. Describe the pathophysiology of Type 1 and Type 2 Diabetes Mellitus, highlighting the role of insulin in each condition.

b. Explain the different types of insulin preparations their mechanisms of action, and how they are used in the treatment of Diabetes Mellitus. Provide clinical examples.

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c. Outline the mechanism of action, indications, and side effects of two classes of oral hypoglycemic agents used in Type 2 Diabetes Mellitus.

d. Discuss the role of lifestyle modifications and patient education in the management of Diabetes Mellitus, particularly in combination with pharmacotherapy.

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ANSWERS

04.

a. **Describe the pathophysiology of Type 1 and Type 2 Diabetes Mellitus, highlighting the role of insulin in each condition**

Type 1 Diabetes Mellitus (T1DM):

- T1DM is an autoimmune condition where the body's immune system attacks and destroys insulin-producing beta cells in the pancreas. As a result, there is an absolute deficiency of insulin.

- **Role of insulin:** In T1DM, since the pancreas cannot produce insulin, external insulin is required to regulate blood sugar levels.

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Type 2 Diabetes Mellitus (T2DM):

- T2DM is characterized by insulin resistance (the body's cells do not respond effectively to insulin) and a relative insulin deficiency (the pancreas does not produce enough insulin to overcome the resistance).

- **Role of insulin:** In T2DM, insulin production is impaired, but there is still some endogenous insulin. In advanced cases, insulin therapy may be required when oral medications are insufficient.

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b. Explain the different types of insulin preparations, their mechanisms of action, and how they are used in the treatment of Diabetes Mellitus. Provide clinical examples.

Insulin Used for DM

Types of Insulin:

- Rapid-Acting Insulin
- Short-Acting Insulin
- Intermediate-Acting Insulin
- Long-Acting Insulin
- Biphasic Insulin

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Examples and Clinical Uses:

- **Rapid-Acting Insulin:**
- Example: Insulin Lispro (Humalog).
- Clinical Use: Administered before meals to control postprandial glucose levels (concentration of glucose in the blood after eating).

Short-Acting Insulin:

- Example: Regular Insulin (Humulin R).
- Clinical Use: Used for mealtime glucose control, typically administered 30 minutes before a meal.

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Intermediate-Acting Insulin:

- Example: Insulin NPH (Humulin N).
- Clinical Use: Provides basal insulin coverage (provides a consistent insulin supply to cover the body's basic metabolic needs), typically administered once or twice daily.

Long-Acting Insulin:

- Example: Insulin Glargine (Lantus).
- Clinical Use: Administered once daily to provide continuous basal insulin coverage.

Biphasic Insulin:

- Example: Biphasic Insulin Aspart (NovoMix 30).
- Clinical Use: Administered before meals to cover both basal and prandial insulin needs, simplifying the insulin regimen.

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c. Outline the mechanism of action, indications, and side effects of two classes of oral hypoglycemic agents used in Type 2 Diabetes Mellitus

Biguanides (e.g., Metformin):

- **Mechanism of action:** Metformin reduces hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity in peripheral tissues.
- **Indications:** First-line therapy for Type 2 Diabetes Mellitus, particularly in overweight patients.
- **Side effects:** Gastrointestinal disturbances (e.g., diarrhea, nausea), lactic acidosis (rare but serious).

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Sulfonylureas (e.g., Glibenclamide, Glipizide):

- **Mechanism of action:** Sulfonylureas stimulate insulin release from pancreatic beta cells by binding to specific receptors.
- **Indications:** Used in patients with T2DM who have some remaining beta cell function.
- **Side effects:** Hypoglycemia, weight gain, and potential for cardiovascular risks.

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Thiazolidinediones (TZDs)

- **Examples:** Pioglitazone
- **Mechanism of action:** TZDs enhance insulin sensitivity by activating peroxisome proliferator-activated receptor-gamma (PPAR-γ) in adipose tissue, skeletal muscle, and liver, improving glucose uptake and reducing hepatic glucose production.
- **Indications:** Used in T2DM to improve insulin resistance, often as an add-on therapy.
- **Side effects:** Weight gain, fluid retention (which can worsen heart failure), increased risk of bone fractures, and a potential link to bladder cancer (for pioglitazone).

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Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

- **Examples:** Sitagliptin, Saxagliptin, Linagliptin.
- **Mechanism of action:** DPP-4 inhibitors block the enzyme DPP-4, which degrades incretin hormones. By inhibiting DPP-4, these drugs prolong the action of incretins like GLP-1 and GIP, leading to increased insulin secretion and reduced glucagon levels after meals.
- **Indications:** Used as an adjunct in T2DM when diet, exercise, and other medications do not provide adequate glycemic control.
- **Side effects:** Generally well-tolerated but may cause mild side effects like upper respiratory tract infections, nasopharyngitis, and headaches. Rarely, they may cause pancreatitis.

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Sodium-Glucose Cotransporter-2 (SGLT2) Inhibitors

- **Examples:** Empagliflozin.
- **Mechanism of action:** SGLT2 inhibitors block the reabsorption of glucose in the proximal renal tubules, promoting its excretion in the urine and thereby lowering blood glucose levels.
- **Indications:** Used in T2DM to improve glycemic control and have additional benefits, including weight loss and lowering blood pressure. They have also been shown to reduce cardiovascular events in high-risk patients.
- **Side effects:** Increased risk of urinary tract infections, genital infections, dehydration, and a rare risk of ketoacidosis (even in the absence of significant hyperglycemia).

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d. Discuss the role of lifestyle modifications and patient education in the management of Diabetes Mellitus, particularly in combination with pharmacotherapy.

Lifestyle modifications:

- **Diet:** A balanced diet low in refined carbohydrates and high in fiber helps control blood sugar levels. Portion control and carbohydrate counting are essential in managing post-meal glucose spikes.

- **Exercise:** Regular physical activity enhances insulin sensitivity and promotes weight loss, which can improve glycemic control, particularly in T2DM.

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Patient education:

- Patients should be educated on the **proper use of medications** (e.g., timing of insulin injections), **monitoring blood glucose** levels, recognizing symptoms of hypoglycemia and hyperglycemia, and the importance of **adherence to treatment**.

- **Foot care**, **routine health checks**, and understanding how to adjust lifestyle habits to manage their condition effectively are also important.

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Questions

05). With respect to the poisons, opium and dangerous drugs ordinance, answer the following questions.

i. How do you dispense a Poison to an unknown Person?

ii. Name the persons who can handle dangerous drugs.

iii. What are the essential requirements in a prescription for a dangerous drugs.

iv. Give one example for the followings.

   a. Part I poison
   b. Part II poison
   c. Poisonous substances

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05)

i. Sale to unknown persons

- Only for a valid prescription form a registered medical practitioner

- If purchaser is introduced by some person known to the vender (3rd person)

ii. Persons who can handle dangerous drugs

- R/Pharmacist
- R/Medical practitioner
- R/Dentist
- R/Government apothecary
- R/Veterinary surgeon
- A person holding a license from the local authority
- A wholesale druggist
- R/Dispenser/Estate dispenser
- R/Vederala
- R/Master of any ship

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iii. Essential requirements in a prescription for a dangerous drug

- Should be in writing
- Date
- Prescriber’s usual signature, surname, and address
- Name and address of the patient
- Total amount of the drug to be supplied
- In emergency prescriptions given without using the form - marked with the words "Official form not available "

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- a prescription given by a dentist - marked "For dental treatment only"
- a prescription shall be given by a veterinary surgeon - marked "For animal treatment only"

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iv.

a. Poisons – Part I

- Arsenic and its preparations
- Aconite, aconitine and their preparations
- Alkaloids and glucosides
- Atropine and its salts
- Belladonna and all preparations
- Cyanide of potassium and all poisonous cyanides
- Nux vomica

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b. Poisons – Part II

- Carbolic acid and its preparations
- Chloral hydrate
- Chloroform
- Digitalis
- Mercuric iodide
- Oxalic acid
- Strophanthus

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c. Poisonous substances

- Ammonia: liquid, preparations containing more than 5 *per centum* by weight of free ammonia.
- Carbolic
- Hydrochloric acid
- Nitric acid
- Sulphuric acid

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Poisons

Schedule	Part	Type	
First Schedule	I	Poison	Arsenic , Cyanide, Atropin
	II	Poison	Chloral hydrate, Chloroform
	III	Poison	Antihistamine , Hypnotics, CNS Drugs
	IV	Poisonous Substances	HCL, H2SO4,HNO3
	V	Sales of Poisons Book	

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Thank you