GPAT Pharmaceutics

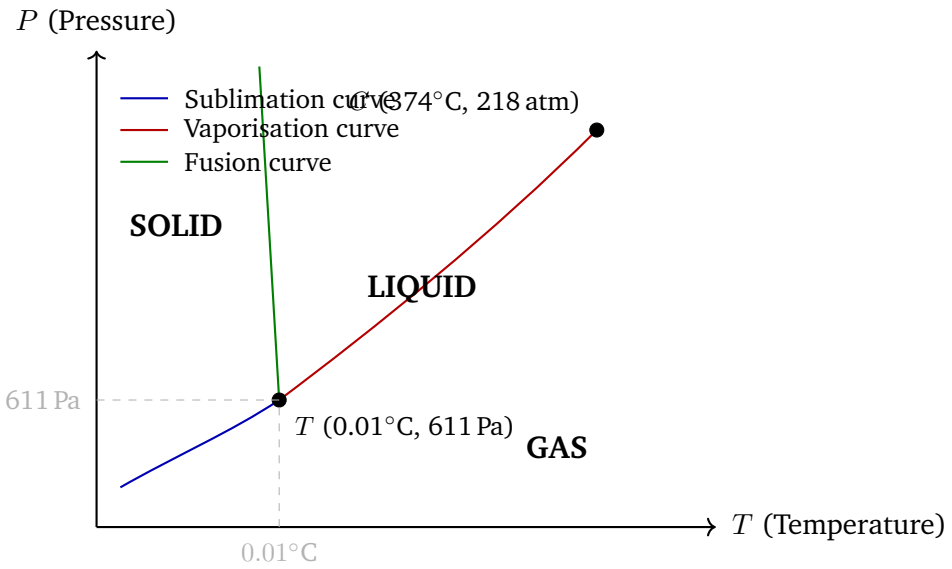
Sample Paper – 4

Duration: 36 Minutes **Maximum Marks: 100**

Instructions

- This paper contains **25** Multiple Choice Questions (Single Correct Answer), modelled on the Pharmaceutics portion of **GPAT** entrance.
- Each correct answer carries **+4 marks**. There is **a penalty of −1 mark** for each incorrect answer. Unattempted questions carry no marks.
- Only **one** option is correct per question.
- Syllabus: **GPAT Pharmaceutics — Physical Pharmacy, Sterilization, Cosmetics, Packaging, Quality Control, Regulatory.**
- Personal calculators, mobile phones, and electronic gadgets are strictly prohibited. A simple on-screen calculator is provided in the CBT interface; rough sheets are supplied at the centre.

Q1. The schematic below shows the pressure–temperature phase diagram of pure water.



Applying Gibbs phase rule $F = C - P + 2$ to the triple point T of pure water (one-component system, $C = 1$), where *solid*, *liquid*, and *vapour* all coexist simultaneously ($P = 3$), the number of degrees of freedom F is:

(A) $F = 3$; the system has full thermodynamic mobility.

(B) $F = 2$; both temperature and pressure can be varied independently without destroying a phase.

(C) $F = 1$; only temperature is independently variable while the other phases coexist.

(D) $F = 0$; the triple point is an *invariant* point — neither temperature nor pressure can change without eliminating at least one phase.

Q2. EMLA® cream is a topical anaesthetic formulation containing lidocaine (melting point $\approx 68^{\circ}$C) and prilocaine (melting point $\approx 37^{\circ}$C) in a 1 : 1 mass ratio. At room temperature ($\approx 25^{\circ}$C), this mixture is an *oily liquid*, even though both pure components are solids at room temperature. Which statement BEST explains this observation?

(A) The mixture has a higher melting point than either pure component due to strong hydrogen bonding between lidocaine and prilocaine molecules in the solid lattice.

(B) The 1 : 1 mixture is the *eutectic composition*, whose melting point ($\approx 16^{\circ}$C) falls *below* the melting point of each pure component, causing it to exist as a liquid oil at room temperature.

(C) Prilocaine chemically decomposes on mixing with lidocaine, releasing a liquid by-product that dissolves the remaining solid.

(D) Lidocaine is highly hygroscopic and absorbs sufficient atmospheric moisture to dissolve both components into an aqueous solution.

Q3. A 1% w/v aqueous glucose solution ($M_r = 180\ \mathrm{g\,mol^{-1}}$) is prepared at $25°$C. The mole fraction of glucose (x_{glucose}) is approximately 0.001, and the vapour pressure of pure water is $P°$. The lowering of vapour pressure obeys $\Delta P = x_{\text{solute}} \times P°$. Which law *directly* predicts this colligative lowering of solvent vapour pressure by a dissolved non-volatile solute?

(A) Raoult's law: $P_{\text{solvent}} = x_{\text{solvent}} \cdot P°_{\text{solvent}}$; the vapour pressure of each volatile component equals its mole fraction multiplied by its pure-component vapour pressure.

(B) Henry's law: relates the partial pressure of a *volatile solute* (gas dissolved in liquid) to its mole fraction — not applicable to solvent vapour pressure lowering.

(C) Fick's first law: describes the rate of diffusion of molecules down a concentration gradient; unrelated to vapour pressure.

(D) Van 't Hoff's law: predicts osmotic pressure ($\pi = iMRT$) but does not directly describe vapour pressure lowering.

Q4. Normal (isotonic) saline is a 0.9% w/v aqueous solution of sodium chloride ($M_r = 58.5\ \mathrm{g\,mol^{-1}}$). Assuming complete

dissociation of NaCl into Na^+ and Cl^-, the approximate osmolality of this solution is:

(A) $154\,\text{mOsm}\,\text{kg}^{-1}$ — equivalent to the molar concentration of NaCl without accounting for ionic dissociation ($\nu = 1$).

(B) $200\,\text{mOsm}\,\text{kg}^{-1}$

(C) $308\,\text{mOsm}\,\text{kg}^{-1}$ — NaCl dissociates into two osmotically active ions ($\nu = 2$): $0.154\,\text{mol}\,\text{kg}^{-1} \times 2 = 308\,\text{mOsm}\,\text{kg}^{-1}$.

(D) $616\,\text{mOsm}\,\text{kg}^{-1}$

Q5. β-Cyclodextrin (β-CD) is widely used to increase the apparent aqueous solubility of poorly water-soluble drugs by forming a 1 : 1 inclusion complex (stability constant $K_s = [\text{complex}] \,/\, ([\text{drug}][\beta\text{-CD}])$). The drug molecule fits inside the hydrophobic inner cavity of β-CD. What is the PRIMARY thermodynamic driving force for entry of a drug molecule into the β-CD cavity?

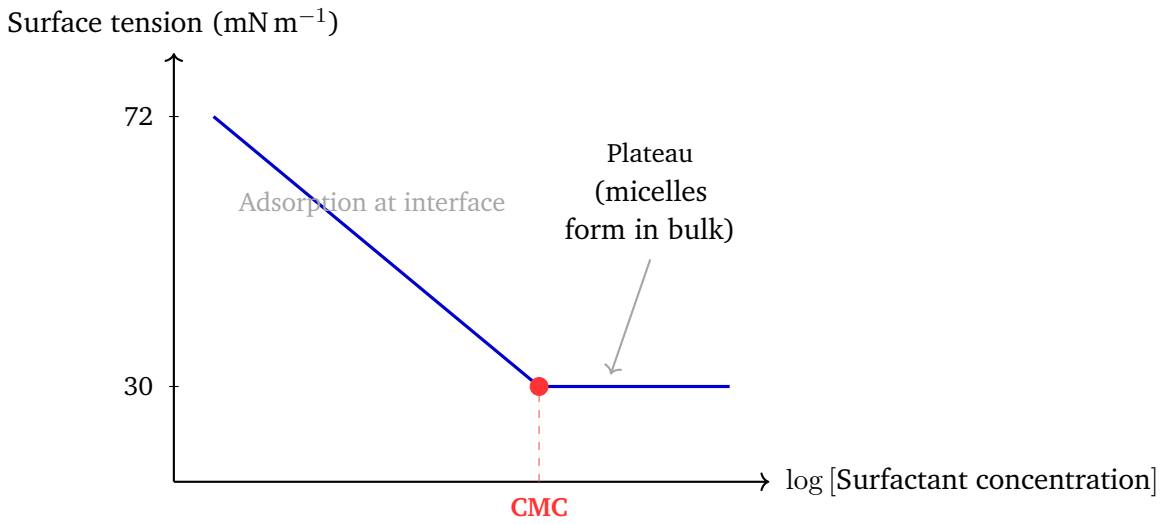
(A) Formation of covalent ester bonds between the drug and the hydroxyl groups lining the rim of the cyclodextrin cavity.

(B) Release of high-energy water molecules from the hydrophobic cavity (entropically and enthalpically favourable) combined with hydrophobic interactions between the apolar cavity and non-polar regions of the drug.

(C) Ionic attraction between a positively charged inner cavity wall and anionic drug molecules at physiological pH.

(D) Specific enzymatic recognition of the drug molecular geometry by the β-cyclodextrin macrocycle.

Q6. The graph below shows surface tension ($\mathrm{mN\,m^{-1}}$) plotted against the logarithm of surfactant concentration for an aqueous solution of an ionic surfactant.



On this plot, the **Critical Micelle Concentration (CMC)** represents:

(A) The concentration at which the surfactant solution becomes visibly turbid due to precipitation of surfactant aggregates.

(B) The concentration above which surface tension *increases* with further surfactant addition, due to counter-ion shielding.

(C) The lowest concentration at which any surfactant molecule begins to adsorb at the air–water interface, initiating the fall in surface tension.

(D) The concentration at which surface tension reaches a constant minimum (plateau) as the air–water interface is saturated, marking the *onset of micelle formation* in the bulk solution.

Q7. The spreading coefficient S for a liquid spreading over a solid (or second liquid) surface is defined as:

$$S = \gamma_{\mathrm{S/V}} - \gamma_{\mathrm{L/V}} - \gamma_{\mathrm{S/L}}$$

where $\gamma_{\mathrm{S/V}}$ is the solid–vapour surface energy, $\gamma_{\mathrm{L/V}}$ is the liquid surface tension, and $\gamma_{\mathrm{S/L}}$ is the solid–liquid interfacial tension. What condition must be satisfied for a liquid to SPONTANEOUSLY and COMPLETELY spread over the substrate?

(A) $S > 0$: the solid surface energy must exceed the sum of the liquid surface tension and the solid–liquid interfacial tension, making spreading energetically favourable.

(B) $S < 0$: the liquid surface tension must exceed the solid surface energy for spreading.

(C) The contact angle θ must be greater than 90° (non-wetting condition).

(D) The solid–liquid interfacial tension $\gamma_{\mathrm{S/L}}$ must be greater than $\gamma_{\mathrm{L/V}}$ for spontaneous spreading.

Q8. The Langmuir adsorption isotherm is expressed as:

$$q = \frac{q_{\max} K C}{1 + K C}$$

where q is the amount adsorbed per unit mass of adsorbent, $q_{\max}$ is the monolayer adsorption capacity, K is the Langmuir equilibrium constant, and C is the equilibrium solute concentration. Which assumption is UNIQUE to the Langmuir isotherm and is *not* shared by the empirical Freundlich isotherm?

(A) Adsorption energy decreases exponentially with increasing fractional surface coverage (heterogeneous surface).

(B) Multi-layer adsorption can build up on the surface simultaneously, with each layer having the same energy.

(C) The adsorbent surface has a *finite, fixed* number of equivalent and energetically uniform adsorption sites; each site can hold at most one adsorbate molecule, leading to monolayer saturation at $q_{\max}$.

(D) Adsorption occurs irreversibly and preferentially at surface defects and high-energy grain boundaries.

Q9. Knowing the fraction of drug bound to plasma proteins is essential for pharmacokinetic characterisation. Numerous *in vitro* methods can quantify this binding. Which technique is widely regarded as the **GOLD STANDARD** for measuring drug–plasma protein binding because it measures the true thermodynamic equilibrium without disturbing the bound/free equilibrium?

(A) Ultrafiltration, in which centrifugal force drives free drug through a semi-permeable membrane — rapid but may

shift equilibrium by concentrating protein.

(B) Equilibrium dialysis, in which the drug–protein solution is separated from protein-free buffer by a dialysis membrane and allowed to reach complete thermodynamic equilibrium before sampling.

(C) Ultracentrifugation, which sediments protein–drug complexes by density difference.

(D) Size-exclusion (gel filtration) chromatography, which separates protein-bound from free drug by molecular size.

Q10. For a weakly acidic drug that binds extensively to *albumin* in the systemic circulation, an increase in the degree of plasma protein binding (higher K_a or plasma albumin concentration) will produce which of the following effects?

(A) Increases the free fraction f_u and increases the apparent volume of distribution V_d by redistributing drug to peripheral tissues.

(B) Increases V_d substantially, as high plasma protein binding drives the drug away from the central compartment into tissue sites.

(C) Has no significant effect on hepatic or renal clearance, because total (bound + free) plasma concentration drives organ elimination.

(D) Decreases f_u (since $f_u = 1/(1 + K_a[P])$), decreases V_d (drug is retained in plasma rather than distributing to tissues), and for low-extraction drugs reduces total clear-

ance ($CL \approx f_u \cdot CL_{\text{int}}$), thereby prolonging half-life.

Q11. In validation of terminal moist-heat sterilisation (autoclaving) of parenteral products, the F_0 value is a key process parameter computed by integrating the lethality over the entire heat cycle. What does the F_0 value *specifically* represent?

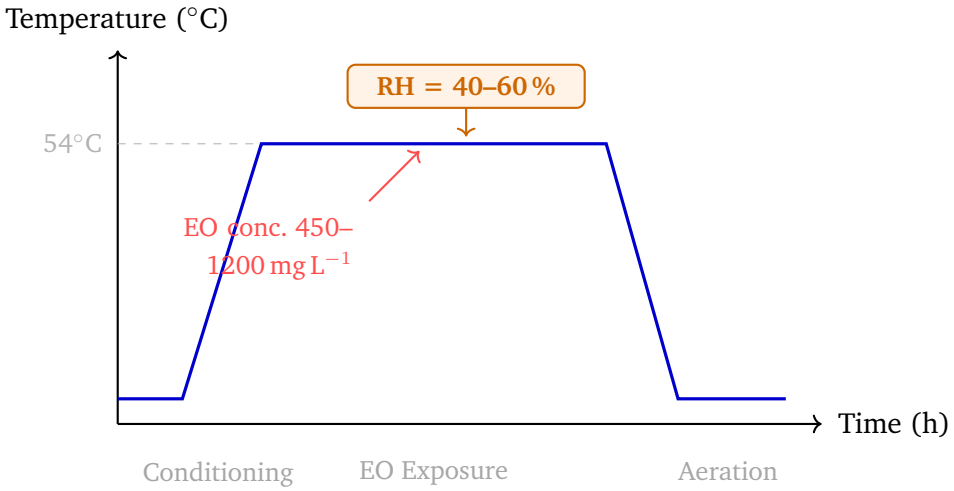
(A) The equivalent exposure time (in minutes) at a *reference temperature of* $121°C$ ($Z = 10°$C for bacterial spores) that delivers the same cumulative lethal effect as the actual time–temperature sterilisation cycle.

(B) The actual temperature (in °C) maintained inside the autoclave chamber at the sterilisation hold phase.

(C) The minimum time in minutes required for sterilisation, regardless of the temperature used or the Z-value of the target organism.

(D) The number of logarithmic reductions in bioburden achieved per minute at the peak sterilisation temperature.

Q12. The profile below represents a typical ethylene oxide (EO) sterilisation cycle, showing the chamber temperature over time.



Based on established guidelines, which *combination* of parameters is CRITICAL for ensuring adequate sterilisation by ethylene oxide?

(A) EO gas concentration alone determines sterilisation efficacy; temperature and humidity are negligible variables.

(B) Only relative humidity and exposure time are important; temperature has no effect on EO reactivity with biomolecules.

(C) EO gas concentration (450–1200 mg L^{-1}), chamber temperature (54 ± 10°C), relative humidity (30–60 %), and adequate exposure time must all be simultaneously controlled.

(D) High temperature (> 121°C) and elevated pressure (> 15 psi) are required, similar to steam autoclave conditions.

Q13. Sterilisation by filtration is employed for heat-sensitive pharmaceutical solutions such as ophthalmic drops, intravenous infusions, and biological products. What pore size of mem-

brane filter achieves *sterilising-grade* bacterial retention, as defined by pharmacopoeial and regulatory standards?

(A) 0.45 μm — used for bioburden (total viable count) testing and pre-filtration, but does not reliably retain all bacteria.

(B) 0.22 μm (nominally 0.2 μm) — the sterilising-grade pore size validated by challenge with $\geq 10^7$ CFU cm^{-2} of *Brevundimonas diminuta* ATCC 19146.

(C) 1.2 μm — used for removing sub-visible particulate matter and as a pre-filter to protect the sterilising filter.

(D) 5.0 μm — used for clarification of bulk liquids; cannot retain bacteria.

Q14. The European Pharmacopoeia (EP) 5.1.3 Preservative Efficacy Test defines acceptance **Criteria A** for **Category 1** products (aqueous preparations for parenteral and ophthalmic use). The challenge organisms include *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli*, *Candida albicans*, and *Aspergillus brasiliensis*. Which criteria must be met?

(A) Zero growth of any challenge organism at all sampling points (days 2, 7, 14, and 28) from the initial inoculum.

(B) At least 1 log reduction in viable bacterial count from the initial inoculum by day 7, with no increase by day 14.

(C) At least 3 log reduction in bacterial count by day 7 and no recovery of fungi at any time point.

(D) At least 2 log reduction in viable bacterial count from the initial inoculum by day 14, with no increase in count at day 28; for fungi, no increase in count from the initial inoculum at days 14 and 28.

Q15. Two classical agar-plate methods are routinely used for Total Viable Count (TVC) determination in pharmaceutical microbiology: the *pour plate* method and the *surface spread plate* method. What is the DISTINGUISHING feature of the **pour plate** method?

(A) The sample inoculum is *mixed* with molten nutrient agar (cooled to 44–47°C) and poured into a Petri dish; after solidification and incubation, *both surface and subsurface colonies* are counted.

(B) The sample is spread over the surface of pre-solidified agar using a glass spreader; only surface colonies develop.

(C) The sample is filtered through a 0.45 μm membrane which is then placed face-up on nutrient agar for incubation.

(D) The sample is serially diluted in broth and turbidity is used to estimate the viable count without agar.

Q16. A pharmacist receives two unmarked white cream preparations — one is an oil-in-water (O/W) emulsion and the other is a water-in-oil (W/O) emulsion. Which simple bench-top test reliably *distinguishes* an O/W cream from a W/O cream?

(A) Staining with Sudan III dye: O/W cream turns uniformly

red throughout; W/O cream turns orange.

(B) Addition of water: W/O cream disperses uniformly in water, while O/W cream does not.

(C) Conductance (electrical) test and dilution test: O/W cream conducts electricity (aqueous continuous phase carries ions) and disperses uniformly in water; W/O cream does not conduct and does not disperse in water.

(D) pH measurement: O/W creams always have a higher pH than W/O creams of the same formulation.

Q17. The Sun Protection Factor (SPF) is the standard measure of sunscreen efficacy. Which statement MOST ACCURATELY describes what the SPF value primarily measures?

(A) The ratio of UVA protection to UVB protection provided by the sunscreen formulation.

(B) The ratio of the minimum erythema dose (MED) on sunscreen-protected skin to the MED on unprotected skin: $\mathrm{SPF} = \mathrm{MED}_{\text{protected}}/\mathrm{MED}_{\text{unprotected}}$, primarily reflecting protection in the UVB range (290–320 nm).

(C) The total UV-absorbing capacity expressed in $\mathrm{mJ\,cm^{-2}}$ per gram of sunscreen applied per unit skin area.

(D) The percentage of total solar UV radiation (UVA + UVB combined) that is completely blocked by the sunscreen film.

Q18. In the formulation of a modern shampoo, several different

classes of surfactant are incorporated for specific functions. Which type of surfactant serves as the **PRIMARY CLEANSING AGENT**, responsible for removing sebum, oils, and particulate soil from hair and scalp?

(A) Amphoteric surfactant (e.g., cocamidopropyl betaine) — used as a *secondary* co-surfactant to reduce irritation and improve foam quality.

(B) Cationic surfactant (e.g., cetyltrimethylammonium chloride) — incompatible with anionic surfactants; used in conditioners, not cleansers.

(C) Non-ionic surfactant (e.g., polysorbate 20) — provides mildness and emulsification but has limited detergency and foaming power.

(D) Anionic surfactant (e.g., sodium laureth sulfate, SLES) — provides the principal detergency, foaming, and soil-removal action in shampoo formulations.

Q19. High-density polyethylene (HDPE) and low-density polyethylene (LDPE) are both used in pharmaceutical packaging. Which statement correctly explains why **HDPE** is preferred over LDPE for solid oral dosage form (tablet/capsule) bottles?

(A) HDPE has a lower moisture vapour transmission rate (MVTR) and greater rigidity than LDPE due to its higher crystallinity ($> 90\%$), making it superior for moisture-sensitive solid oral products.

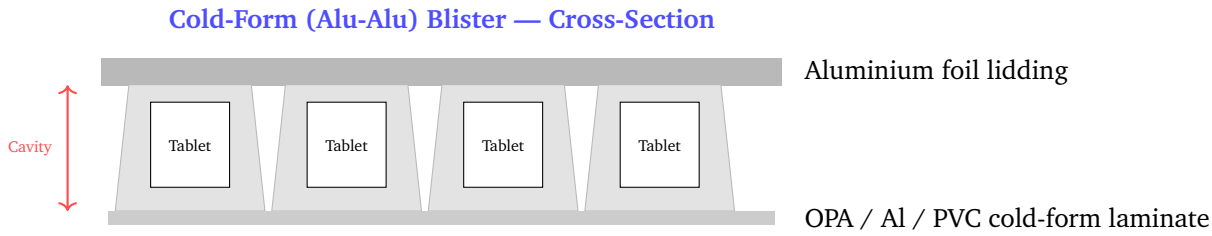
(B) LDPE provides a better moisture barrier than HDPE, and

its higher flexibility makes tablet bottles easier to open; therefore LDPE is the preferred material.

(C) HDPE and LDPE have essentially identical permeability to water vapour; HDPE is selected purely on cost grounds.

(D) HDPE is chemically incompatible with common tablet excipients (e.g., lubricants) and is therefore rarely used for pharmaceutical bottles.

Q20. The cross-section below illustrates a blister pack structure.



A **cold-form (Alu-Alu) blister** pack for highly moisture- and light-sensitive tablets uses which material combination?

(A) PVC thermoforming film heat-sealed to a paper/foil laminate lid — standard push-through blister.

(B) PVDC-coated PVC thermoforming film heat-sealed to aluminium foil lidding — a high-barrier thermoform blister.

(C) *Oriented polyamide (OPA) / aluminium foil / PVC* cold-form laminate for the base, heat-sealed to aluminium foil lidding — provides near-perfect barrier to moisture, oxygen, and light.

(D) HDPE rigid tray insert with tablets loose-filled and sealed inside a polyester/foil laminated pouch.

Q21. A pharmaceutical manufacturer intends to launch a new modified-release tablet to the market. The validation team collects process performance data from three consecutive full-scale production batches manufactured under the defined commercial process conditions *before* any batch is released for sale. Which type of process validation does this describe?

(A) Retrospective validation — uses accumulated historical batch-record data for a product already on the market to demonstrate prior process consistency.

(B) Prospective validation — establishes documented evidence that the process will consistently produce product meeting its specifications *before* commercial distribution, using a pre-approved protocol with three or more consecutive full-scale batches.

(C) Concurrent validation — validating the process while simultaneously releasing production batches to the market; acceptable only when prospective validation is infeasible.

(D) Revalidation — triggered by a significant change in formulation, process, equipment, or site; follows a prospective or concurrent approach.

Q22. ICH Q1A(R2) defines climatic zones for long-term stability testing to represent global storage conditions. Which climatic zone has conditions of **30°C / 75% RH** and is specifically designated for pharmaceutical products marketed in countries with hot and very humid climates?

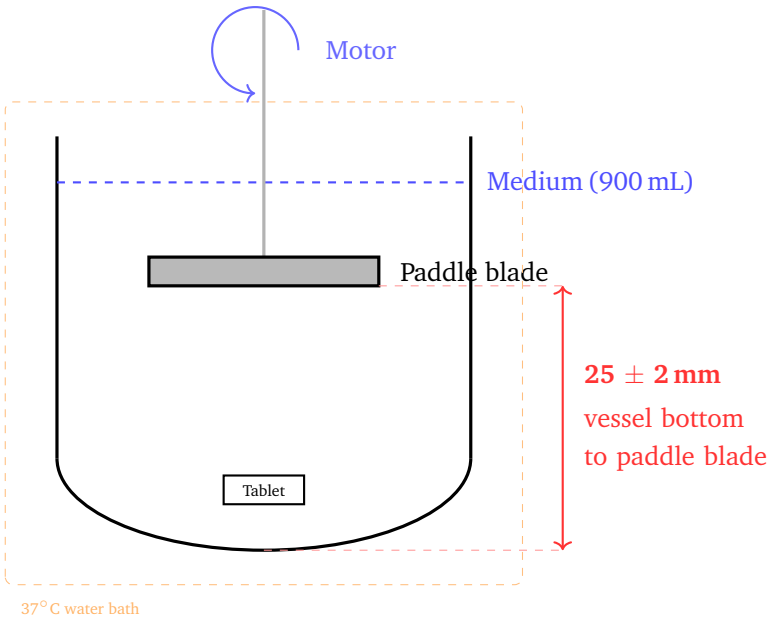
(A) Zone I (21°C / 45% RH) — temperate climates (e.g., UK, northern Europe).

(B) Zone II (25°C / 60% RH) — subtropical and Mediterranean climates; also the standard ICH long-term stability condition.

(C) Zone III (30°C / 35% RH) — hot and dry climates (e.g., Middle East, parts of Africa).

(D) Zone IVb (30°C / 75% RH) — hot and very humid climates (e.g., India, South-East Asia, parts of Latin America and Africa); required by ASEAN, WHO, and regional regulatory bodies.

Q23. The diagram below depicts a cross-section of USP Dissolution Apparatus 2 (Paddle Apparatus).



In USP Dissolution Apparatus 2, which parameter is specified to be maintained within ± 2 mm and is therefore CRITICAL for reproducible dissolution testing results?

(A) The distance between the *bottom face of the paddle blade* and the *inside bottom* of the dissolution vessel, specified as 25 ± 2 mm.

(B) The volume of dissolution medium in the vessel, which must be 900 ± 2 mL.

(C) The rotational speed of the paddle, which must be 50 ± 2 rpm for immediate-release tablets.

(D) The temperature of the dissolution medium, which must be 37 ± 2°C.

Q24. In vitro–in vivo correlations (IVIVC) are classified into levels by regulatory agencies (FDA Guidance, 1997) based on the nature of the relationship between in vitro dissolution and in vivo absorption. Which IVIVC level provides a **point-to-point** mathematical relationship between the *entire* in vitro dissolution profile and the *entire* in vivo drug absorption profile (typically derived by deconvolution)?

(A) Level D — a rank-order qualitative relationship between formulations; provides no quantitative predictive power.

(B) Level B — correlates a statistical moment of dissolution (e.g., mean dissolution time) with a statistical moment of the in vivo profile (e.g., mean residence time); does not predict the shape of the plasma profile.

(C) Level A — a one-to-one point-to-point correlation between the complete in vitro and in vivo profiles; the highest and most predictive level; may support a biowaiver

for formulation changes.

(D) Level C — a single-point correlation between one dissolution parameter (e.g., $t_{50\%}$ or $Q_{45\,\text{min}}$) and one pharmacokinetic parameter (e.g., $C_{\max}$ or AUC); least predictive of the plasma profile.

Q25. A health technology assessment (HTA) body evaluates a new antifungal agent versus the current standard of care for invasive fungal infections. The analysis computes the additional cost per additional quality-adjusted life year (QALY) gained by the new therapy:

$$\text{ICER} = \frac{C_{\text{new}} - C_{\text{standard}}}{\text{QALY}_{\text{new}} - \text{QALY}_{\text{standard}}}$$

The ICER is then compared with a willingness-to-pay threshold (e.g., £20,000–30,000/QALY per NICE). Which pharmacoeconomic analysis methodology is being applied?

(A) Cost-minimisation analysis (CMA) — assumes *equal* effectiveness of both options and compares only their costs.

(B) Cost-effectiveness analysis (CEA) / cost-utility analysis (CUA) — compares interventions using the ICER expressed as cost per natural unit of effect (life-year, event prevented) or cost per QALY, enabling resource-allocation decisions.

(C) Cost-benefit analysis (CBA) — converts all health outcomes into monetary (currency) values so that the net benefit can be expressed entirely in financial terms.

(D) Cost-consequence analysis (CCA) — lists all relevant costs and outcomes of each option separately, without aggregating them into a single summary ratio.

Detailed Solutions

Q1.

Solution

Concept — Gibbs Phase Rule for a One-Component System: The Gibbs phase rule states $F = C - P + 2$, where F is the number of degrees of freedom (intensive variables that can be changed independently), C is the number of components, and P is the number of phases present in equilibrium. For pure water $C = 1$.

Step 1 — Identify the phases at the triple point: At the triple point, solid ice, liquid water, and water vapour all coexist simultaneously, so $P = 3$.

Step 2 — Apply the phase rule: $F = C - P + 2 = 1 - 3 + 2 = 0$. Zero degrees of freedom means the triple point is a fixed, invariant state: both temperature (0.01°C) and pressure (611 Pa) are uniquely determined, and neither can be altered without destroying at least one phase.

Why other options are wrong:

- Option A: $F = 3$ would require $C - P + 2 = 3$, impossible for a single-component system with three phases ($1 - 3 + 2 = 0$).
- Option B: $F = 2$ applies to a single-phase region ($P = 1$; $1 - 1 + 2 = 2$), not to the triple point.
- Option C: $F = 1$ applies to any two-phase equilibrium curve in a one-component system ($1 - 2 + 2 = 1$), not the triple point.
- Option D: $F = 0$; the triple point is an invariant, fixed point in P–T space. **Correct.**

Final Answer: $F = 1 - 3 + 2 = 0$; the triple point is fully invariant $\Rightarrow$ $\boxed{\text{D}}$

Answer: (D) Go Back to Q1

Q2.

Solution

Concept — Eutectic Mixtures and Melting Point Depression: A eutectic mixture is a specific composition of two (or more) substances at which the mixture has the *lowest* possible melting point, below the melting point of each pure component. At the eutectic composition, the liquid and solid phases coexist at a single invariant temperature (the eutectic temperature).

Step 1 — Identify the eutectic composition of EMLA: Lidocaine (MP $\approx 68^\circ$C)

and prilocaine (MP $\approx 37^\circ$C) in a $1:1$ mass ratio form the eutectic composition with a eutectic temperature of $\approx 16^\circ$C.

Step 2 — Explain why the mixture is liquid at room temperature: Because the eutectic temperature ($\approx 16^\circ$C) is *below* room temperature (25°C), the $1:1$ mixture exists as a liquid (oily layer) at 25°C even though both pure components are solid at the same temperature. This liquid eutectic enhances transdermal penetration.

Why other options are wrong:

- Option A: A higher melting point due to hydrogen bonding would make the mixture solid, not liquid; eutectic formation *lowers* the MP.
- Option B: The $1:1$ mixture is the eutectic composition with MP $\approx 16^\circ$C, below room temperature. **Correct.**
- Option C: Prilocaine does not chemically decompose on mixing with lidocaine; both are stable local anaesthetics under normal conditions.
- Option D: Lidocaine is not markedly hygroscopic; the liquid arises from the eutectic phenomenon, not moisture absorption.

Final Answer: $1:1$ lidocaine/prilocaine = eutectic composition, MP $\approx 16^\circ$C $<$ room temperature $\Rightarrow$ B

Answer: (B) Go Back to Q2

Q3.

Solution

Concept — Raoult's Law and Vapour Pressure Lowering: Raoult's law states that the partial vapour pressure of the solvent above an ideal solution equals the mole fraction of the solvent multiplied by the pure solvent vapour pressure: $P_{\text{solvent}} = x_{\text{solvent}} \cdot P^\circ_{\text{solvent}}$. Since $x_{\text{solvent}} = 1 - x_{\text{solute}}$, this gives the colligative vapour pressure lowering: $\Delta P = x_{\text{solute}} \times P^\circ$.

Step 1 — Connect the formula to Raoult's law: $\Delta P = P^\circ - P_{\text{solvent}} = P^\circ - x_{\text{solvent}} \cdot P^\circ = (1 - x_{\text{solvent}}) \cdot P^\circ = x_{\text{glucose}} \cdot P^\circ \approx 0.001\, P^\circ$. This is exactly the form given in the question and is a direct consequence of Raoult's law.

Step 2 — Confirm it is a colligative property: Vapour pressure lowering depends only on the number of solute particles (mole fraction), not on their identity — the hallmark of a colligative property described by Raoult's law.

Why other options are wrong:

- Option A: Raoult's law directly predicts solvent vapour pressure lowering by

a non-volatile solute. **Correct.**

- Option B: Henry's law describes the solubility of a *volatile* gas in a liquid ($p_{\text{gas}} = k_H\, x_{\text{gas}}$); it does not apply to solvent vapour pressure lowering.
- Option C: Fick's first law ($J = -D\, dC/dx$) governs diffusion rates; it is unrelated to vapour pressure.
- Option D: Van 't Hoff's law ($\pi = iMRT$) predicts osmotic pressure, a different colligative property, not vapour pressure lowering.

Final Answer: Raoult's law: $P_{\text{sol}} = x_{\text{solvent}} \cdot P^{\circ}$; $\Delta P = x_{\text{solute}} \cdot P^{\circ} \Rightarrow \boxed{\text{A}}$

Answer: (A) Go Back to Q3

Q4.

Solution

Concept — Osmolality and Ionic Dissociation: Osmolality is the number of osmotically active particles per kilogram of solvent (mOsm kg^{-1}). For an electrolyte that dissociates completely into ν ions, the osmolality is ν times the molality.

Step 1 — Calculate the molality of 0.9% NaCl: 0.9% w/v = 9 g L^{-1}.
Molar mass of NaCl $= 58.5$ g mol^{-1}.
Molality $= 9/58.5 \approx 0.1538$ mol kg^{-1} (dilute solution, so mol/L $\approx$ mol/kg).

Step 2 — Multiply by the osmotic coefficient ν: NaCl dissociates completely: $Na^+ + Cl^-$, so $\nu = 2$.
Osmolality $= 0.1538 \times 2 \times 1000 = 307.7 \approx 308$ mOsm kg^{-1}.
This matches plasma osmolality (≈285–310 mOsm kg^{-1}), confirming isotonicity.

Why other options are wrong:

- Option A: 154 mOsm kg^{-1} is the molar concentration of NaCl (0.154 mol kg^{-1}) without applying the dissociation factor $\nu = 2$.
- Option B: 200 mOsm kg^{-1} has no basis in the calculation for 0.9% NaCl.
- Option C: 308 mOsm kg^{-1} correctly accounts for complete dissociation ($\nu = 2$). **Correct.**
- Option D: 616 mOsm kg^{-1} would imply $\nu = 4$ ions, which NaCl does not yield.

Final Answer: 0.1538 mol/kg $\times\, 2 \times 1000 = 308$ mOsm/kg $\Rightarrow \boxed{\text{C}}$

Answer: (C) Go Back to Q4

Q5.

Solution

Concept — Thermodynamics of β-Cyclodextrin Inclusion Complex Formation: β-Cyclodextrin possesses a truncated-cone structure with a hydrophilic outer surface (hydroxyl groups) and a hydrophobic inner cavity. In aqueous solution, the cavity is occupied by energetically unfavourable, highly ordered water molecules. Displacing these "high-energy" water molecules when a hydrophobic drug enters the cavity is both enthalpically and entropically favourable.

Step 1 — Identify the primary thermodynamic driving forces: (i) *Hydrophobic interaction*: the apolar drug molecule partitions from the aqueous phase into the hydrophobic cavity, analogous to the hydrophobic effect.
(ii) *Release of strained water*: ordered water molecules confined in the small cavity are released to bulk water, increasing entropy ($\Delta S > 0$) and releasing enthalpy ($\Delta H < 0$).

Step 2 — Confirm 1 : 1 stoichiometry and non-covalent character: The complex is held by non-covalent forces (van der Waals, hydrophobic interactions). No covalent bonds are formed. Stability constant K_s reflects the equilibrium between free and complexed forms.

Why other options are wrong:

- Option A: Covalent ester bonds would constitute a chemical reaction, not an inclusion complex; β-CD does not form covalent bonds with guest molecules.
- Option B: Release of high-energy cavity water + hydrophobic interaction are the established primary driving forces. **Correct.**
- Option C: The inner β-CD cavity carries no permanent ionic charge; the cavity walls present hydroxyl and C–H groups, not charged sites.
- Option D: β-CD is not an enzyme; complex formation is purely physical (host–guest chemistry) with no enzymatic recognition.

Final Answer: Hydrophobic effect + release of strained cavity water drives inclusion complex formation $\Rightarrow$ B

Answer: (B) Go Back to Q5

Q6.

Solution

Concept — Critical Micelle Concentration (CMC): When surfactant molecules are added to water, they preferentially adsorb at the air–water interface, orienting their hydrophilic heads into the bulk water and their hydrophobic tails away. This adsorption progressively lowers the surface tension. Once the interface is saturated, additional surfactant self-assembles into micelles in the bulk solution. The concentration at which this transition occurs is the CMC.

Step 1 — Interpret the graph: The surface tension decreases linearly with $\log[\text{surfactant}]$ as molecules adsorb at the interface. At the CMC (breakpoint), the interface is fully saturated; further addition produces no further decrease in surface tension — the curve becomes flat (plateau at $\approx 30\,\text{mN}\,\text{m}^{-1}$).

Step 2 — Identify what the CMC represents: The CMC is the breakpoint concentration marking the *onset of micelle formation* in the bulk phase. Above the CMC, additional surfactant forms micelles (not adsorbed at the interface), so surface tension does not change further.

Why other options are wrong:

- Option A: Turbidity from precipitation would indicate supersaturation and crystal nucleation — a distinct phenomenon unrelated to CMC.
- Option B: Surface tension does not *increase* above the CMC; it remains constant. Counter-ion shielding alters CMC magnitude but does not cause a surface tension rise.
- Option C: The first adsorption at the interface begins at concentrations well *below* the CMC; this is not what the CMC represents.
- Option D: CMC = concentration at which surface tension reaches constant minimum = onset of micelle formation. **Correct.**

Final Answer: CMC is the breakpoint where surface tension plateaus and micelle formation begins $\Rightarrow$ $\boxed{\text{D}}$

Answer: (D) Go Back to Q6

Q7.

Solution

Concept — Spreading Coefficient and Spontaneous Spreading: The spreading coefficient $S = \gamma_{S/V} - \gamma_{L/V} - \gamma_{S/L}$ represents the net energy change per unit area when a liquid replaces the solid–vapour interface. A positive S means the energy is lowered when the liquid spreads, making the process spontaneous.

Step 1 — Thermodynamic criterion for spontaneous spreading: Spreading is spontaneous if and only if $S > 0$, i.e., the solid–vapour surface energy ($\gamma_{S/V}$) exceeds the sum of the liquid surface tension ($\gamma_{L/V}$) and the solid–liquid interfacial tension ($\gamma_{S/L}$). The total interfacial area and total surface energy decrease when the liquid spreads.

Step 2 — Physical interpretation: When $S > 0$, replacing the bare solid–vapour interface with the solid–liquid and liquid–vapour interfaces releases net free energy $= S$ per unit area, driving complete, spontaneous spreading.

Why other options are wrong:

- Option A: $S > 0$ is the correct thermodynamic requirement for spontaneous complete spreading. **Correct.**
- Option B: $S < 0$ means spreading is *not* spontaneous; the liquid contracts to a lens or droplet.
- Option C: $\theta > 90^\circ$ defines non-wetting (hydrophobic) behaviour — the opposite of spontaneous spreading.
- Option D: $\gamma_{S/L} > \gamma_{L/V}$ is not a criterion for spreading; it would make S more negative, hindering spreading.

Final Answer: $S = \gamma_{S/V} - \gamma_{L/V} - \gamma_{S/L} > 0$ for spontaneous spreading $\Rightarrow \boxed{A}$

Answer: (A) Go Back to Q7

Q8.

Solution

Concept — Unique Assumptions of the Langmuir Isotherm: The Langmuir model was derived from kinetic theory by assuming: (i) adsorption occurs on a surface with a *finite, fixed* number of identical sites; (ii) each site binds exactly one adsorbate molecule (monolayer coverage); (iii) all sites are energetically equivalent with no lateral interactions between adsorbed molecules; (iv) adsorption is reversible. The saturation capacity q_{max} arises directly from assumption (i).

Step 1 — Distinguish Langmuir from Freundlich: The empirical Freundlich isotherm $q = K_F C^{1/n}$ is valid for heterogeneous surfaces with an exponential distribution of adsorption energies. It has no saturation limit ($q_{\max}$) and assumes energy decreasing logarithmically with coverage. It does *not* assume a fixed finite number of uniform sites.

Step 2 — Identify the unique Langmuir feature: The finite, fixed, energetically uniform sites leading to monolayer saturation is unique to Langmuir. This is encoded in $q_{\max}$ (saturation plateau) in the equation.

Why other options are wrong:

- Option A: Exponentially decreasing adsorption energy with coverage is a Freundlich/Temkin assumption, not Langmuir.
- Option B: Multi-layer adsorption is the basis of the BET isotherm, not Langmuir.
- Option C: Finite fixed number of equivalent uniform sites with monolayer saturation is unique to Langmuir. **Correct.**
- Option D: Irreversible adsorption at surface defects is not assumed by Langmuir; Langmuir assumes reversible, dynamic equilibrium.

Final Answer: Fixed, finite, energetically uniform sites $\rightarrow$ monolayer saturation at $q_{\max}$ = unique Langmuir assumption $\Rightarrow$ C

Answer: (C) Go Back to Q8

Q9.

Solution

Concept — Gold Standard Method for Plasma Protein Binding: Multiple *in vitro* methods can measure the fraction of drug bound to plasma proteins ($f_b = 1 - f_u$). The ideal method should: (i) allow true thermodynamic equilibrium to be reached between bound and free drug; (ii) not disturb the bound/free equilibrium during the measurement; (iii) physically separate free from bound drug without artefact.

Step 1 — Principles of equilibrium dialysis: In equilibrium dialysis, the drug–plasma mixture is placed in one chamber separated from protein-free buffer by a semi-permeable dialysis membrane with a molecular weight cut-off (MWCO) that retains proteins but allows free drug to diffuse freely. The system is incubated (typically 6–24 h, 37°C) until true thermodynamic equilibrium is reached. Sampling both chambers then gives f_u directly without disturbing the equilibrium.

Step 2 — Why it is the gold standard: Because the bound/free equilibrium is never physically perturbed during measurement, the method provides the most accurate thermodynamic K_a and f_u values. Regulatory agencies (FDA, EMA) regard equilibrium dialysis as the reference technique.

Why other options are wrong:

- Option A: Ultrafiltration is faster but can shift the equilibrium by concentrating protein/drug in the retentate during centrifugation, overestimating binding.
- Option B: Equilibrium dialysis reaches true thermodynamic equilibrium without perturbing the bound/free ratio. **Correct (gold standard).**
- Option C: Ultracentrifugation separates by density but can alter equilibrium and is difficult to validate; not the gold standard.
- Option D: SEC separates by molecular size but drug can re-equilibrate during column migration, giving lower apparent binding.

Final Answer: Equilibrium dialysis reaches true thermodynamic equilibrium = gold standard for protein binding $\Rightarrow$ B

Answer: (B) Go Back to Q9

Q10.

Solution

Concept — Effect of Plasma Protein Binding on Pharmacokinetic Parameters: For a drug that binds to albumin, the free (unbound) fraction is $f_u = 1/(1+K_a[P])$. Increased binding (higher K_a or higher albumin concentration $[P]$) reduces f_u. The apparent volume of distribution is $V_d = V_p + V_t \cdot (f_u/f_{u,t})$, where V_p is plasma volume and V_t is tissue volume. When f_u decreases, less drug partitions into tissues, so V_d decreases (drug is retained in plasma).

Step 1 — Effect on free fraction f_u: Increased protein binding $\Rightarrow$ $f_u \downarrow$ (more drug is bound, less is pharmacologically active free drug).

Step 2 — Effect on V_d and clearance: $V_d \downarrow$ (less tissue distribution; drug retained in plasma bound state).
For *low-extraction* drugs (where $CL \approx f_u \cdot CL_{\text{int}}$), reduced f_u lowers total clearance, prolonging half-life ($t_{1/2} = 0.693\, V_d/CL$; both V_d and CL fall, with opposing effects on $t_{1/2}$, but net $t_{1/2}$ may be prolonged).

Why other options are wrong:

- Option A: Increased binding *decreases* f_u (not increases it) and *decreases* V_d (not increases it); this option is the opposite.
- Option B: High protein binding *retains* drug in plasma, *decreasing* (not increasing) V_d.
- Option C: For low-extraction drugs, $CL \approx f_u \cdot CL_{\text{int}}$; decreased f_u *reduces* clearance, not leaves it unchanged.
- Option D: Decreased f_u, decreased V_d, reduced clearance (low-extraction drugs) — all mechanistically correct. **Correct.**

Final Answer: Increased binding $\Rightarrow$ $f_u \downarrow$, $V_d \downarrow$, $CL \downarrow$ for low-extraction drugs $\Rightarrow$ D

Answer: (D) Go Back to Q10

Q11.

Solution

Concept — F_0 Value in Moist-Heat Sterilisation Validation: The F_0 value is a measure of the *cumulative lethal effect* of an autoclaving cycle expressed in equivalent minutes at a standard reference temperature of 121°C, using a Z-value of 10°C (the Z-value for *Geobacillus stearothermophilus* spores, the reference organism for moist-heat sterilisation).

Step 1 — Mathematical definition of F_0:

$$F_0 = \int_0^t 10^{(T-121)/10}\, dt$$

where T is the product temperature at time t. At $T = 121$°C exactly, the integrand $= 1$, so $F_0 = t$ (equivalent minutes at reference conditions).

Step 2 — Practical interpretation: An $F_0 = 8$ min means the cycle delivered the same microbiological kill as 8 continuous minutes of exposure at 121°C. Regulatory guidance typically requires $F_0 \geq 8$ min for overkill sterilisation cycles.

Why other options are wrong:

- Option A: F_0 = equivalent minutes at 121°C ($Z = 10$°C) delivering the same cumulative lethality as the actual cycle. **Correct.**
- Option B: The actual hold temperature is a process parameter, not F_0; F_0 integrates the entire temperature–time profile.
- Option C: F_0 is not a minimum time independent of temperature; it explicitly accounts for the temperature profile via the Z-value exponent.

- Option D: Log reductions per minute is the concept of the death rate (k_d), not the F_0 value, which is an integrated lethality measure.

Final Answer: F_0 = equivalent minutes at 121°C ($Z = 10$°C) for the same cumulative lethality $\Rightarrow$ A

Answer: (A) Go Back to Q11

Q12.

Solution

Concept — Critical Parameters for Ethylene Oxide (EO) Sterilisation: EO is an alkylating agent that inactivates microorganisms by reacting with nucleic acids and proteins. Its sterilisation efficacy depends on four interdependent physicochemical parameters that must all be simultaneously controlled.

Step 1 — Identify the four critical parameters:

- **EO gas concentration** (450–1200 mg L^{-1}): determines the concentration of the alkylating agent available at the microbial cell.
- **Temperature** (54±10°C): higher temperature increases the reaction rate of EO with biomolecules (Arrhenius effect).
- **Relative humidity** (30–60 %): essential to hydrate bacterial spores, making their DNA/proteins accessible to EO alkylation; dry spores are highly resistant to EO.
- **Exposure time**: sufficient contact time ensures the EO reaction goes to completion.

Step 2 — Why all four must be controlled simultaneously: Inadequate humidity leaves spores in a resistant, desiccated state regardless of EO concentration. Insufficient temperature slows alkylation. Inadequate exposure time means incomplete kill.

Why other options are wrong:

- Option A: EO concentration alone is insufficient; humidity is critical for spore inactivation.
- Option B: Temperature significantly affects the rate of EO alkylation; it cannot be ignored.
- Option C: All four parameters (EO conc., temperature, RH, time) must be controlled. **Correct.**
- Option D: EO sterilisation uses mild temperatures (∼54°C), not $>$ 121°C autoclave conditions; those would destroy the device.

Final Answer: EO conc. + temperature (54°C) + RH (30–60%) + exposure time must all be controlled $\Rightarrow$ C

Answer: (C) Go Back to Q12

Q13.

Solution

Concept — Sterilising-Grade Membrane Filtration: Sterilising filtration removes viable microorganisms (bacteria and fungi) from pharmaceutical solutions without applying heat, making it the method of choice for heat-sensitive products. Regulatory and pharmacopoeial standards define a "sterilising-grade" filter by its ability to withstand a defined microbial challenge.

Step 1 — Pharmacopoeial definition of sterilising-grade filtration: USP ⟨1229.4⟩, EU GMP Annex 1, and ISO 13408-2 define a sterilising-grade filter as one with a nominal pore size of **0.22 μm** (often labelled 0.2 μm) that achieves a complete bacterial retention (titer reduction $\geq 10^7$ CFU cm^{-2}) when challenged with the small, rigid-cell bacterium *Brevundimonas diminuta* ATCC 19146.

Step 2 — Confirm the pore size: *Brevundimonas diminuta* cells are 0.3–0.4 μm in width, the smallest known bacterium used as a filter-validation challenge organism. A 0.22 μm filter reliably retains them; a 0.45 μm filter does not.

Why other options are wrong:

- Option A: 0.45 μm is used for bioburden enumeration and pre-filtration; it does not reliably retain all bacteria, especially small organisms.
- Option B: 0.22 μm is the sterilising-grade pore size, validated by *B. diminuta* challenge. **Correct.**
- Option C: 1.2 μm retains particles and cells larger than $\sim$1 μm; used as a depth pre-filter, not a sterilising filter.
- Option D: 5.0 μm is used for bulk liquid clarification; it cannot retain any bacteria.

Final Answer: 0.22 μm (0.2 μm nominal) validated by *B. diminuta* challenge = sterilising-grade $\Rightarrow$ B

Answer: (B) Go Back to Q13

Q14.

Solution

Concept — EP 5.1.3 Preservative Efficacy Test: Criteria A, Category 1: The European Pharmacopoeia (5.1.3) classifies pharmaceutical preparations into categories based on their route of administration. **Category 1** covers aqueous preparations for *parenteral and ophthalmic* use — the highest-risk category requiring the most stringent antimicrobial criteria. **Criteria A** is the preferred, more stringent set of criteria.

Step 1 — Criteria A for bacteria (Category 1): The log reduction from the initial inoculum count at each time point must be:

- No increase at 6 h (for parenteral products only, some guidelines)
- ≥ 2 $\log_{10}$ reduction at **day 14**
- No *increase* in viable count compared to the 14-day value at **day 28**

Step 2 — Criteria A for fungi (Category 1): No increase in viable fungal count at days 14 and 28 compared to the initial inoculum.

Why other options are wrong:

- Option A: Zero growth at *all* time points is a stricter criterion than EP Criteria A; EP allows bacteria to survive up to day 14 provided the 2-log reduction is achieved by day 14.
- Option B: Only 1-log reduction by day 7 is less stringent than Criteria A (2-log by day 14).
- Option C: 3-log reduction by day 7 corresponds to Criteria B or USP requirements for certain categories, not EP Criteria A, Category 1.
- Option D: ≥ 2 log reduction by day 14, no increase at day 28 (bacteria); no increase in fungi at days 14 and 28. **Correct.**

Final Answer: EP Criteria A, Cat. 1: ≥ 2 log reduction at day 14, no increase day 28; fungi: no increase days 14/28 $\Rightarrow$ $\boxed{\text{D}}$

Answer: (D) Go Back to Q14

Q15.

Solution

Concept — Pour Plate vs. Surface Spread Plate for Total Viable Count: The two principal agar-plate methods for enumerating viable microorganisms differ in how the inoculum contacts the agar. The distinguishing feature of the pour plate method is that the sample is *incorporated into* the agar before solidification.

Step 1 — Pour plate procedure:

- A measured volume (usually 1 mL) of sample or dilution is pipetted into an empty sterile Petri dish.
- Molten nutrient agar cooled to 44–47°C (below solidification but not hot enough to kill bacteria) is poured into the dish and swirled to mix.
- After solidification and incubation, colonies develop both *on the surface* (upper layer) and *within the agar* (subsurface/embedded colonies).
- Both surface and embedded colonies are counted.

Step 2 — Comparison with spread plate: In the surface spread plate method, the inoculum is spread over the surface of *pre-solidified* agar using a sterile glass rod; only surface colonies form. The pour plate allows higher sample volume, but some heat-sensitive organisms may be killed by the molten agar.

Why other options are wrong:

- Option A: Sample mixed with molten agar $\rightarrow$ poured $\rightarrow$ surface + subsurface colonies. **Correct distinguishing feature of the pour plate method.**
- Option B: Spreading on pre-solidified agar is the surface spread plate method, yielding surface colonies only.
- Option C: Filtering through 0.45 μm membrane then placing on agar is the membrane filtration method for low-count samples.
- Option D: Serial dilution plus turbidity estimation is the most probable number (MPN) or nephelometric method, not a colony-count method.

Final Answer: Pour plate = sample mixed with molten agar (44–47°C), poured, produces surface + subsurface colonies $\Rightarrow$ $\boxed{\text{A}}$

Answer: (A) Go Back to Q15

Q16.

Solution

Concept — Identification of Emulsion Type (O/W vs. W/O): The emulsion type is determined by the nature of the continuous (external) phase. In O/W emulsions, water is the continuous phase; in W/O emulsions, oil is the continuous phase. Several bench-top tests exploit this difference.

Step 1 — Conductance (electrical) test: Water carries dissolved electrolytes (ions) and therefore conducts electricity. Oil does not. An **O/W cream** (aqueous continuous phase) will *conduct* electricity when tested with a conductivity meter or simple circuit; a **W/O cream** (oil continuous phase) will *not conduct*.

Step 2 — Dilution (water miscibility) test: An O/W emulsion disperses uniformly when diluted with water (water is miscible with the external phase). A W/O emulsion does not disperse in water; it forms globules or phase-separates.

Why other options are wrong:

- Option A: Sudan III (red oil-soluble dye) stains the *oil phase* red. In a W/O emulsion (oil continuous), the entire sample turns red; in O/W, discrete red droplets are seen on microscopy. The description "uniformly red" for O/W is incorrect.
- Option B: The reverse is true: O/W emulsions (aqueous external) disperse in water; W/O emulsions do not.
- Option C: Conductance test (O/W conducts; W/O does not) and dilution test (O/W disperses in water; W/O does not) reliably distinguish emulsion types. **Correct.**
- Option D: pH is not a reliable discriminator between O/W and W/O creams of the same formulation; both types can be formulated at any pH.

Final Answer: Conductance + dilution tests: O/W conducts and disperses in water; W/O does not $\Rightarrow$ C

Answer: (C) Go Back to Q16

Q17.

Solution

Concept — Sun Protection Factor (SPF) and Minimum Erythema Dose: SPF is a measure of UVB photoprotection and is determined by a standardised *in vivo* testing protocol (ISO 24444, FDA 21 CFR 352). Erythema (sunburn) is the primary biological endpoint because UVB radiation (290–320 nm) is the principal cause of acute sunburn.

Step 1 — Definition of SPF: The minimum erythema dose (MED) is the lowest UV dose causing perceptible erythema on unprotected skin. SPF is defined as:

$$\text{SPF} = \frac{\text{MED}_{\text{protected}}}{\text{MED}_{\text{unprotected}}}$$

A higher SPF means more UV energy is required to cause erythema on protected skin, i.e., greater protection. SPF 30 means ∼97% of UVB photons are absorbed by the sunscreen film.

Step 2 — UVB vs. UVA relevance: SPF primarily measures protection in the **UVB range** (290–320 nm) because erythema is predominantly caused by UVB. Separate UVA protection ratings (e.g., PA+++ system, critical wavelength) are assessed by different test methods.

Why other options are wrong:

- Option A: SPF is not a ratio of UVA-to-UVB protection; it measures UVB protection specifically via the erythema endpoint.
- Option B: SPF = $\text{MED}_{\text{protected}}/\text{MED}_{\text{unprotected}}$, primarily reflecting UVB (290–320 nm) protection. **Correct.**
- Option C: SPF is a dimensionless ratio, not expressed in energy units per gram of sunscreen.
- Option D: SPF does not measure total UV blockage as a percentage; it quantifies the factor by which the erythema dose is multiplied.

Final Answer: $\text{SPF} = \text{MED}_{\text{protected}}/\text{MED}_{\text{unprotected}}$, primarily UVB protection $\Rightarrow$ $\boxed{\text{B}}$

Answer: (B) Go Back to Q17

Q18.

Solution

Concept — Surfactant Roles in Shampoo Formulation: Modern shampoo formulations contain multiple surfactant classes, each fulfilling a specific functional role. The formulation is designed around a primary detergent (high detergency, high foam) supplemented by secondary surfactants to optimise mildness, foam quality, and conditioning.

Step 1 — Primary cleansing agent in shampoos: The **anionic surfactant** (most commonly sodium laureth sulfate, SLES, or ammonium lauryl sulfate, ALS) serves as the primary cleansing agent. Its strongly hydrophilic sulfate head group and long hydrophobic alkyl tail provide:

- High detergency (soil and sebum solubilisation via micelle formation)
- Copious, stable lather (foam generation)
- Strong adsorption at the oil–water interface (emulsification of scalp oils)

Step 2 — Functions of other surfactant classes: Amphoteric surfactants (cocamidopropyl betaine) are secondary co-surfactants that reduce irritation and improve foam quality. Cationic surfactants are conditioning agents used in rinse-off conditioners, not shampoo cleansers. Non-ionic surfactants add mildness and stability.

Why other options are wrong:

- Option A: Amphoteric (cocamidopropyl betaine) is a secondary surfactant for mildness and foam enhancement, not the primary cleansing agent.
- Option B: Cationic surfactants (e.g., CTAC) are chemically incompatible with anionic surfactants and are reserved for conditioners.
- Option C: Non-ionic surfactants have low detergency and limited foaming power; they are supporting agents, not primary cleansers.
- Option D: Anionic surfactant (SLES/ALS) provides the principal detergency, foaming, and soil-removal action. **Correct.**

Final Answer: Anionic surfactants (SLES/ALS) deliver primary detergency and foaming in shampoos $\Rightarrow$ D

Answer: (D) Go Back to Q18

Q19.

Solution

Concept — HDPE vs. LDPE for Pharmaceutical Packaging: Both high-density polyethylene (HDPE) and low-density polyethylene (LDPE) are widely used in pharmaceutical packaging, but their physical properties differ because of their polymer microstructure. HDPE has a predominantly linear backbone with minimal branching, enabling tight chain packing and high crystallinity ($> 90\%$). LDPE has extensive short-chain branching, reducing chain packing and crystallinity ($\sim$50%).

Step 1 — Moisture vapour transmission rate (MVTR): Crystalline regions in polyethylene are essentially impermeable to moisture vapour because water molecules cannot diffuse through tightly packed crystalline lamellae. The higher the crystallinity, the lower the MVTR. HDPE ($> 90\%$ crystallinity) has a *much lower MVTR* than LDPE ($\sim$50% crystallinity), making HDPE a superior moisture barrier.

Step 2 — Rigidity: HDPE's high crystallinity also gives it greater stiffness, hardness, and tensile strength, making it suitable for rigid tablet/capsule bottles that withstand stacking, capping, and transport forces.

Why other options are wrong:

- Option A: HDPE has lower MVTR and greater rigidity due to higher crystallinity ($> 90\%$) — the correct mechanistic explanation. **Correct.**
- Option B: LDPE has *higher* MVTR (worse moisture barrier) due to lower crystallinity; LDPE is used for squeeze bottles, not for rigid moisture-sensitive tablet containers.
- Option C: HDPE and LDPE have significantly different permeabilities; HDPE is selected primarily for its superior barrier properties, not cost.
- Option D: HDPE is chemically inert and compatible with essentially all common tablet excipients; it is among the most widely used materials for pharmaceutical bottles.

Final Answer: HDPE ($> 90\%$ crystallinity) $\Rightarrow$ lower MVTR and greater rigidity than LDPE $\Rightarrow$ preferred for solid oral bottles $\Rightarrow$ $\boxed{\text{A}}$

Answer: (A) Go Back to Q19

Q20.

Solution

Concept — Cold-Form (Alu-Alu) Blister Packaging: Blister packaging can be divided into *thermoform* blisters (heated plastic film formed over a mould) and *cold-form* blisters (aluminium-based laminate pressed at room temperature without heat). Cold-form blisters provide the highest barrier to moisture, oxygen, and light because aluminium foil is essentially impermeable.

Step 1 — Structure of the cold-form base laminate: The cold-form base (forming web) is a three-layer laminate:

- **OPA** (oriented polyamide/nylon) — outer protective layer providing mechanical strength and cold-forming ability (prevents pinhole formation)
- **Aluminium foil** ($\sim$60 μm) — provides the near-perfect moisture and oxygen barrier; WVTR ≈ 0
- **PVC** (polyvinyl chloride) — inner heat-sealable layer bonded to the aluminium foil lidding

Step 2 — The lidding foil: A plain aluminium foil (with a heat-seal lacquer on the inner surface) is used as the lidding material, giving aluminium on both sides ("Alu-Alu").

Why other options are wrong:

- Option A: PVC + paper/foil lid is a standard (low-barrier) push-through blister; PVC is permeable to moisture.
- Option B: PVDC-coated PVC is a high-barrier thermoform blister but is still plastic-based and inferior to the near-zero permeability of the Alu-Alu design.
- Option C: OPA/Al/PVC cold-form laminate + Al foil lidding = true Alu-Alu cold-form blister with maximum barrier. **Correct.**
- Option D: HDPE rigid tray in a laminated pouch is a bottle/pouch combination, not a unit-dose cold-form blister.

Final Answer: OPA/Al/PVC cold-form laminate base + aluminium foil lid = Alu-Alu cold-form blister, highest moisture/oxygen barrier $\Rightarrow$ C

Answer: (C) Go Back to Q20

Q21.

Solution

Concept — Types of Process Validation (ICH Q7 / FDA Guidance): Pharmaceutical manufacturing processes must be validated to ensure consistent production of quality product. The timing of the validation relative to commercial distribution distinguishes the three main validation approaches.

Step 1 — Definition of prospective validation: Prospective validation is conducted *before* the commercial distribution of a new drug product. It follows a pre-approved validation protocol and typically requires data from at least **three consecutive full-scale batches** (process performance qualification batches) manufactured under the defined commercial process. All batches must meet their pre-specified acceptance criteria before any batch is released for sale.

Step 2 — Match to the scenario: The scenario describes: new product, three consecutive full-scale batches under commercial process conditions, no release before validation completion $\Rightarrow$ textbook definition of prospective validation.

Why other options are wrong:

- Option A: Retrospective validation uses *accumulated historical data* for a product *already on the market*; it is not applicable to new products and is generally no longer acceptable under current guidelines.
- Option B: Prospective validation is conducted before commercial distribution with a pre-approved protocol and ≥ 3 consecutive batches. **Correct.**
- Option C: Concurrent validation validates the process while releasing batches to market simultaneously; only acceptable in exceptional circumstances.
- Option D: Revalidation is triggered by significant post-approval changes (formula, process, equipment, site); not applicable to a new product launch.

Final Answer: Three consecutive batches before commercial release = prospective process validation $\Rightarrow$ $\boxed{\text{B}}$

Answer: (B) Go Back to Q21

Q22.

Solution

Concept — ICH Q1A(R2) Climatic Zones for Stability Testing: ICH Q1A(R2) (2003) classifies global climates into zones to define appropriate long-term stability testing conditions that represent real-world storage conditions across different regions.

Step 1 — Recall the four ICH climatic zones:

- **Zone I:** 21°C / 45% RH — temperate (northern Europe, UK, Canada)
- **Zone II:** 25°C / 60% RH — subtropical/Mediterranean; the standard ICH long-term stability condition
- **Zone III:** 30°C / 35% RH — hot and dry (Middle East, parts of Africa)
- **Zone IVa:** 30°C / 65% RH — hot and humid (general tropical)
- **Zone IVb:** 30°C / 75% RH — hot and *very* humid (India, South-East Asia, parts of Latin America and Africa)

Step 2 — Identify Zone IVb: Zone IVb (30°C / 75% RH) was introduced to reflect the extreme humidity of the Indian subcontinent and equatorial South-East Asia. It is required by ASEAN, WHO, and the Central Drugs Standard Control Organisation (CDSCO, India) for registration dossiers in these regions.

Why other options are wrong:

- Option A: Zone I (21°C / 45% RH) is temperate, not hot/humid.
- Option B: Zone II (25°C / 60% RH) is the standard ICH long-term condition for subtropical climates; not 30°C / 75% RH.
- Option C: Zone III (30°C / 35% RH) is hot and *dry*, not hot and humid.
- Option D: Zone IVb (30°C / 75% RH) = hot and very humid; required for India, SE Asia, parts of Latin America and Africa. **Correct.**

Final Answer: Zone IVb = 30°C / 75% RH, hot and very humid (India, SE Asia) $\Rightarrow$ D

Answer: (D) Go Back to Q22

Q23.

Solution

Concept — USP Dissolution Apparatus 2 (Paddle Apparatus) Critical Parameters: USP ⟨711⟩ specifies precise mechanical and operational requirements for Apparatus 2 to ensure reproducible hydrodynamic conditions during dissolution testing. Several parameters carry tight tolerances, but only one is expressed as "± 2 mm."

Step 1 — The ± 2 mm specification: USP explicitly specifies that the **distance between the bottom face of the paddle blade and the inside bottom** of the dissolution vessel must be **25 $\pm$ 2 mm** (i.e., 23–27 mm). This is the only dimension in Apparatus 2 carrying a ± 2 mm tolerance in the monograph.

Step 2 — Why this distance is critical: The paddle-to-vessel bottom distance determines the hydrodynamic shear environment immediately beneath the paddle where the dosage form rests during dissolution. Too close (< 23 mm) creates excessive turbulence; too far (> 27 mm) reduces the agitation intensity. Both deviations alter dissolution profiles for poorly soluble drugs, making this parameter critical for inter-laboratory reproducibility.

Why other options are wrong:

- Option A: 25 ± 2 mm paddle-to-vessel bottom distance is the specification carrying "± 2 mm" in USP ⟨711⟩. **Correct.**
- Option B: Volume of dissolution medium is 900 ± 9 mL ($\pm 1\%$), not expressed as ± 2 mm.
- Option C: Rotational speed is specified as $\pm 4\%$ (e.g., 50 ± 2 rpm), expressed in rpm, not mm.
- Option D: Temperature is 37.0 ± 0.5°C, expressed in °C, not mm.

Final Answer: Paddle blade to vessel bottom = 25 ± 2 mm is the ± 2 mm critical parameter in USP Apparatus 2 $\Rightarrow$ A

Answer: (A) Go Back to Q23

Q24.

Solution

Concept — IVIVC Levels and Their Regulatory Significance: The FDA Guidance for Industry (1997) classifies in vitro–in vivo correlations into levels based on the degree of mathematical relationship between the *entire* in vitro dissolution profile and the *entire* in vivo absorption profile.

Step 1 — Identify Level A: Level A is a *point-to-point* (one-to-one) mathematical correlation between the complete in vitro dissolution profile $[F_{\text{dissolved}}(t)]$ and the complete in vivo drug absorption profile $[F_{\text{absorbed}}(t)]$, typically derived by deconvolution of plasma concentration–time data (using Wagner–Nelson or numerical deconvolution). It is the **highest** and most **predictive** level of IVIVC. A validated Level A IVIVC can support a *biowaiver* for post-approval formulation changes within the validated design space.

Step 2 — Distinguish from other levels: Level B uses statistical moments (mean dissolution time vs. mean residence time); Level C uses a single-point correlation ($t_{50\%}$ or $Q_{45\,\text{min}}$ vs. $C_{\max}$ or AUC); Level D is qualitative/rank-order only.

Why other options are wrong:

- Option A: Level D is only a rank-order qualitative comparison; no quantitative predictive relationship exists.
- Option B: Level B correlates mean dissolution time with mean residence time — a moment-to-moment (not point-to-point) correlation; it cannot predict the shape of the plasma profile.
- Option C: Level A = complete point-to-point correlation between the full in vitro and in vivo profiles; highest predictive level; supports biowaiver. **Correct.**
- Option D: Level C is a *single-point* (not full-profile) correlation, providing the least predictive power.

Final Answer: Level A = complete point-to-point correlation, entire profiles, highest IVIVC level, supports biowaiver $\Rightarrow$ $\boxed{\text{C}}$

Answer: (C) Go Back to Q24

Q25.

Solution

Concept — Pharmacoeconomic Analysis Methods and the ICER: Pharmacoeconomics evaluates the clinical and economic value of pharmaceutical interventions to guide resource allocation in healthcare. Different analysis frameworks aggregate costs and outcomes in different ways.

Step 1 — Identify the analytical framework in the question: The question describes: (i) comparing a new drug vs. standard of care; (ii) computing the incremental cost-effectiveness ratio (ICER) as cost per quality-adjusted life year (QALY) gained; (iii) comparing the ICER to a willingness-to-pay (WTP) threshold (e.g., £20,000–30,000/QALY per NICE). Using QALYs as the outcome measure makes this specifically a **cost-utility analysis (CUA)**, which is a subtype of **cost-effectiveness analysis (CEA)**.

Step 2 — Role of the ICER: ICER $= \Delta C/\Delta E = (C_{\text{new}} - C_{\text{std}})/(\text{QALY}_{\text{new}} - \text{QALY}_{\text{std}})$. If ICER $<$ WTP threshold, the new therapy is considered cost-effective. This ratio enables decision-makers to compare resource efficiency across different interventions.

Why other options are wrong:

- Option A: Cost-minimisation analysis (CMA) requires *proven equal effectiveness* of both options and then simply compares costs; it does not compute an ICER.
- Option B: CEA/CUA uses the ICER (cost per natural unit of effect such as life-year saved or QALY gained) and compares it to a WTP threshold. **Correct.**
- Option C: Cost-benefit analysis (CBA) converts health outcomes into monetary (currency) units (e.g., willingness-to-pay for the health gain in £) so the net monetary benefit can be compared directly; QALYs are not the outcome measure in a pure CBA.
- Option D: Cost-consequence analysis (CCA) lists all costs and outcomes side-by-side without aggregating them into a single summary ratio like the ICER; it is descriptive, not decisional.

Final Answer: ICER (cost/QALY) vs. WTP threshold = cost-effectiveness/cost-utility analysis $\Rightarrow$ B

Answer: (B) Go Back to Q25

Answer Key

Q	Ans	Q	Ans	Q	Ans	Q	Ans	Q	Ans
1	D	2	B	3	A	4	C	5	B
6	D	7	A	8	C	9	B	10	D
11	A	12	C	13	B	14	D	15	A
16	C	17	B	18	D	19	A	20	C
21	B	22	D	23	A	24	C	25	B