2020 SEQ

INDEX NUMBER .....

CEYLON MEDICAL COLLEGE COUNCIL

PHARMACISTS' EXAMINATION (EXTERNAL) – DECEMBER 2020

PAPER II – STRUCTURED ESSAY QUESTIONS (SEQ)

Date: 12.12.2020 **Time: 8.30 a.m. – 12.15 p.m.**

ANSWER ALL FIVE (5) QUESTIONS WITHIN THE SPACE PROVIDED

Write your index number in EACH and EVERY page

Duration is 3 hours and 45 minutes (225 minutes) for both MCQ Paper and Structured Essay Paper. (Suggest spending 75 minutes for the SEQ Paper and 150 minutes for the MCQ Paper)

Question 1.

1.1 Write the method and calculations to prepare 500 ml of 1 in 4000 solution from a 1 in 800 solution

4 marks

Strength of concentrate solution 1 in 800 $= \frac{1}{800} \times 100 = 0.125\%$

Strength of dilute solution 1 in 4000 $= \frac{1}{4000} \times 100 = 0.025\%$

By applying the formula 4 marks

$C_1V_1 = C_2V_2$

$0.125 \times V_1 = 0.025 \times 500$ 4 marks

$V_1 = 100$ ml. 4 marks.

Method.

Dilute 100 ml of 1 in 800 solution to 500 ml. 4 marks
by using Purified water.

1.2 Calculate the quantities of ingredients required to prepare 500 ml of 4% w/v dextrose in hypertonic saline solution

Dextrose 4% w/v	$\frac{4}{100} \times 500 = 20$ g.
Hypertonic Saline Solution to 100	to 500 ml

10 marks.

Hypertonic saline solution.

Sodium Chloride 1.8% w/v	$\frac{1.8}{100} \times 500 = 9$ g.
Purified water to 100	to 500 ml

10 marks

P.T.O.

1.3 Explain why buffers are used in pharmaceutical formulations

Buffers are used as ingredient in Pharmaceutical formulations:

- To adjust the pH of the product
- To achieve stability of the product
- For maintaining the pH of the product within the optional pH range.
- Used in tablet and capsule formulations to control the pH in the micro environment surrounding the drug particles.
- Buffering agents are used in solid oral dosage forms include antacids to minimise gastric irritation.
- To achieve solubility of the drug (in ophthalmic preparations)
- To prevent discomfort and injury to the surface of the eye. (any 5 x 4 marks = 20 mark

(Each part carries a maximum of 20 marks)

Question 2.

2.1 What are the conditions laid down by the NMRA Act No. 5 of 2015 for a person who has received a Licence to Transport Therapeutic Goods?

- Every distributer shall follow "Good Distribution Practice" guidelines issued by the authority.
- Every vehicle used to transport therapeutic goods shall be adequately equipped with proper storage facility to preserve the quality.
- Ensure that the person responsible for the therapeutic goods to supervise and control the distribution and preservation.
- Allow any authorise officer to stop any vehicle in which used to transport therapeutic goods. Inspect and taking samples for investigation, test, examination or analysis.
- Not transport any therapeutic goods bearing the state logo.
- Can't deliver unregistered drugs.
- No transport poisonous substances with Therapeutic Goods

P.T.O.

- Allow only the registered vehicle with NMRA. (any 5 x 4 marks = 20 marks).

2.2 Write the information required for registration of a drug

a. Pharmacological information:
- Pharmacological action:
- Mechanism of action:
- Pharmacokinetic data: any 3 - 5 marks
- Bioequivalence / Bio availability data:

b. Pharmaceutical information:
- dose / strength
- dosage form
- colour, shape, size
- standards (BP, USP) any 3 - 5 marks

c Clinical information:
- Indications
- contraindications
- Precautions
- warnings
- adverse effects
- Drug interactions
- Dosage regimen

any 3 - 5 marks

(d) Information about applicant: - Name / Type address

5 marks - any 3

2.3 With respect to NMRA Act, No 5 of 2005, answer the following

Mention the requirements essential for obtaining a licence to start a pharmacy

- Applicant a registered pharmacist registered with the Sri Lanka Medical Council or any person employed a registered pharmacist:
- Premises holding a license issued by the NMRA of Sri Lanka for the sale of medicines by retail:
  Premises facilities - adequate space, parking area, air condition, dispensing area, counselling area, storage etc..
- Business registration:
- The owner not a minor or mentally deficient person or a person addicted to narcotics
- Should renew annually (5 x 4 marks = 20)

(Each part carries a maximum of 20 marks)

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Question 3.

3. Briefly describe the following terms

(i) Authorized officer

List -10

Function -10

* Authorized officers are Provincial director of health service Regional Health service, Medical officer of Health Service Divisional Pharmacist, food and drug Inspectors, Drug inspectors, Pharmacist attached to the Authority.
* They have powers to examine the article and take samples, or search, stop or detain any vehicles and take samples Examine any books and documents.

(ii) Write the functions of the Opium Board, as defined in the "Poisons, Opium, and Dangerous Drugs Ordinance"

- Scrutinizing the received application for opium.
- Allocate the amount of opium for applicant.
- Cancellation and suspension licence.
- Given new licence
- Maintain register of opium handle ... licensed holder
- Refer to the suitable opium depot.
- Increase or decrease the quarter
- Issuing licence for Ayurvedic Medical Practitioner.

(any 5 x 4 marks = 20)

(iii) Storage of poisons

- Vessel contain poison labeled as "Poison" in three languages.
- Closing or locking impermeable containers.
- Stored in a seperate cupboard "Poison cupboard"
- Key should be in hand of most senior officer / Pharmacist
- Quantity less than 40 floz, Container should be fluted.
- Should be kept away from other consumable items
- no visitors
- Not store with foods.
- Need seperate warehouse.

(Each part carries a maximum of 20 marks)

(any 5 x 4 marks) = 20

P.T.O.

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Question 4.

Drying is one of the unit processes used in pharmaceutical tablet manufacturing

4.1 Write five factors that have to be considered in selecting dryers for tablet manufacturing

- Properties of the powder granules.
- Drying characteristics of the material (powder or granules)
- Quantity of the material to be handle.
- Operation type (batch or continuous).
- Facilities available at the proposed site of installation.
- Economic consideration.

(any 5x4 marks = 20)

4.2 Draw a schematic diagram of fluidized bed dryer by showing the important parts

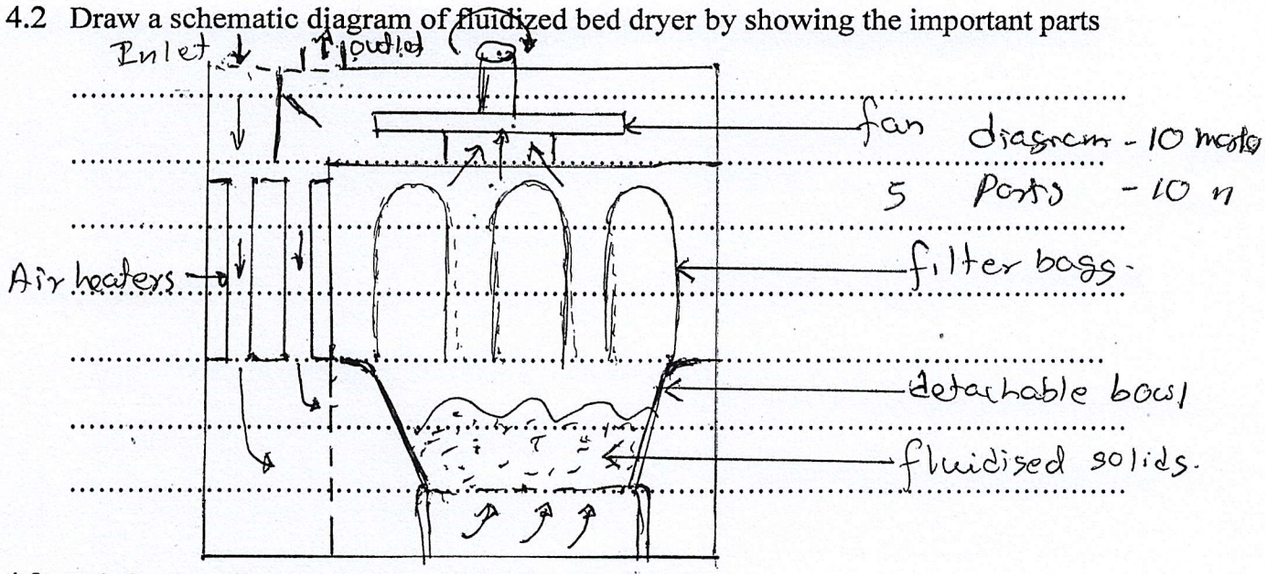

diagram - 10 marks
5 Parts - 10 m

4.3 Briefly describe the process of fluidized bed drying

- Direct drying where direct contact between a heated air and products.
- The hot air generated is fed into the material basket through gas distributor.
- Fluidized air stream is induced by the blower.
- When the velocity of gas increases the solid particles undergo vigorous movement to mix with gas to give fluidized mixture of solid and gas.
- Temperature is maintained uniformly throughout the process to achieve mixing completely.

(Each part carries a maximum of 20 marks)

5 x 4 marks = 20

P.T.O.

Question 5.

When a weakly basic or acidic drug is administered to the body, the drug will ionize.

5.1 Derive an equation to show the fraction of ionized weakly basic drug in the body.

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5.2 Phenytoin is formulated as its salt, phenytoin sodium, to make it more water soluble.

Calculate the percentage unionized fraction of phenytoin (pKa=8.3) at plasma (pH = 7.4).

Ionized fraction of Phenytoin $= \frac{1}{1 + \text{antilog}(pKa - pH)}$ 5 marks

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pka = 8.3 pH = 7.4 $= \frac{1}{1 + \text{antilog}(8.3 - 7.4)}$ 3 marks

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$= \frac{1}{1 + 7.943}$

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$= \frac{1}{8.943}$

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Fraction ionized $= 0.112$ 5 marks

% Ionized $= 0.112 \times 100 = 11.18\%$

% unionized fraction $= 100 - 11.18 = 88.8\%$ 5 marks

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P.T.O.

5.1 When a weakly basic drug B ionizes.

$$B + H_2O \rightleftharpoons BH^+ + OH^-$$

Dissociation constant, $K_b = \frac{[BH^+][OH^-]}{[B]}$ (5 marks)

$$[OH^-] = K_b \cdot \frac{[B]}{[BH^+]}$$

Taking lg $\longrightarrow$ $\lg [OH^-] = \lg K_b + \lg [B]/[BH^+]$

Multiply by $-$ $\longrightarrow$ $-\lg [OH^-] = -\lg K_b - \lg [B]/[BH^+]$

$$pOH = pK_b - \lg [B]/[BH^+]$$ (2 marks)

$$\lg [B]/[BH^+] = pK_b - pOH \quad \text{—— (1)}$$

$$pOH = pK_w - pH \quad \text{—— (2)}$$

Substitute (2) in (1) $\longrightarrow$ $\lg [B]/[BH^+] = pK_b - pK_w + pH$. (2 marks)

Concentration - B $= [BH^+] \cdot \text{antilog}^{pK_b - pK_w + pH}$ —— (3)

The fraction of the total drug B ionized is given by

$$\frac{[BH^+]}{[B] + [BH^+]} \quad \text{—— (4)} \qquad \text{(2 marks)}$$

Substitute (3) in (4) $\longrightarrow$ $\dfrac{[BH^+]}{[BH^+] \cdot \text{antilog}^{(pK_b - pK_w + pH)} + [BH^+]}$ (2 marks)

$$= \frac{1}{\text{antilog}^{(pK_b - pK_w + pH)}}$$ (5 marks)

K_w - ionic product of water

pH - for the basic drug environment or plasma (2 marks)

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5.3 List the factors that affect pH of buffer solutions

1. Fluctuation in the temperature:
2. Dilution with a solvent:
3. Addition of a neutral salt:
4. Nature of solute

3 – 20 marks
2 – 10 "
1 – 5 "

(5 marks for each)

(Each part carries a maximum of 20 marks)

END