DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE – RAIGAD -402 103

Mid Semester Examination – October – 2017

First Periodic Test

Model Answer

Branch: Pharmacy Sem.:- I

Subject with Subject Code: Pharmaceutical Inorganic Chemistry (BP104T)

Date:- 04/10/2017 Time:- 1:30 Hr. Marks: 30

I. Multiple Choice Questions (10)

Each of the following questions have four alternatives. Only one of them is correct. Choose the correct answer:

1. Impurities in pharmaceutical preparation may be due to following sources:
   (a) Raw material (b) Manufacturing process
   (c) Chemical instability (d) All of the above
   Ans. (d)
2. Pharmaceutical buffer system could be categorizes into
   (a) 1 (b) 2 (c) 3 (d) none of these
   Ans. (b)
3. Fluoride inhibits caries formation via
   (a) Increase acid solubility of enamel (b) Bacterial inhibition
   (c) Both the above (d) Decrease acid solubility of enamel
   Ans. (d)
4. In Brousted-Lowry concept acid is
   (a) Proton donor (b) electron donor (c) proton accepter (d) electron accepter
   Ans. (a)
5. Hypochloremia can be caused by
   (a) salt losing nephritis (b) metabolic acidosis
   (c) both (a) and (b) (d) metabolic alkalosis
   Ans. (c)
6. In physiological acid-base imbalance K excretion will be decreased
   (a) the amount of Na reaching distal tubule is low
   (b) the proton secretion by kidney tubule is increased
   (c) both (a) and (b)
   (d) none of the above
   Ans. (c)
7. Calcium gluconate is prepared by
   (a) lactic acid and $CaCO_3$ (b) oxalic acid and $CaCO_3$
   (c) gluconic acid and $CaCO_3$ (d) gluconic acid and $Ca(OH)_2$
   Ans. (c)

8. Which one of the followings is used as systemic alkalizer?
(a) Sodium chloride (b) Sodium bicarbonate
(c) Sodium sulphate (d) Sodium acetate
Ans. (b)

9. The principle function of chloride is
(a) maintenance of proper hydration (b) maintenance of osmotic pressure
(c) normal electrolytic balance (d) all of the above
Ans. (d)

10. The advantage of sodium lactate over sodium bicarbonate
(a) rapidly metabolized (b) it may be sterilized by boiling
(c) both of the above (d) none of the above
Ans. (c)

Q.No. 2 Attempt any one of the following (10)

a.) What are the sources of impurities in pharmaceutical substances? Explain the Principle for the Limit test for sulphate.

Ans. A compound is said to be impure if it is having foreign matter. Pure chemical compound refer to that compound which is having no foreign matter.

Impurities commonly found in Medicinal preparations:

1. Activity depressing impurities.
2. Due to coloring or flavoring substances, e.g., Sodium Salicylate.
3. Humidity.
4. Decrease shelf life.
5. Physical and chemical properties.
6. Impurities due to which substances become incompatible.

SOURCES OF IMPURITIES:

A list of impurities which are likely to be present in a given pharmaceutical substance can be easily compiled from the knowledge of the raw materials employed, the manufacturing process and stability of the final product. Impurities may also arise from physical contamination and improper storage conditions. The various sources of impurities in pharmaceutical substances are as follows:

1. Raw Materials Employed in the Manufacturing of the Pharmaceutical Substance

Pharmaceutical substances are either isolated from natural sources or synthesized from chemical starting materials.

Rock salt used for the preparation of sodium chloride is contaminated with small amounts of calcium and magnesium chlorides, so that sodium chloride prepared from rock salt will definitely contain traces of calcium and magnesium compounds impurities.

2. Method of Manufacture

The process or method of manufacture may introduce new impurities into the final product arising due to contamination by reagents, catalysts and solvents employed at various stages of the manufacturing process

(A) Reagents employed in the manufacturing process

(B) Regents used to eliminate other impurities

(C) Solvents
(D) Reaction vessels
(E) Intermediates
(F) Atmospheric contamination during the manufacturing process:
(G) Manufacturing hazards
1. Contamination from the particulate matter:
2. Instability of the Product (A) Chemical instability (B) Changes in physical Properties (C) Reaction with container material (D) Temperature

Principle for the limit test for sulphate:

Principle:

Limit test of sulphate is based on the reaction of soluble sulphate with barium chloride in presence of dilute hydrochloric acid to form barium sulphate which appears as solid particles (turbidity) in the solution.

$$SO_4^{2-} + BaCl_2 \xrightarrow{HCl} BaSO_4 + KCl$$

Procedure:

Test sample	Standard compound
Specific weight of compound is dissolved in water or solution is prepared as directed in the pharmacopoeia and transferred in Nessler cylinder	Take 1ml of 0.1089 % W/V solution of potassium sulphate in Nessler cylinder
Add 2ml of dilute hydrochloric acid	Add 2ml of dilute hydrochloric acid
Dilute to 45 ml in Nessler cylinder	Dilute to 45 ml in Nessler cylinder
Add 5ml of barium sulphate reagent	Add 5ml of barium sulphate reagent
Keep aside for 5 min	Keep aside for 5 min
Observe the Turbidity	Observe the Turbidity

Barium sulphate reagent contains barium chloride, sulphate free alcohol and small amount of potassium sulphate.

Observation:

The turbidity produce in sample solution should not be greater than standard solution. If turbidity produces in sample solution is less than the standard solution, the sample will pass the limit test of sulphate and vice versa.

Reasons:

Hydrochloric acid helps to make solution acidic. Potassium sulphate is used to increase the sensitivity of the test by giving ionic concentration in the reagent. Alcohol helps to prevent super saturation.

b.) Discuss the method of preparation, uses and assay of sodium chloride and calcium Gluconate.

Ans. **Sodium Chloride**
NaCl 58.44
Sodium Chloride
DEFINITION
Sodium Chloride contains NLT 99.0% and NMT 100.5% of NaCl, calculated on the dried basis.
ASSAY
• Procedure
Sample: 50 mg of Sodium Chloride
Analysis: Dissolve the Sample in 50 mL of water, and titrate with 0.1 N silver nitrate VS determining the endpoint potentiometrically. Each mL of 0.1 N silver nitrate is equivalent to 5.844 mg of NaCl.
Acceptance criteria: 99.0%–100.5% on the dried basis

Calcium Gluconate
ASSAY
• Procedure
Sample: 800 mg of Calcium Gluconate
Blank: 150 mL of water containing 2 mL of 3 N hydrochloric acid
Titrimetric system
Mode: Direct titration
Titrant: 0.05 M edetate disodium VS Endpoint detection: Visual
Analysis:
Dissolve the Sample in 150 mL of water containing 2 mL of 3 N hydrochloric acid. While stirring, add 30 mL of Titrant from the titration buret. Add 15 mL of 1 N sodium hydroxide and 300 mg of hydroxy naphthol blue, and continue the titration to a blue endpoint. Perform the Blank determination.
Calculate the percentage of calcium gluconate ($C_{12}H_{22}CaO_{14}$) in the Sample taken:
Result = {[(VS − VB) × M × F] / W} × 100

VS = = Titrant volume consumed by the Sample(mL)
VB = = Titrant volume consumed by the Blank (mL)
M = = Titrant molarity (mM/mL)
F = = equivalency factor, 430.4 mg/mM
W = = Sample weight (mg)

Acceptance criteria: Anhydrous form, 98.0%–102.0%; monohydrate form, 99.0%–101.0% where labeled as intended for use in preparing injectable dosage forms; and monohydrate form, 98.5%–102.0% where labeled as not intended for use in preparing injectable dosage forms

Q.No .3 **Attempt any two of the following** (10)

a.) Give the composition of Oral Rehydration Solution as per WHO norms. Justify its use.

Ans. Composition of standard and reduced osmolarity ORS solutions

	Standard ORS solution	Reduced Osmolarity ORS solutions		
	(mEq or mmol l-)	(mEq or mmol l)	(mEq or mmol l)	(mEq or mmol l)
Glucose	111	111	75 – 90	75
Sodium	90	50	60 – 70	75
Chloride	80	40	60 – 70	65
Potassium	20	20	20	10
Citrate	10	30*	10	20
Osmolarity	311	251	210 -260	245

* 30 mmol l of bicarbonate

c.) What are dentifrices? Role of fluoride in the treatment of dental caries.

Ans.

(gums) using a finger or a toothbrush. They are available as tooth powder, toothpastes, gels, dental creams and even as dental foams. They are meant to enhance the personal appearance of the teeth (daily removal of pellicles) by maintaining cleaner teeth, reduction of bad odor (removal of putrifying food particles from spaces between teeth) and also make the gum healthy

Role of fluoride

Dental caries is an infectious disease caused by the complex interaction of cariogenic (caries-causing) bacteria with carbohydrates (i.e., sugars) on the tooth surface over time. Cariogenic bacteria metabolize carbohydrates for energy and produce organic acids as byproducts. The acids lower the pH in the plaque biofilm.

Anti-caries mechanisms of fluoride have been elucidated in considerable detail using data from in vitro studies. According to our knowledge base today, fluoride works to prevent and control dental caries through the following two primary mechanisms that affect 1) enamel solubility and 2) reversal of the caries process.

d.) Write about physiological acid-base balance and its importance.

Ans. Your blood needs the right balance of acidic and basic (alkaline) compounds to function properly. This is called the acid-base balance. Your kidneys and lungs work to maintain the acid-base balance. Even slight variations from the normal range can have significant effects on your vital organs.

Acid and alkaline levels are measured on a pH scale. An increase in acidity causes pH levels to fall. An increase in alkaline cause's pH levels to rise.

When the levels of acid in your blood are too high, it's called acidosis. When your blood is too alkaline, it is called alkalosis.

Respiratory acidosis and alkalosis are due to a problem with the lungs. Metabolic acidosis and alkalosis are due to a problem with the kidneys.

Each of these conditions is caused by an underlying disease or disorder. Treatment depends on the cause.