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Diploma in Pharmacy 1st Year
Pharmaceutical Chemistry
Important Questions
Chapter 1 : Introduction to Pharmaceutical Chemistry

Chapter 1
Introduction to Pharmaceutical Chemistry
IMPORTANT Questions

Q1. Write a short note on scope and objective of pharmaceutical chemistry and type of error.

Ans. **Scope of Pharmaceutical chemistry**

Skills required in pharmaceutical chemistry

- Good writing and verbal communication skills
- Synthetic organic chemistry skills
- Ability to purify drugs and intermediates Spectoscopic techniques
- Understanding of biological roles drugs
- Team work and interpersonal skills
- Good communication skills etc

Objective of Pharmaceutical chemistry

Its main aim is to ensure the fitness for the purpose of medicinal products by analsing and evaluating them as per the quality controlstandards Following are some objectives of pharmaceutical chemistry

- To enhance the knowledge base required for synthesis, Isolation, Purification
- To enhance Skill for effective handling of chemicals, glasswear etc.
- To provide proper qualities and skills to the students required to fulfill their job responsibilities as chemist
- To train the students about effect of chemicals

Errors of Pharmaceutical Chemistry

An error is an action which is inaccurate or incorrect.. In some usages, an error is synonymous with a mistake. In statistics, "Error" refers to the difference between the value which has been computed and the c9rrect value. An error could result in failure or in a deviation from the intended performance or behaviour.

Sources of Errors

- **Improper sampling:** Error may occur due to improper sampling.
- **Error during sample preparation :** Error may occur during sample preparation.
- **Error by the analyst :** Analyst can do errors during analysis it is also known as manual error.
- **Error by the equipment :** Errors may occur due to improper working of instrument
- **Reporting Error :** Errors may occur due to improper reporting of data or observation.
- **Calculation errors:** Errors may occur due to wrong calculation or may be used of wrong data in formula.
- **Error in method selection:** Errors may occur due to wrong method selection.
- **Error during storage and transport :** Errors may occur due travelling and storage condition.
- **Errors due to laboratory condition :** Errors may occur due unsuitable laboratory condition during lab.

Q2. Write a detail note on Source of impurities in pharmaceutical substance.

Ans.

- The impurities in pharmaceuticals are unwanted chemicals that remain with the active pharmaceutical ingredients (APIs) or develop during formulation or upon aging of both API and formulation.
- The presence of these unwanted chemicals even in trace amount may influence the efficacy and safety of pharmaceutical product.
- The control of impurities is currently a critical issue to the pharmaceutical industry.
- International Conference on Harmonization (ICH) formulated guidelines regarding the control of impurities.
- The various sources of impurity in pharmaceutical products are reagents, heavy metals, ligands, catalysts other materials like filter aids, charcoal, and the like, degraded end products obtained during\after manufacturing of bulk drugs from hydrolysis, photolytic cleavage, oxidative degradation, decarbox ylation.

Source & effect of impurities in pharmacopoeial substances

- **Raw material employed in manufacture :-** Impurities resulting from raw material many affect the process of manufacture and contaminate the resultant product

  Eg: Calcium sulphate & magnesium chloride present rocksalt some amount of calcium & magnesium will present in sodium chloride

- **Reagents used in the manufacturing process :-**The impurities from the reagents may contaminate the final product if they are not washed away properly

  Eg : Mixing mercuric chloride solution with dilute ammonia solution result in ammoniated

  $$HgCl_2 + 2NH_4OH \longrightarrow NH_2Hgcl + NH_4cl + 2H_2O$$

  - Ammonium hydroxide present in the final product

- **Process used in manufacture :-** Different manufacturing process are used for producing many drugs and chemicals during there process of manufacturing, some impurities get an access into the materials
  - Formulation related impurities
  - Synthesis intermedicates & byproduct
  - Residual solvent
  - Method related impurities
  - Chemicals process used in manufacture

- **Environment related impurities :-**Atmosphere in industial areas is adulterated with gases like Hydrogen, sulphide, smoke,etc

Q3. Write a short note on Limit test of Chloride , Sulphate, Iron, Heavy metals, Arsenic.

Ans. Limit test of chloride

This test is carried out for identifying the chloride ions present in a standard solution

Principal

- The limit test for chloride is based on a reaction that occurs between silver nitrate and soluble chloride which is insoluable in dilute nitric acid
- The test solution appears turbid due to the formation of silver chloride in the presence of dilute nitric acid . Amount of chloride present in the test samples influences the degree of turbidity
- Test solution is compared with the standard solution
- By viewing transversly through both the solution against a black background in nessler's cylinder is compared the samples passes the limit test if the test solution is less turbid than the standard solution and fails in vice versa condition

Procedure

In this limit test a standard solution and test solution is prepared and then the appearance of there two solution is compared

Test solution :- 1.0 gm of sample is accurately weighted and transferred to nessler cylinder dislove in 10 ml distill water . 1 ml of nitric acid is added to this sol and volume up to 50 ml with distill water . 1 ml of silver nitrate be added to the solution stirring for 5 min after which turbidity develop

Specified substance (1gm) + 10 ml of water + 1 ml of nitric acid + water up to 50 ml + 1 ml silver nitrate → turbidity

Standard solution :- 1 ml of 0.01 m Hcl is mixed with 1 ml of nitric acid in nessler cylinder B and volume up to 50 ml with distill water . 1 ml of silver nitrate solution which produce turbidity after 5 min

The sample passes the limit test if it is less turbid than the standard solution

Sulphate

Limit test for sulphate

This test is carried out for controlling the sulphate impurity in inorganic substance

Principle

In the limit test for sulphate, barium chloride reacts with soluable sulphate in the presence of dilute Hcl solution . The resulting turbid solution is compared with the standard solution of acceptable limit.

The barium sulphate reagent contain barium chloride , sulphate free alcohol, and potassium sulphate

Procedure

Test solution :- 1 gm of sulphate is weighted and 2 ml of Hcl is added to 45 ml of solution . 5 ml of $BaSo_4$ reagent is added to prepare the solution

Standard Solution : 1 ml of 0.1089 % w/v solution of K_2So_4 is weighted and treated with 2ml of Hcl . This solution is diluated up to 45 ml .At the last the standard solution is prepared by adding 5 ml of $BaSo_4$ reagent

The limit test of sulphate is passes if it is less turbid than the standard solution

Iron

Limit test of Iron

This test is carried out for controlling the iron impurities in inorganic sunstance

Principle:- The limit test for iron relies on the reaction in which iron reacts with thioglycollic acid in a solution. With ammonium citrate buffer

It results in the formation of a purple colour solution due to the formation of mercaptoacetate

This purple colour is compared with the standard colour containing a known amount of iron

Procedure

Test solution :- 40 ml of water is added to the sampleand treated with 2 ml of 20% w/v citric acid .Then 2 drop of thioglucollic acid is added the solution is mixed made alkaline with ammonia , and volume made up to 50 ml . Then the solution is allowed to stand for 5 min so that a colour develop which is viewed vertically & compared with the standard solution

Standard solution :- 40 ml of water is added to 2 ml of standard solution of iron .Then 2 ml of 20 % w/v citric acid and 2 drop of thioglycollic acid is added to the solution the solution is made alkaline with ammonium and volume is made up to 50 ml .The solution is allowed to stand for 5 min so that a colour develop which is viwed vertically and compared with the test solution

When the colour of both the solution is compared the intensity of the colour of the test solution should be less than that of standard solution

Heavy Metals

Limit test for Heavy metals

This limit test is carried out for determining the content of metallic impurities coloured by sulphide ion , under specific condition

Principle:-

Limit test for heavy metals are based on the reaction between a solution of a heavy metals and a saturated solution of H_2S in an acidic medium

A reddish / black colour resulted is compared with the standard solution of lead nitrate solution

Procedure:-

Test solution :- 25 ml of test solution is prepared in a 50 ml of nessler cylinder and ph is adjusted between 3-4 using dilute acetic acid or dilute ammonia solution , After PH adjustment the solution is diluted up to 35 ml with water

Standars solution :- 2 ml of standard lead solution is prepared out in a 50 ml nessler cylinder and diluted up to 25 ml with water. The pH is adjusted between 3-4 using dilute acetic acid pr dilute ammonia solution After pH adjustment the solution is diluted u to 35 ml with water

After that

10 ml of freshly prepared hydrogen sulphide solution is added into both the cylinder containing standard solution and test solution and diluted up to 50 ml with Water .After dilution the solution is krpt aside over a white surface for 5 min and viewed down wards the test solution colour is lighter than the standars solution colour

Arsenic

This test is carried out for controlling the arsenic impurities on inorganic substance

Principal :- The limit test for arsenic is based on the reaction in which arsenic is converted in arsine (AsH_3) by undergoing reduction with zinc and hydrochloric acid. The use of Stannated hydrochloric acis is prescribed in the I.P

Procedure :

Test solution : The test solution is prepared as directed in the monograph and placed in the generator bottle 5 ml of 1m potassium iodide, 5ml of stannous chloride acid solution and 10gm of zinc AsT are added to the test solution

A test paper of mercuric chloride is placed in the rubber slit and the bottle is immediately stopped . The reaction is allowed to continus for 40 min at above $40^{o}c$.

Standard solution : 0.33 gm of arsenic triocide is dissolved in 5 ml of 2m NaOH solution and volume is made up to 250 ml with water 1ml of this solotion is further diluted with distilled water up to 100 ml

The stain produced by the test sample passes the test if the stain produced by it is less intense than that of the standard solutio