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Diploma in Pharmacy 1st Year
Pharmaceutical Chemistry
Chapter 1 : Introduction to pharmaceutical chemistry

Topics	Page No
Pharmaceutical chemistry **Objective** **Scope**	3
Source and Types of Errors **Accuracy** **Precision** **Significants**	4
Impurities in pharmaceuticals	5
Limit Tests for Chlorides, Sulphates, Iron, Heavy Metals, and Arsenic.	6

Chapter 1
INTRODUCTION TO PHARMACEUTICAL CHEMISTRY

Pharmaceutical chemistry

- The chemistry which studies about the drug design and synthesis of biologically active molecules is known as pharmaceutical chemistry
- Pharmaceutical Chemistry involves development and the study of drugs , Drug discovery, Metabolism, absorption, delivery etc. are included in this

Careers

- Pharmacetical companies
- Biotechnology companies
- Drug development & research facilities etc.

Objective

Its main aim is to ensure the fitness for the purpose of medicinal products by analsing and evaluating them as per the quality control standards

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

Scope

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.

ERRORS

→ Error is a mistake but rather a difference between a computed / estimated measured value and the accepted true / specified / theoretically correct value

Classification of error

- ❖ Systematic / Determinate / Non random errors
- ❖ Non systematic / Indeterminate / Random / Accidental errors
- ❖ Gross error

1) Systemic error :- The error is constant or changes slightly bu consistent fault during the analysis.
Eg : - error in titration

- **Instrumental error :-** Error occurs due to faulty instrument or reagent containing impurities
- **Operational / Personal :-** When error occur during operation or carryout the experiment is calles as operational error
- **Methological error :-** These error are most serious errorr of analysis most of above error can be minimized or corrected but errors that are not changeable unless the condition of the determinations are alterted.
  Eg : Errors occer due to co-precipitation of impurities

2) Non-systematic error :- The error unpredictable and difficult to identify

Source

- Presence of bubbles in burette
- Sample handling improperly

3) Gross error :- These error are a combination of both systematic and non-systematic error
They are the result of big mistake made during analysis and can be identified easily
Gross error is also known as Avoidable mistake

Source

- Calculation error
- Wrong sample sizes
- Mix up of samole / reagent
- Transcription error

Accuracy and Precision

Accuracy :- It can be said that the difference between calculated value and accepted real value is known as accuracy

Precision :- Reproducibility or Repeatability can be defined as the precision of measurement system in which the degree of repeated measurement is considered under the static condition given the same result

Repeatability :- It is the variation which arise in spite of all the efforts made to keep the condition constant wheather relased to instrument and repeating in short term span

Reproducibility :- It is the variation which arise by applying the same process for the measurement by using different instrument and operators over a longer time span

Significant figure

The significant figure of any number are the digits that add up to the precision

Rule

- Non – zero digits are significant
  Eg : 89, 56,78,etc
- Zero between teo non – zero digits are significant
  Eg : 108, 805 etc
- Leading zero are consider insignificant
  Eg : 0.00098, 0.000643 etc
- Trailing zeros after a decimal point are significant
  Eg : 12.7900, 6.900 etc

Impurities in pharmaceuticals

→ An impurities is generally considered as an there various organic material except the other drug substance that arises during the manufacturing process.

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

- Exposure to adverse temperature
- Uv ligits
- Humidity

Effects of impurities in pharmacopoeial substance

A little amount of impurities always remain in a material

- After a certain period , even a minute quantity of impurite cause toxic effect
- Impurities also bring about technical difficulties in the formulation
- Impurities also reduce the self-life of a substance
- Some impurities result in incompatility with other substance
- Impurities also effect in physical and chemical properties of substance

Limit tests

Quantitive tests intended for identifying and controlling small quanties of impurities which may occer in a substance are termed as limit test

Limit test used for :-

1. Finding out the quantity of harmful impurities
2. Finding out the quantity of avoidable impurities

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

$$H_3Aso_4 \longrightarrow H_3Aso_3$$

Arsenic Acid — Arseneous Acid

$$H_2Aso_3 + 6H_2 \longrightarrow AsH_3 \uparrow + 3H_2o$$

Arsine

When arsine comes in contact with dry paper daturated with mercuric chloride | bomide it produce a yellow or brown stain

$$2AsH_3 + Hgcl_2 \longrightarrow Hg \rightarrow AgH_2 + 2Hcl$$
$$\searrow AgH_2$$

The intensity of the colour produce is proportional to the amount of arenic present, if the diameter of the paper exposed to arsine os constant

The test solution of the sample is compared with the standard solution with known amount of arsenic

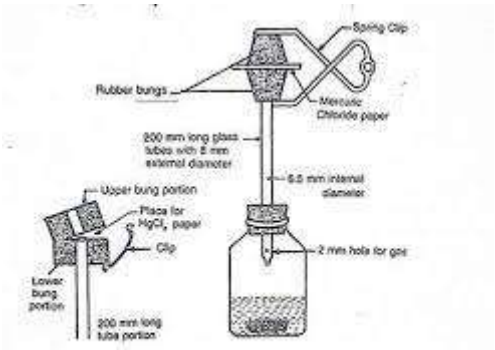
The strain are the compared in natural light

Apparatus : Rubbercork,springclip,mercuric chloride,paper,200mm long glass tube with 8mm external diameter 200mm, etc

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°c.



. Apparatus used for arsenic limit test; on the left is an alternative device for securing mercuric chloride paper.

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 solution

Chloride

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 45ml 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

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