Errors

Presented By;-

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Errors

Definition:- an **error** is the difference between the **measured value** and the **true or accepted value**.

It can affect the **accuracy**, **precision**, or both.

Sources of Errors

Source	Explanation	
Instrumental errors	Due to faulty calibration, improper functioning, or poor maintenance of instruments (e.g., spectrophotometers, balances).	
Environmental errors	Caused by fluctuations in temperature, humidity, vibrations, or dust.	
Personal errors	Human mistakes such as reading instruments incorrectly or poor lab practices.	
Method errors	Result from non-ideal chemical reactions, wrong reagents, or faulty analytical methods.	
Sample errors	Impurities in sample, wrong sampling, or incorrect preparation.	
Reagent errors	Use of impure or expired reagents can lead to inaccurate results.	

Types of Errors

Type of Error	Description	Example
Systematic Error	Consistent and repeatable errors due to faulty equipment or methods; affects accuracy.	Using an uncalibrated balance.
Random Error	Occurs unpredictably and varies from one measurement to another; affects precision.	Slight fluctuations in room temperature.
Gross Error	Serious human errors such as misreading instruments, spilling samples, etc.	Titrating with the wrong solution.
Blunder	Obvious mistakes like recording wrong data or using wrong reagent.	Writing 50 mL instead of 5.0 mL.

Methods to Minimize Errors

Method	Description
Calibration of instruments	Regularly calibrate balances, pH meters, spectrophotometers, etc.
Standard operating procedures (SOPs)	Follow defined SOPs to reduce variability in technique.
Use of standard reagents	Use freshly prepared or certified reagents to ensure purity.
Environmental control	Maintain constant lab temperature, humidity, and cleanliness.
Training and supervision	Train personnel in good lab practices (GLP) and analytical techniques.
Blanks and replicates	Use reagent blanks and repeat samples to detect and correct errors.
Proper documentation	Record all observations and changes promptly and clearly.

Accuracy, Precision and Significant Figures

In pharmaceutical analysis, achieving reliable, repeatable, and reportable results is essential for ensuring drug quality, safety, and efficacy. Here's how accuracy, precision, and significant figures play a crucial role in this field.

Accuracy

▶ Definition:

Accuracy refers to how close a measured value is to the true or accepted value.

≪ Example:

If the true concentration of a drug in a tablet is **100 mg**, and your measurements are:

- > 99.8 mg,
- > 100.1 mg,
- ➤ 100.0 mg

These values are **accurate** because they are very close to the true value.

Precision

▶ Definition:

Precision refers to **how close repeated measurements** are to each other, regardless of their closeness to the true value.

≪ Example:

If you measure the drug content multiple times and get:

- ≥ 95.2 mg,
- ≥ 95.3 mg,
- ➤ 95.1 mg

These values are **precise** (they are very close to each other), but **not accurate** (they are far from the true value of 100 mg).

Significant Figures

Definition:-Significant figures are the digits in a number that carry **meaning related to precision**. They include all **certain digits** plus **one uncertain (estimated) digit**. In **pharmaceutical analysis**, significant figures ensure that the **reported data reflects the true precision** of the measurement.

Rules for Counting Significant Figures:

Rule	Example	Significant Figures
All non-zero digits are significant	123.45	5
Zeros between non-zero digits are significant	1002	4
Leading zeros are not significant	0.0056	2
Trailing zeros after decimal are significant	12.300	5
Trailing zeros in whole numbers without decimal are not significant	1500	2 (unless written as 1.50×10^3)

Use of Significant Figures in Pharmaceutical Calculations

1. Analytical Assays:

If an assay of a tablet gives a result of **98.543%**, but the instrument supports only 3 significant figures, you must report as **98.5%** or **98.54%**, not more.

2. Dosage Formulation:

When weighing an active ingredient as **0.010** g, it should be reported with the same significant digits that the balance can support — possibly as **0.0100** g if the balance has 4 decimal place accuracy.

3. Standard Solutions:

A solution prepared with **0.100 mol/L** NaOH should be reported as such if the preparation involved volumetric instruments capable of 3 significant figures.

Pharmacopoeia

A pharmacopoeia is a legally recognized book that sets standards for the identity, purity, strength, and quality of medicines and other related substances.

Indian Pharmacopoeia (IP)

1. Definition:

The Indian Pharmacopoeia (IP) is the official book of standards for drugs manufactured and marketed in India, describing the quality standards for active pharmaceutical ingredients (APIs), excipients, dosage forms, and herbal products. Published By:-Indian Pharmacopoeia Commission (IPC), Ghaziabad. Under the Ministry of Health and Family Welfare, Government of India

2. Purpose:

- > To ensure the quality, safety, and efficacy of medicines in India.
- > Provides legally enforceable standards for drugs under the **Drugs and Cosmetics Act**, 1940.
- > Guides manufacturers, analysts, pharmacists, and regulators.

3. History & Evolution:

Year	Event
1946	Indian Pharmacopoeia Committee formed
1955	First edition of Indian Pharmacopoeia published
Subsequent Editions	1966, 1985, 1996, 2007, 2010, 2014, 2018, 2022 (latest)
Recent Additions	IP Addendum (e.g., 2019, 2021) issued for updates

Impurities in Medicinal Agents

Definition of impurity:-an impurity is any component of a pharmaceutical product that is not the chemical entity defined as the drug substance or an excipient, and is undesired in the final product.

Sources of impurities in medicinal agents

Source	Explanation / Examples
Raw Materials	Impurities present in starting materials or intermediates used during synthesis. E.g., solvents, reagents, catalysts.
Manufacturing Process	Incomplete reactions, side reactions, or degradation during synthesis. E.g., unreacted starting material, by-products.
Solvents	Traces of residual solvents (organic or inorganic) used in manufacturing. E.g., ethanol, acetone, dichloromethane.
Reagents and Catalysts	Remnants of acids, bases, metal catalysts used in synthesis. E.g., palladium, iron, sodium hydroxide.
Packaging Materials	Leaching of chemicals from packaging materials into the drug. E.g., plasticizers, rubber components.
Environmental Contaminants	Contamination from air, water, or equipment. E.g., dust, microbes, heavy metals.
Decomposition Products	Degradation due to light, temperature, humidity, or pH. E.g., hydrolysis of esters, oxidation of vitamins.
Cross-contamination	Contamination from other drugs during production in shared facilities. E.g., mixing of traces of another drug.
Storage Conditions	Improper storage can cause the drug to degrade or form impurities. E.g., hygroscopic substances absorbing moisture.
Formulation Additives	Impurities from excipients or preservatives. E.g., oxidation products of parabens.

