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'A Review on RAW MATERIAL ANALYSIS'

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ABSTRACT

It is basically the chemical ingredients of a process. Basic raw materials are starting material, which is used in production of final product. Raw materials can be either active drug or inactive substances, The basic material from which a product is made.

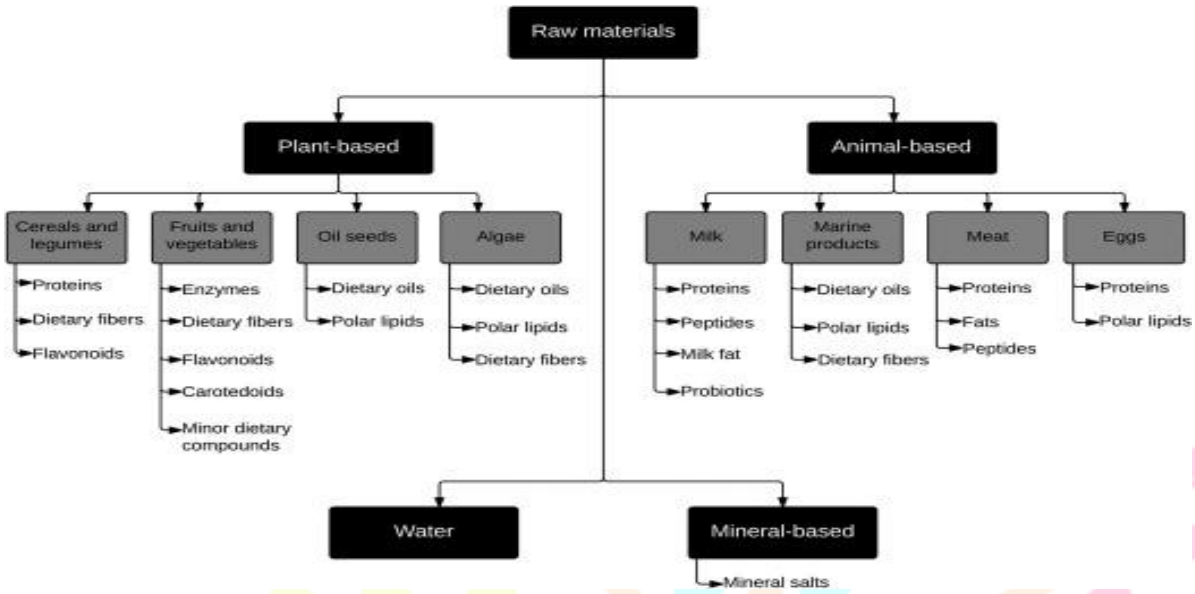
The development of functional foods and nutraceuticals relies on raw materials that serve as sources of nutrients. The suitability of a specific raw material is determined by the availability of complete and accurate specifications regarding its quality, safety, and authenticity. These specifications cover various aspects such as chemical composition, physical-chemical properties, structure, sensory characteristics, and sometimes, origins. Since functional foods and nutraceuticals are not only consumed domestically but also in the global market, it is necessary to use internationally recognized analytical methods. Therefore, this chapter focuses solely on these techniques and methods for analyzing raw materials. It offers a classification of raw materials, explains the prerequisites for raw materials analysis, outlines the fundamentals of analytical methods, and presents standard food analysis and authentication methods.

INTRODUCTION

In the initial stages of pharmaceutical production, it is crucial to have quality assurance (QA) and quality control (QC) processes in place to ensure that raw materials are free from impurities that can be harmful to health or complicate purification processes and reduce yields.

Raw material identification involves assessing these raw materials to detect and eliminate any impurities or adulterants that could negatively impact the end product.

Various analytical instruments are used in raw material analysis to conduct QA and QC assessments using different techniques.



IMPORTANCE

Raw material testing is crucially important for ensuring safety, quality and efficacy of pharmaceutical products.

There are many things to be considered that could impact the way raw materials need to be blended, such as polymorphism, the particle size of raw materials and other properties.

Hence, raw material analysis is essential to determine the purity, identity and quality of the raw materials before they go into the manufacturing process.

NEED

As hundreds of raw materials and ingredients are used in the process of formulating the final pharmaceutical product, it is quite tough to check every ingredient for quality.

Unless the ingredients have undergone quality testing, beginning the manufacturing process won't be possible. Moreover, if low-quality raw

materials are used, it will result in a low-quality finished product which could face product recall.

This can cause significant damage to material costs as well as reputation. Therefore, raw material testing in pharmaceuticals is necessary.

A) Ensuring a Quality product

Pharmaceutical raw material testing is carried out to establish that all the incoming raw materials match the right specifications and requirements. Needless to say, incorrect supply of raw materials will lead to a compromise in the safety and quality of the end product.

Besides, it will also cause manufacturing delays and significant wastage of time and costs. Therefore, testing labs help pharmaceutical companies lay down the specifications for the raw materials right from the initial stages of drug development.

B) Labs: Standards and approvals needed

Every pharmaceutical product or medical device has to be approved by the State FDA and the Central Drugs Standards Control Organisation (CDSCO) before it is rolled out for public use or commercialization.

Testing laboratories can help carry out material analysis, DSC analysis, chemical tests, physical characterisation, NMR testing, FTIR testing and more, all according to the specifications and safety protocols established by the FDA and CDSCO.

Traditionally, chemical testing laboratories perform the raw material testing and prepare the reports to determine their quality and suitability to be used in pharmaceutical drug formulations. They are well equipped to carry out the sophisticated procedures involved in raw material tests.

Guidelines for Handling Raw Materials

When raw materials are received, it is important to visually inspect them for labels and any container damage. After inspection, the raw materials should be moved to a designated quarantine area where their labels are replaced with “under test” labels.

Quality control personnel are responsible for sampling, and they should take the samples from the quarantine area.

During sampling, it is crucial to ensure that the sample is representative of the entire batch, that the sampling equipment is clean, and that the containers are resealed after sampling.

Upon receiving approval or rejection for the raw material, it must be moved to the designated areas for approved or rejected materials.

The raw material should be stored in a container that is clean. Storage should be at the optimal temperature and humidity.

Regular intervals should be scheduled for inspection. The material should be stored in a way that ensures the first material received is the first one issued.

Quality Control Raw Material Testing

Before manufacturing begins, all raw materials must be tested for purity. Identity and quality. Depending on the type of product (tablets and capsules vs. biotech products), as few as 15-20 to as many as 60 raw materials might be needed for product development. The extent of raw material testing is determined by the manufacturer. A conservative approach would be to perform complete analysis of each lot of raw materials received.

Pharmacopoeia provides monographs for the most commonly used raw materials in the pharmaceutical industry.

These monographs detail several different analytical techniques. Karl Fischer moisture analysis, pH, viscosity and titrations are common but more complex techniques such as HPLC, GC-MS and ICP-MS are sometimes required.

The analytical chemistry and microbiology teams can help you with the necessary testing for raw materials, APIs, finished products, packaging materials and medical devices.

Testing Services for Raw Materials

Physicochemical Properties

Identity and Purity-Small Molecules

Identity and Purity- Large Molecules

Physicochemical Properties Testing Services

Physicochemical property tests are integral to the verification, manufacturing support, and lot release programs for pharmaceuticals and biologics.

It is essential that certain physical and chemical properties do not vary between or within lots, as they can determine critical compound features like drug delivery and absorption of the product in vivo.

➢ Appearance

This guarantees that all the solutions that are tested do not contain any visible particulates.

- Physical State
- Colour
- Odour

➢ pH

pH will determine whether the sample's acidity/alkalinity meets the client's expected specifications. The pH of a small molecule pharmaceutical or biologic formulation can significantly affect its stability. Solubility, and in vivo delivery, making this test a crucial element of any lot release program.

➢ Moisture Content

Water is a component found in many pharmaceutical and biologic products either as hydrates or adsorbed water. The amount of water present can impact the effectiveness, quality, and lifespan of these products, making it necessary to adhere to specific standards.

➢ Osmolality

Osmolality is another important factor of lot release for a developed drug and is defined as the total number of solute particles per kilogram of solvent.

Freezing point technology to test the osmolality of prepared solutions to ensure correct isotonicity, consistency, formulation, and product stability.

➢ Viscosity

A fluid's resistance to flow, measured as viscosity, is a principal component of lot conformance.

Viscosity is fundamental to a formulation's intended propagation and activity, and may be used as a benchmark for compound concentration or degradation

➢ Optical Activity

Many pharmaceutical compounds are chiral and hence optically active, given that they rotate plane polarized light.

The measure of optical activity of the provided solution can then be used by the client for many different aspects of a lot release program. By comparing with predetermined target specifications, polarimetry may be used to detect impurities or to determine the concentration of the intended chiral drug product.

➢ Spectral Analysis

The distinct absorption patterns of chemical and biochemical products can be used to differentiate pharmaceutical and biologic substances based on their physical and chemical characteristics. To determine the specific compounds and their concentrations, Ultraviolet-Visible (UV-Vis) and Fourier

Transform Infrared (FTIR) Spectroscopy are utilized in the analysis. Additionally, spectral analysis can help identify impurities in the final product.

Identity and Purity – Small Molecules

Identity and purity testing are crucial requirements of a lot release.

Testing Services for Identity and Purity

HPLC

Mass Spectrometry

UV-Vis

FTIR

➢ HPLC (High-Performance Liquid Chromatography)

Chromatography describes the use of high-performance liquid chromatography for qualitative and quantitative analyses.

This is done by comparing the chromatogram with the reference peak.

Discrepancies between the expected and experimental chromatograms may indicate sources of impurity within the lot.

➢ Mass Spectrometry

LC-MS (Liquid Chromatography Mass Spectrometry) is an accurate and reliable method of chemical analysis that combines the advantages of liquid chromatography and mass spectrometry.

Mass to charge ratios derived from this analytical technique can reveal molecular weight of each compound and therefore help with the identification of the analytes and impurities.

➢ UV-Vis (Ultraviolet-Visible Spectroscopy)

Spectrophotometric tests are critical for the identification of many chemical substances

These tests yield absorption spectra that demonstrates rough identification of the formulation and any contamination.

➢ FTIR (Fourier Transform Infrared Spectroscopy)

Infrared spectroscopy is notably the most powerful test in confirming the identity of small molecules and pharmaceuticals.

FTIR results may be used to compare multiple specific peaks in the IR spectrum with those of a reference standard, establishing a robust acceptance criteria.

Identity and Purity – Large Molecules

Large Molecule – Identity and Purity Testing

When manufacturing biological products (large molecules), it is imperative that each lot produced conforms to predetermined specifications.

Testing Services for Identity and Purity

HPLC

Mass Spectrometry

Western Blot

ELISA

➢ Mass Spectrometry

Mass spectrometry is a technique that can be employed to detect impurities in biological products and inform the manufacturer. When it comes to SDS-PAGE, it is a procedure that segregates proteins in a polyacrylamide gel depending on their size.

➢ Western Blot

To perform a western blot, start by running an SDS-PAGE gel and subsequently transferring the proteins onto a membrane. This technique allows for the identification of the protein product or any impurities associated with it.

➢ ELISA (Enzyme-Linked Immunosorbent Assay)

ELISA is used to detect proteins and determine the concentration of the protein of interest. Indirect, direct and sandwich ELISA are the most common variations of ELISA.

The absorbance readings from each well are compared with the standard curve to determine the concentration of the protein of interest from each sample.

CONCLUSION

The availability of raw materials is crucial for economic development. A country's reliance on another for specific raw materials or its ability to produce them domestically impacts the entire supply chain. Testing these materials in pharmaceutical products ensures they are suitable for their intended purpose, which helps avoid expensive production issues and delays.

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