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Perspective

Pharmaceutical Analysis of Handling Raw Materials before Manufacturing

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DESCRIPTION

Raw material testing is critical for assuring pharmaceutical product safety, quality, and efficacy. Many parameters, such as polymorphism, particle size of raw materials, and other qualities, must be addressed while blending raw materials. Raw material analysis is therefore required to determine the purity, identification, and quality of raw materials prior to their use in the manufacturing process.

All raw materials must be checked for purity, identity, and quality before manufacturing will commence. Depending on the type of product (tablets and capsules *vs* biotech items), product development could require anywhere from 15-20 to 60 raw components. The manufacturer determines the extent of raw material testing. Complete analysis of each batch of raw materials received would be a conservative approach.

Monographs for the most regularly used raw materials in the pharmaceutical industry are available from USP. These books frequently cover a variety of analytical techniques. Moisture analysis, pH, viscosity, and titrations are all frequent, although more advanced procedures like HPLC, GC-MS, and ICP-MS are occasionally necessary.

Necessity of testing raw materials

It is difficult to evaluate every ingredient for quality because hundreds of raw materials and compounds are needed in the process of producing the final pharmaceutical product. It will not be feasible to start the production process until the ingredients have been thoroughly tested. Furthermore, using low-quality raw materials will result in a low-quality end product, which may be subject to return. This can have a significant impact on material pricing as well as reputation. As a result, pharmaceutical raw material testing is required.

Providing a high-quality product

Pharmaceutical raw material testing is carried out to ensure that all incoming raw materials meet the required parameters. Without a doubt, an inaccurate supply of raw materials will damage the finished product's safety and quality. It will also result in manufacturing delays and severe time and expense waste. As a result, testing labs assist pharmaceutical companies in establishing raw material standards from the inception of drug development.

Standards and approvals are required in testing labs

Any pharmaceutical product or medical device must be approved by the State FDA and the Central Drugs Standards Control Organization (CDSCO) before being released for public use or sale. Testing laboratories can assist with material analysis, DSC analysis, chemical tests, physical characterization, NMR testing, FTIR testing, and other procedures, all in accordance with FDA and CDSCO specifications and safety protocols. Chemical testing facilities have traditionally conducted raw material testing and reporting to ensure their quality and suitability for use in pharmaceutical medication formulations. They have the requisite equipment to perform the sophisticated raw material testing processes. Chemical testing, physical characterization, and microbiological analysis in accordance with pharmacopeial criteria assist you in meeting these capacity and capability problems.

Below is a summary of some of the most typical tests for pharmaceutical raw materials that we do utilizing pharmacopoeial, client, or in-house procedures:

- Assay
- Impurities and related substances
- Residual solvents and organic volatile impurities
- FTIR, chemical analysis, and other methods of identification
- Heavy metal limit tests using chemical techniques or ICP or ICP MS as per US 232, 233
- Microbiological experiments
- Particle size distribution by optical microscopy
- Particle size distribution by laser diffraction particle size analyzer
- Crystallinity test
- Melting point test
- Differential Scanning Calorimetry (DSC) test
- X-ray Diffraction test (XRD)

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- Nuclear Magnetic Resonance (NMR)
- And more tests

The pharmaceutical sector works with a wide range of raw materials, and a single product can contain hundreds of different chemicals. A pharmaceutical manufacturer's ability to test all of the chemicals and products in-house is typically challenging, if not impossible. Even if all of the facilities are available in-house, there will always be a demand for capacity, so having a reliable partner who can analyze pharmaceutical raw materials before they are released and utilized for producing pharmaceutical goods is critical. We perform method validation and development studies for all of these tests in addition to regular analysis for release testing of pharmaceutical raw materials.