FINISHED PRODUCT ANALYSIS AND RAW MATERIAL TESTING

Pharmaffiliates

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A) WHAT IS FINISHED PRODUCT ANALYSIS AND RAW MATERIAL TESTING?

- Finished Product Analysis and Raw Material Testing is the physical and chemical quality assessment of pharmaceutical items or materials.
- These parameters are assessed and performed for raw material testing prior to manufacturing and for finished product testing on a batch basis prior to product release as part of routine QC checks.

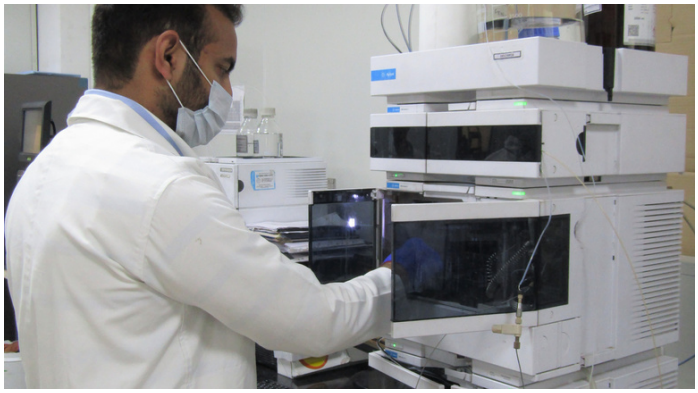
PHYSICAL AND CHEMICAL QUALITY ASSESSMENT

From drug discovery and development to clinical research trials, each pharmaceutical product innovation undergoes a substantial journey; with safety, efficacy and quality closely monitored throughout the process to confirm its continuation.

The last line of defense before a pharmaceutical can hit the shelf is finished product quality testing. This valuable stage ensures compliance with regulatory standards, performing the final safety and quality evaluations prior to determining whether a product can be released to the market.

- These tests provide a comprehensive and final assessment to ensure the product is safe, reliable, and meets its intended purpose.
- The analytical tests conducted assess all essential parameters, including identity, potency, purity, microbiological content and more.
- A range of testing methods validated in accordance with ICH guidelines are employed. These quality control testing methods are designed to ensure that each product is in conformance with the approved specifications and performs exactly as it should.

B) WHY DO WE DO IT?



- It is a regulatory requirement defined within every pharmacopoeia that products, both sterile and non-sterile, must be assessed for their chemical quality. As such, each product must have an associated, validated method for chemical analysis which is performed routinely on every batch.

- This provides confidence on the quality of every batch manufactured, to ensure the safety of the end user.

- This analysis is performed accordance with the monographs detailed in the following pharmacopoeias:
  (i) European Pharmacopoeia (Ph. Eur.); (ii) United States Pharmacopoeia (USP);
  (iii) British Pharmacopoeia (BP); (iv) Japanese Pharmacopoeia (JP);
  (v) In-house methods

C) HOW DO WE ASSURE COMPLIANCE?

The complement of testing required differs from product to product and is highly variable. Below are common QC release tests performed at analytical testing laboratory for finish products, batch release & raw material testing :-

- Physical Parameters for solid dosage forms (Avg. weight, friability, disintegration etc.)
- Dissolution
- Content Uniformity
- Identification by HPLC, FTIR and UV Spectrophotometry
- Product Assay by HPLC and UV
- Organic Impurities identification
- Related Substances by HPLC
- Water content by Karl Fischer method
- Titrations (Complexiметric, Acid-Base, Oxidation Reduction and Non-Aqueous)
- Autotitrations (Potentiometric)
- Residual solvents by GC
- Elemental analysis by ICP-OES or ICP-MS

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