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# Quality Control Tests for Tablets and Capsules

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**Abstract: In the pharmaceutical industry, quality control (QC) testing of tablets and capsules is a crucial procedure to guarantee that pharmaceutical goods fulfill predetermined standards for safety, efficacy, and quality prior to being put on the market. Since these dosage forms are among the most commonly utilized in healthcare, it is essential to uphold stringent quality standards in order to safeguard patient health and adhere to legal requirements .Official pharmacopoeia tests and unofficial evaluations are combined in QC testing to confirm the product's identity, strength, purity, and functionality. Weight variation, hardness, friability, disintegration time, dissolution profile, content uniformity, and assay of the active pharmaceutical ingredient (API) are among the official tests listed in pharmacopeias like the Indian Pharmacopoeia (IP), United States Pharmacopoeia (USP), and British Pharmacopoeia (BP). These factors guarantee consistent dose, stability, mechanical strength, and bioavailability. Organoleptic examination, physical appearance inspection, and defect analysis are examples of non-official or supplemental testing that help find problems like cracks, discolouration, or coating flaws that may affect patient acceptability and product stability. To guarantee uniformity and traceability, regulatory bodies mandate that all quality control operations adhere to Good Manufacturing Practices (GMP).**

***Keywords:*** *Pharmaceutical Tablets, Pharmacopoeia, Weight Fluctuation, Hardness, Friability, Dissolution, and Disintegration Time.*

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## I. INTRODUCTION OF QUALITY CONTROL TESTS (TABLET AND CAPSULE)

To guarantee that tablets and capsules fulfill the necessary requirements for quality, safety, and efficacy, quality control tests are an essential part of the pharmaceutical production process. These tests are intended to assess the physical, chemical, and biological characteristics of tablets and capsules in order to confirm that they meet specifications and legal requirements.[1]

Tablets, which are made by compression or molding and are meant to be taken orally for both local and systemic effects, are a solid dosage form of medications with or without excipients. Depending on the medication and how it is administered, they may differ in size, shape, and weight.

The first step in quality control is testing the raw materials, such as excipients and active pharmaceutical ingredients (APIs), for quality, identity, and purity.[2] In-process quality control tests are carried out to keep an eye on variables including weight, hardness, thickness, and disintegration once the production process has begun. Before being put on the market, completed goods must pass final quality control inspections.[3]

In the pharmaceutical sector, quality control (QC) tests are crucial processes used to guarantee that tablets and capsules fulfill the necessary requirements of safety, efficacy, and quality.[4] These tests aid in verifying that the dosage forms meet pharmacopeial standards like IP (Indian Pharmacopoeia), BP, and USP and are consistent in their physical, chemical, and biological characteristics.

The most popular solid dose forms are tablets and capsules. Therapeutic results may be impacted by any variation in their quality.[5] Strict quality control testing is therefore required both during production and prior to distribution.

➢ *Quality Control Tests for Tablets*

- *Weight Variation Test:*

Guarantees consistent tablet weight, which is essential for precise dosage.

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- *Disintegration Test:*
  Assesses the tablet's capacity to disintegrate within a predetermined amount of time, guaranteeing the release of the active substances.

- *Dissolution Test:*
  Determines how quickly the active chemicals are released, which is essential for effectiveness.

➢ *Quality Control Tests for Capsules*

- *Weight Variation Test:*
  Assures consistency in capsule weight, much like tablets.

- *Content Uniformity Test:*
  Confirms that the active components are dispersed uniformly throughout the capsule.

## II. IMPORTANCE OF QUALITY CONTROL TESTS

➢ *Ensuring Standards:*
Whether established by the business, industry, or regulatory agencies, quality control (QC) guarantees that goods and services fulfill predetermined standards and specifications.[6]

➢ *Error Detection and Prevention:*
This proactive strategy finds and fixes flaws in production so they don't reach customers.

➢ *Continuous Improvement:*
Quality control involves more than just identifying mistakes; it also involves applying that knowledge to enhance procedures and avert problems in the future.[7]

➢ *Ensures Product Efficacy:*
Quality Control makes ensuring that goods fulfill their intended requirements and performance benchmarks.

➢ *Fosters Customer Trust:*
Maintaining the manufacturer's reputation and fostering customer trust are two benefits of consistent quality.

➢ *Adheres to Regulatory Requirements:*
Regulatory bodies frequently require quality control and compliance is crucial to avoiding financial and legal repercussions.[8]

## III. TYPES OF QUALITY CONTROL TESTS

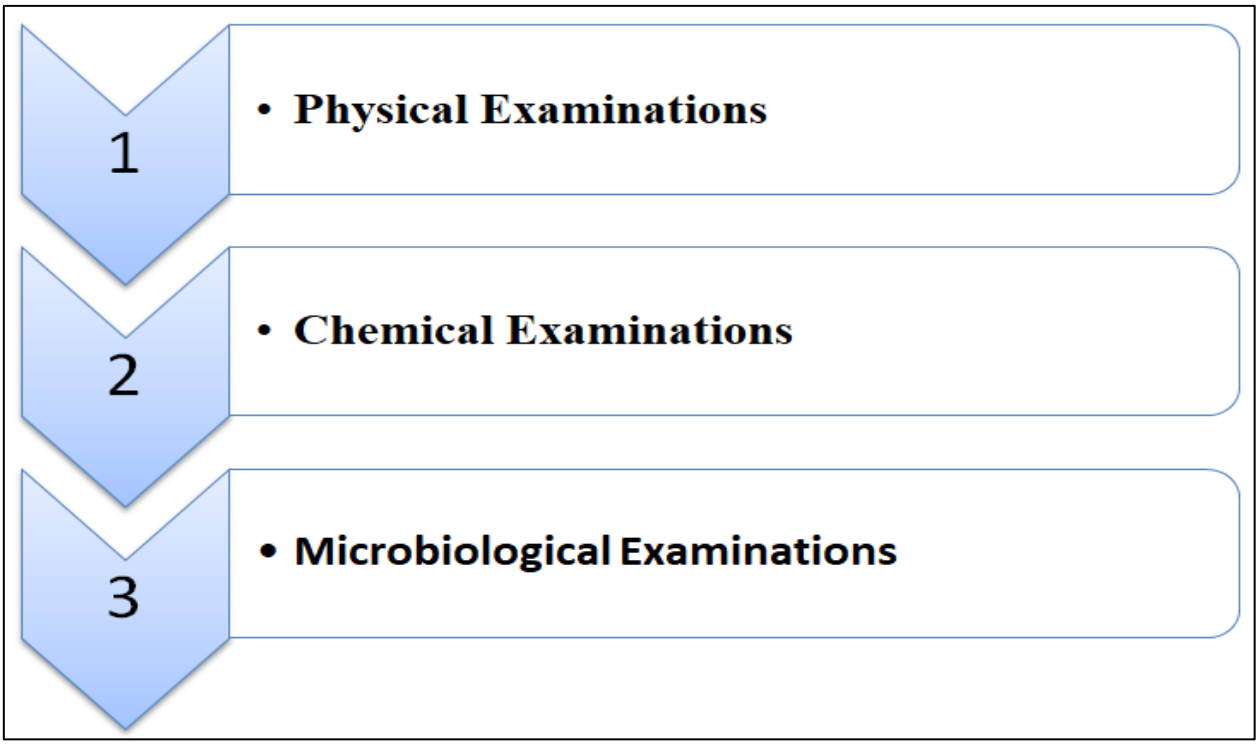


Fig 1 Types of Quality Control Tests

To make sure that pharmaceutical items, such as tablets and capsules, fulfill the necessary requirements for identification, purity, strength, and performance, quality control (QC) tests are methodical processes[9] To ensure that pharmaceutical products are safe, effective, and consistent, these tests are crucial.

*A. Physical Examinations*
Physical tests assess the mechanical and exterior characteristics of dosage forms, including size, shape, hardness, and appearance.[10]

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➢ *For Instance:*

- Variation in weigh
- Hardness
- Friendliness
- The thickness
- Disintegration

✓ Ensure the integrity of the dose form: Check that pills, capsules, or other dosage forms adhere to regulations.[11]
✓ Find flaws: Look for flaws in physical characteristics such friability, hardness, or weight fluctuation.
✓ Verify product uniformity: Verify that goods adhere to uniformity requirements.[12]

*B. Chemical Examinations*

Chemical tests ascertain the drug substance's identity, purity, and chemical makeup.[13]

➢ *For Instance:*

- Assay (estimating drug content)
- Consistency of content
- A test of identification Testing for impurities

➢ *Goal:*

To verify that the medication has the appropriate active component in the appropriate quantity.

- Check active ingredient content: Make sure products have the right amount of active ingredient.
- Detect impurities: Determine and measure degradation products or contaminants.
- Verify product potency: Verify that goods fulfill potency requirements.

*C. Microbiological Examinations*

These tests evaluate pharmaceutical goods' microbiological safety and biological activity.[14]

➢ *For Instance*

- The sterility test
- The microbial limit test

➢ *Bioassay*

- Assure sterility: Make sure sterile goods are devoid of microbes.
- Identify and measure microorganisms in non-sterile products to detect microbial contamination.
- Ensure product safety: Verify that goods adhere to microbiological safety regulations.

These tests evaluate pharmaceutical goods' microbiological safety and biological activity.

➢ *Goal:*

To guarantee that the product has the desired biological effect and is free of dangerous bacteria.[15]

Table 1 Quality Control Test Applicable For Tablets and Capsules[16-21]

| S. No. | Test Name | Purpose/Function | Tablet | Capsule |
|---|---|---|---|---|
| 1 | Appearance Test | Checks color, shape, size, and defects | ✔ | ✔ |
| 2 | Weight Variation | Test Ensures uniformity in dosage weight | ✔ | ✔ |
| 3 | Hardness Test | Measures mechanical strength of tablets | ✔ | ✘ |
| 4 | Friability Test | Checks tablet resistance to breakage/chipping | ✔ | ✘ |
| 5 | Disintegration Test | Time taken to break down in solution | ✔ | ✔ |
| 6 | Dissolution Test | Determines drug release profile | ✔ | ✔ |
| 7 | Content Uniformity | Ensures even distribution of active ingredient | ✔ | ✔ |
| 8 | Moisture Content Test | Detects moisture that may affect stability | ✔ | ✔ |
| 9 | Thickness Test | Measures tablet thickness consistency | ✔ | ✘ |
| 10 | Capsule Integrity Test | Ensures capsule shell is intact and strong | ✘ | ✔ |
| 11 | Microbial Limit Test | Ensures product is free from harmful microbes | ✔ | ✔ |
| 12 | Stability Test | Checks drug stability under different conditions | ✔ | ✔ |
| 13 | Organoleptic Test | Evaluates taste, odor, color, and feel | ✔ | ✔ |
| 14 | Defective Test | Cracks ,mottling, or other defects | ✔ | ✔ |

## IV. QUALITY CONTROL TESTS FOR TABLETS AND CAPSULES

➢ *Official (Pharmacopoeial) Examinations:*

- Drug Content Uniformity
- Weight Uniformity
- Test for Disintegration
- Rate of Dissolution

➢ *Non-Pharmacopoeial, Non-Official Tests:*

- Crushing strength, or hardness
- The friability of
- Thickness Uniformity
- Overall look.
- Weight Uniformity
- Test for Disintegration
- Rate of Dissolution

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➢ *Tests for Capsule Integrity:*

Pharmaceutical capsules undergo a quality control check called a capsule integrity test to make sure their chemical and physical characteristics are up to par.[24] Important testing include tests for stability, content homogeneity, and weight change; tests for moisture permeation (the capacity of the packaging to retain moisture); and tests for disintegration and dissolution (the speed at which they break down and release the medicine)[25]. According to Torontech, further testing can gauge mechanical characteristics like hardness or bending strength

➢ *Key Capsule Integrity Tests.*

- *Weight Variation:*

To guarantee consistency in medication dosage, this measures how uniformly each capsule weighs.

- *Disintegration and Dissolution:*

These tests measure how rapidly a capsule dissolves and releases its contents in a liquid medium,[26] which is essential for the body to absorb the medication.

- *Moisture Permeation:*

This confirms that the capsule's packaging adequately shields it from moisture, which might deteriorate the shell and its contents.[27]

- *Content Uniformity:*

This test makes sure that every capsule has the right amount of the active ingredient.

- *Stability Testing:*

This entails putting the capsule through a variety of tests to ascertain its shelf life and evaluate the long-term integrity of the shell and its contents. [28]

- *Mechanical Testing:*

A capsule's hardness, strength, and bending resistance can be determined using certain.

## V. WEIGHT VARIATION TESTS

➢ *Tablet Weight Variation Test:*

The amount of fill in the die of an tablet press determines the weight of a tablet. To get the right weight and content, the first few pills are used to alter the fill volume .A reliable indicator of the corresponding fluctuation in the medication content is the weight variation of individual tablets.[29] Improved tablet hardness and friability can be achieved by keeping tablet weights within a narrow range. Weigh each of the twenty tablets separately. Determine the average weight and contrast it with the weight of each tablet. None of the individual weights differ from the average weight by more than twice that amount, and no more than two deviate by more than the percentage indicated in the table below. [30]Depending on the average weight of each tablet, different tablets have different weight variation tolerances.

➢ *Capsule Weight Variation Test:*

One crucial quality control method for guaranteeing the consistency of dose forms is the weight variation test of capsules.[31] It is crucial that every capsule in a batch has almost the same weight of the medicine formulation because capsules are meant to provide a precise amount of active pharmaceutical ingredient (API). In order to ascertain the net content of the fill material, a predetermined number of capsules are weighed separately both before and after the shell is removed[32]

- *Method:*

✓ Choose the right balance for the required precision and quantity.
✓ The balance is positioned in an appropriate area with a low enough air current and vibration level
✓ Press the proper tare key on the balance after placing the receiver (watch glass) in the middle of the pan. • Weigh each of the twenty complete tablets separately, then compute the average weight.[33]
✓ If the weights of no more than two tablets deviate from the weight by more than the percentage shown in the accompanying table and no tablet deviates from the weight by more than twice that percentage, the requirements are satisfied.[34]
✓ If the coated tablets don't meet the requirements listed in the following table, put 20 tablets in a beaker of water at 37° and gently swirl for no more than five minutes. Check the cores for signs of disintegration, and if disintegration has started, repeat the process for a shorter period of time. For half an hour, dry the cores at 50°. Weigh each of the twenty tablet cores precisely, then compute the average weight.

Table 2 Average Weight of Capsule

| Average Weight of Capsule (According to IP/BP) | Limit | Average Weight of Capsule (According to USP) |
|---|---|---|
| Less than 300 mg | ±10%<br>±20% | Minimum 18<br>Maximum 2 |
| 300mg or more | ±7.5%<br>±15% | Minimum 18<br>Maximum 2 |

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- *Weight Variation Test Calculation:*

The maximum and lowest weight variations for each tablet were determined using the following mathematical formula.[35]

- *The Highest Weight Variation (%) is Calculated as Follows:*

(Highest weight – Average weight *100)/(Average weight)

(Lowest weight – Average weight * 100)/(Average weight) is the lowest weight variation (%).[36]

## VI. DISINTEGRATION TESTS

The disintegration test is a quality control procedure used to ascertain how long it takes for tablets or capsules to disintegrate into smaller particles under particular circumstances. [37]In order for the medication to be released and absorbed by the body, this test makes that the dose form breaks down appropriately after delivery.

IP, BP, and USP all mention this significant pharmacopoeial test.[38]

You may be curious about the particular pill and capsule disintegration test. This is the breakdown:

➢ *Tablets:*

- In water or SGF, immediate-release pills must dissolve in 30 minutes.
- Coated tablets are tested for up to 60 minutes using auxiliary disks.
- A two-stage test is used for enteric-coated tablets, first in an acidic medium and subsequently in buffer.[39]

➢ *Capsules*

- Hard gelatin capsules need to break down in 20 minutes.
- Depending on the formulation, softgel capsules are tested in water or by rupturing them.
- For certain formulations, you will retest with six more capsules to confirm if one fails.

The disintegration process guarantees the dosage form's full breakdown, which is essential for its bioavailability and therapeutic impact.

➢ *Disintegration Test's Significance*

- *Guarantees Appropriate Drug Release:*

Before the drug dissolves and is absorbed by the body, it must first disintegrate. The medicine will be ready for absorption at the appropriate moment if it disintegrates properly.[40]

- *Bioavailability Indicator:*

A tablet or capsule that breaks down correctly will typically have higher bioavailability, which means that more of the medication enters the bloodstream.

- *Ensures Constant Performance:*

Each tablet or capsule functions in the same manner since the test guarantees consistent quality across batches. [41]

- *Identifies Formulation or Manufacturing Flaws:*

If a product fails the disintegration test, it may be a sign of issues such excessive binder, incorrect compression, or subpar excipients.

## VII. FRIABILITY TESTS

In order to assess a tablet's resistance to chipping, breaking, or crumbling during handling, packing, and transit, a friability test assesses the tablet's physical strength.[42] In order to determine whether the tablets fulfill the necessary standard—typically less than −1\%\) weight loss—a sample of tablets is subjected to a predetermined number of drops in a spinning drum. The percentage of mass lost is then calculated.[43]

The objective is to assess a tablet's resistance to mechanical stress, which is critical to its integrity during production, packing, and transportation.

What it measures is a tablet's propensity to chip, crumble, or shatter under mechanical stress.

➢ *How It's Carried Out*

- *Equipment:*

The tablets are tumbled by a revolving drum with a baffle. Sample preparation: Prior to the test, a certain quantity of tablets are weighed and cleaned.

- *Procedure*

✓ Before testing, the tablets should be thoroughly cleaned.
✓ Place the tablets in the drum after precisely weighing the tablet sample.
✓ Remove the pills after rotating the drum 100 times at a speed of 25 rpm.
✓ As before, remove any loose dust from the tablets and weigh them precisely.

- *Evaluation:*

After the tablets are taken out, any loose dust is removed, and their ultimate weight is determined. The friability of the tablet is determined by calculating the percentage of mass lost.[44]

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➢ *Why It's Significant*

- *Guarantees patient safety:*

A broken or chipped tablet may result in an inaccurate dosage, which could compromise the effectiveness of treatment.

- *Preserves product quality:*

It helps avoid product loss and guarantees that tablets reach the patient undamaged and at the proper weight.

- *Evaluates formulation problems:*

A high friability result may point to formulation difficulties including low moisture content, inadequate binder, or poor tablet design.[45]

## VIII. ORGANOLEPTIC TESTS

In order to guarantee quality, consistency, and patient compliance, organoleptic testing for tablets and capsules use sensory evaluation to check the physical characteristics like color, odor, and taste. In order to find any defects like improper taste or discoloration,[46] these are frequently unofficial, in-house tests carried out by skilled analysts under the guidance of color charts or descriptive guidelines.[47]

➢ *Organoleptic Properties of Tablets and Capsules*

- *Appearance:*

Examine the product's general appearance, taking into account its size, shape, and surface roughness.

- *Color:*

Look for any indications of deterioration and make sure the color is consistent and adheres to the stated standard.

- *Odor:*

Take note of any noticeable smell; this is especially crucial for products that have flavorings added to them to guarantee consistency.

- *Taste:*

Taste is a crucial organoleptic characteristic for chewable or oral disintegrating tablets to confirm that the desired flavor has been correctly and consistently included.

- *Physical Flaws:*

Check for any physical imperfections like indentations, pinholes, or cracks.

➢ *Importance of Organoleptic Properties*

- *Patient Identification:*

Patients can identify the right medication based on how it looks. It Is Consistency: These tests guarantee that the product is consistent between batches.

- *Quality Assurance:*

It is a rapid and simple method of identifying possible production mistakes early on. Quality and Safety Assurance: Verifies that products are safe to eat by identifying spoilage, contamination (such as off scents or discolouration), and processing mistakes.

- *Product Development:*

Provides direct sensory feedback on constituent effects or formulation modifications to lead the development of new recipes and the optimization of current ones.

## IX. DISSOLUTION TESTS.

❖ *Dissoultion Apparatus According to USP14*

➢ *Apparatus 1 (Basket Apparatus) :*

It comprises of a motor, a metallic drive shaft, a cylindrical basket, and a tank composed of glass or another inert transparent material.[48] The vessel is heated by an appropriate equipment, like a heating jacket, or partially submerged in an appropriate water bath. Throughout the test, the water bath or heating device keeps the temperature within the vessel at 37±0.5°C and keeps the bath fluid moving smoothly and steadily .The cylindrical vessel with the following measurements and capacities has a hemispherical base: The height and inside diameter are 160 mm to 210 mm and 98 mm to 106 mm, respectively, for a nominal capacity of 1 L, 280 mm to 300 mm and 98 mm to 106 mm for a nominal capacity of 2 L, and 280 mm to 300 mm and 145 mm to 155 mm for an anominal capacity of 4 L. It has flanged sides at the top, and evaporation can be slowed with a fitted cover . The shaft is positioned so that its axis is never more than 2 mm from the vessel's vertical axis, and it rotates smoothly and without any noticeable wobble that would compromise the outcome.[49] The basket's overall height is 37 ± 3. a motor with a speed regulator that can keep the rotational speed within ± 4% of the individual monograph's specifications. The vent hole measures 2.0±0.5 mm. 20.2 ± 0.1 mm is the clear opening . The stirring element's shaft and basket are made of type 316 stainless steel or another inert substance. At the start of every test, a dose unit is put in a dry basket. Throughout the test, the gap between the inside bottom of the vessel and the bottom of the basket is kept at 25 ± 2 mm.[50]

➢ *Dissolution Appratus2 (Paddle Type) :*

The assembly is identical to that of Apparatus 1, with the exception that a paddle is used in place of the basket in the stirring element .The shaft is positioned so that it rotates easily and its axis is no more than 2 mm from the vessel's vertical axis. without a significant wobble that might affect the out come .In order to make the blade's bottom flat with the shaft's bottom, the blade's vertical center line crosses through the shaft's axis.[51].Throughout the test, the gap between the inside bottom of the vessel and the bottom of the blade is kept at 25 ± 2 mm. The blade is 19.0±0.5 mm in height and 4.0±1 mm in thickness. The paddle's radius disk measures 41.5 ±0.5 mm. Before the blade begins to rotate, the dose unit is allowed to sink to the bottom of the jar. Dosage units that would otherwise float can have a little,

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loose piece of non-reactive material with a few wire helix turns connected to them.[52]

➢ *The Fundamental Idea*

The test is predicated on the idea that, depending on formulation and circumstances, a medication dissolves at a particular rate when a solid dosage form (tablet or capsule) is submerged in a liquid medium. Uniform mixing is produced by a spinning paddle, guaranteeing steady medication release into the medium.[53]

➢ *The Dissolution Test's Significance* •

Drug release: Confirms that the active component is consistently released from the dosage form (such as tablets or capsules).

- Therapeutic effect: Verifies that the medication is present in the body to have the intended therapeutic impact.
- Batch-to-batch consistency: Guarantees that the dissolving profiles of several batches of the same product are comparable.[54]
- Product quality: Assists in locating possible problems with raw materials, production, or formulation.[55]

## X. DEFECTIVE TEST

*A. Types of Tablet Problems:*

Problems with raw materials, formulation, manufacturing, or coating processes can lead to problems in the quality, appearance, or functionality of tablets. Physical problems such as capping, lamination, and chipping—where tablets split, layer, or break—are common flaws.[56] Additionally common are visual defects such as picking (material clinging to punch faces), sticking (adhesion to equipment), and mottling (uneven color). Finding the underlying causes of these flaws and putting corrective measures in place for formulation and manufacturing are necessary to address them.[57]

*B. Defects in Pharmaceutical Capsules:*

Defects in pharmaceutical capsules, such as holes, air bubbles, deformities, and cracks, can be caused by production problems, inconsistent materials, or inappropriate storage conditions. These defects jeopardize the medication's stability, efficacy, and dose precision, which may result in uneven release, diminished potency, or other negative impacts on human health.[58] In order to guarantee patient safety, product quality, and the dependability of capsule-based medications and nutraceuticals, it is imperative that these flaws be fixed.

*C. Types of Tablet Flaws*

➢ *Capping and Lamination:*

When air is trapped during compression, the tablet's top, bottom, or layers separate.

➢ *Chipping:*

The shattering of tablet edges, which may be caused by worn die walls, too dry granules, or improper machine settings.

➢ *Cracking:*

Tiny surface cracks brought on by the tablet's quick expansion following compression.

➢ *Picking and Sticking:*

The punch face (picking) or the die wall (sticking) adhere to and remove material from the tablet surface.

➢ *Mottling:*

When a colored medication mixes incorrectly with excipients, it results in an uneven color distribution on the tablet surface.

*D. Techniques for Evaluating Tablet Flaws*

➢ *Physical Testing:*

Tablet hardness (crushing strength), disintegration time, and dissolution rate are all evaluated in standard pharmacopeial assays. Drug release may be impacted by tablets that are either manufacture.[59]

➢ *Automated Visual Examination:*

Real-time, 100% visual scanning of tablets is now often accomplished with computer vision and deep learning techniques like the YOLO (You Only Look Once) algorithm. These techniques are highly accurate in identifying and categorizing flaws like as color variations, fissures, and inconsistencies in shape.

➢ *Tablet Drop Tests:*

To replicate impact during handling and transfer, modified drop tests might be utilized. Research has indicated that faults such as chipping and breaking are more likely when drop height and frequency are increased.[60]

*E. Types of Faults in Capsules*

➢ *Visual Defects:*

Holes, oil stains, shrinkage, and deformation are frequently found by visual inspection.

➢ *Print and Color Flaws:*

These are particularly difficult to identify on transparent capsules and include misaligned imprints, smudges, and color variances.

➢ *Manufacturing Flaws:*

Issues such as broken or nested capsules or poorly trapped capsules within blister packaging can result from the manufacturing and packaging process.[61]

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*F. Techniques for Evaluating Capsule Flaws*

➢ *Automated Visual Inspection:*

Defects in hard and soft gelatin capsules are found using computer vision technologies. Convolutional neural network (CNN)-based algorithms are highly accurate in identifying and classifying a variety of faults.

➢ *Dissolution and Disintegration Testing:*

To guarantee the correct release of the medication from the capsule, standard in-vitro procedures, akin to those for tablets, are crucial.[62] The dissolving profile may be adversely affected by flaws in the filling procedure or the capsule shell.

*G. Overview of Capping Defects:*

When a tablet's upper or lower segment breaks horizontally, either whole or partially, from its main body and comes off as a cap during ejection from the tablet press or during subsequent handling, it's referred to as capping.

➢ *Reason:*

Air entrapment in a compact during compression and subsequent tablet expansion upon ejection from a die are typically the causes of capping.[63]

➢ *References*

- The granulation contains a lot of fines.
- An excessively dry or extremely low moisture content (which results in an improper binding action).
- The granules were not completely dry.
- Inadequate or incorrect lubrication.

➢ *Precautions*

- Use a 100–200 mesh filter to remove all or part of the particles.
- Make sure the grains are well moistened. Add a hygroscopic material, such as PEG-4000, sorbitol, or methyl cellulose.
- Make sure the granules are completely dry.
- Adding more binder. At room temperature, compress.

*H. Lamination*

- The division of a tablet into two or more separate horizontal layers is known as lamination. causes air to become trapped during compression and then be released during ejection. [64]
- The turret's increased speed exaggerates the situation.
- Lamination Causes and Solutions Associated with Formulation (Granulation).

➢ *References*

- Granules of waxy or oily compounds.
- An excessive amount of hydrophobic lubricant.

➢ *Take Precautions*

- Adjust the mixing procedure

Reduce the amount of lubricant you use or switch to a different kind.
The causes of lamination and machine-related precautions (dies, punches, and tablet presses)

➢ *References*

When a tablet is ejected from a die, its surrounding areas quickly relax.

➢ *Remedy*

Make use of the pre-compression phase. Lower the ultimate compression pressure and the turret speed.

*I. Chipping*

The term "chipping" refers to the breaking of tablet edges either during the tablet's exit from the press or during handling and coating procedures that follow.[65]

➢ *References*

- Machine settings that are incorrect, particularly when it comes to ejection takeoff.
- The causes of chipping and preventative measures related to formulation (granulation).

➢ *Precautions*

- Too dry grains stick to punch faces.
- Chipping at the bottom is caused by excessive binding.
- Either properly dry the granules or add more lubricant.

To make the granules plastic, moisten them. Add materials that are hygroscopic.

The causes of machine-related chipping and preventative measures (Dies, Punches) Tablet Press) Resources

➢ *Barreled die:*

The punch face's edge is twisted inward or inward; the die's center is wider than its ends. Too deep of a concavity to compress correctly.

➢ *Precautions*

- To make the die cylindrical, polish it. Polish the punch edges and lessen the punch faces' concavity. Make use of flat punches.[66]

*J. Cracking:*

Cracks are tiny, thin fissures found on tablets' upper and lower center surfaces, or extremely infrequently on their sidewalls.

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➢ *Reason:*

It is seen when tablets expand quickly, particularly when deep concave punches are employed. The causes of cracking and how to prevent it in relation to formulation (granulation)

➢ *References*

- The grains are large.
- Granules that are too dry.
- Tablets get bigger.

➢ *Precautions*

Diminish the size of granules. Include penalties .Add the right amount of binder and adequately moisten the granules. At room temperature, compress.[67]

The causes of machine-related cracking and preventative measures (Die Punches and Tablet Press).

*K. Picking:*

- "Picking" refers to the process by which a punch face adheres to and removes a tiny bit of material from a tablet's surface .The higher punch faces are more likely to have the issue than the bottom ones. As more material is added to the already-stuck material on the punch face, the issue gets worse if tablets are produced in this tooling station on a regular basis.[68]

➢ *Reason:*

When granular material is not thoroughly cured and punch tips contain engraved or embossed characters, picking is especially problematic.

➢ *Sources and Precaution Selection Concerning Formulation (Granulation)*

- Granules with too much moisture.
- Inadequate or incorrect lubrication.

Because of their ease of use, stability, and patient compliance, tablets and capsules are the most popular solid dosage forms in the pharmaceutical industry. However, a number of flaws that could compromise the effectiveness, safety, and quality of these dosage forms could occur during production, packing, storage, and transportation.[69] In order to identify, assess, and stop such problems, defecting tests—also known as defect assessment or defect identification tests—are crucial components of quality control.

Defecting tests aid in the detection of both functional (performance-related) and visual (physical) flaws. These tests guarantee that the finished product satisfies pharmacopoeial requirements and is devoid of flaws that can jeopardize therapeutic results.[70]

## XI. CONCLUSION

To guarantee the safety, effectiveness, and dependability of pharmaceutical products, quality control testing of tablets and capsules is essential. Before being administered to patients, these tests verify that every dosage form satisfies predetermined requirements for performance, strength, purity, and consistency. To maintain product quality, the pharmaceutical business adheres to stringent standards established by pharmacopeias including IP, USP, and BP.

Hardness, friability, disintegration, dissolution, weight variation, content uniformity, and moisture analysis were among the crucial evaluation characteristics that were examined throughout the project. Each test has a specific function; for instance, hardness guarantees mechanical strength, friability verifies handling durability, and disintegration and dissolution gauge how quickly the medication is absorbed by the body. Together, these tests ensure that a product functions as intended when given to a patient.

The study emphasizes that tablets and capsules may not provide therapeutic advantages or may provide health hazards in the absence of adequate quality assessment Therefore, pharmaceutical makers have a moral need to ensure quality as well as a legal requirement . Batch-to-batch consistency is ensured and patient confidence in pharmaceutical safety is supported by contemporary methods, established procedures, and ongoing monitoring.

To sum up, quality control testing is the foundation of pharmaceutical production. It guarantees that each tablet and capsule made is high-quality, safe, and effective. This initiative highlighted the importance of numerous analytical and physical tests used in industry for drug approval and market release . In order to enhance public health and regulatory compliance, quality assurance methods will be further strengthened by ongoing improvement, adherence to norms, and technology improvements

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