International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 1 Jan - Feb 2025, pp: 1113-1120 www.ijprajournal.com ISSN: 2456-4494

In Process and Quality Control Tests for Tablets: A Review

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Date of Submission: 05-02-2025 Date of Acceptance: 15-02-2025

ABSTRACT:
All pharmaceutical enterprises aim to create high-quality products, which is accomplished by permitting quality control methods for both in-process and finished products. Assuring that the intermediates, packaging materials, and final pharmaceutical tablets adhere to approved specifications or standards for efficacy, safety, and elegance that reassure the consumer that the products perform consistently and in a manner satisfactory for the purpose for which they are recommended is known as in-process quality control. This concept encompasses all steps that are carried out before, after, and during production, including the establishment of specifications, sampling, pertinent testing, and analytical clearance. Quality control emphasizes product testing for flaws, which makes it easier for the manufacturer to deny product releases or conduct any necessary research to improve pharmaceutical tablets before releasing into the market. Since several pharmacopoeias have established varying stated limitations, the value must fall within these limits to be considered compliant with the standards. In order to verify the quality of pharmaceutical dosage forms, pharmacopoeias are compared in an attempt to communicate the harmonized limitations, which ensure that the goods fulfill the specifications. This study aims to analyze different pharmaceutical tablet quality control evaluations based on distinct pharmacopoeia standards.

Keywords: In process quality control; Finished product quality control; Universal tests; pharmaceutical standard based tests; pharmacopoeia; specification

I. INTRODUCTION:

In-Process Quality Control is referred to as IPQC. Drug discovery, animal research, laboratory testing, clinical trials, and regulatory registration are all part of the difficult process of drug development. Before a drug product is approved and put on the market for use, it must be evaluated for quality, purity, strength, identity, and stability by a number of organizations, including the US Food and Drug Administration (USFDA). The purpose of this testing is to increase the drug's efficacy and safety. Process control and pharmaceutical validation are crucial components in this process to address issues with efficacy, safety, and quality. Process control includes raw material inspection, in-process control, and final product goal. Prior to the production process being finished, these inspections and tests are carried out. The functions of in-process quality control include monitoring and, if necessary, modifying the manufacturing process to fulfill the specifications.

Monitoring the manufacturing process's performance both online and offline and validating it are the primary goals.Even once the manufacturing process has been validated, CGMP still requires a well-written protocol to track its effectiveness.[1]Since quality is a wide concept, it should be incorporated into the product rather than tested.[2] Pharmaceutical production quality has become a sensitive and important topic. The Food and Drug Administration's (FDA) adoption of current good manufacturing practices (cGMP) for the twenty-first century, along with the global community's efforts to integrate its practices and guidelines, has increased awareness of the impact of pharmaceutical quality. Only after the manufactured goods meet their specified quality qualities and criteria are they deemed "fit for use".[3]

In order to ensure that the starting materials, intermediates, packaging materials, and final pharmaceutical products meet approved specifications or standards for identity, strength, purity, and other attributes,quality control of medicinal products encompasses all actions taken, including the establishment of specifications, sampling, applicable testing, and analytical clearance.[4] Quality control places a strong emphasis on checking products for defects which makes it easier for producers to reject product releases or conduct any necessary research to ensure that items are free of defects before going on sale.[5] The term for IPQC is IN-PROCESS QUALITY CONTROL. Prior to the production

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process being finished, these inspections are carried out. The purpose of this testing is to increase the drug's efficacy and safety. Process control and pharmaceutical validation are crucial components in this process to address issues with efficacy, safety, and quality. To address the issues of efficacy, safety, and quality in this process, pharmaceutical validation and process control are crucial. Process control includes raw material inspection, in-process control, and final product goal.[1]

In-process quality control guarantees that the product meets all quality standards, primarily those related to product safety and all procedures performed prior to, during, and following the production of a final product, starting with the receipt of raw materials.

In-process quality control guarantees that the product meets all quality standards, primarily those related to product safety. It also controls all operations that take place prior to, during, and following the manufacturing of a final product, including the receipt of raw materials, processing, packaging, and labeling until the batch is finished.[6] The quality control department should use a variety of quality control evaluations to determine whether to approve or reject in-process products based on their physical characteristics and quality features. Rejected in-process materials should be recognized and managed under a quarantine system to avoid their usage in manufacturing. [7]

The monitoring and assessment of the manufacturing process to create medications with exceptional efficacy, safety, and elegance that reassure the patient is known as in-process quality control.[8]

The purpose of the quality control assessment is to regulate the quality of the products, commencing with the raw materials, processing, packaging, labeling, and testing of the final product. Additionally, batch reviews and stability monitoring are conducted. The form of a written method that clearly explains how to follow the IPQCs and tests should be used to establish control over all maneuvers. Standard operating procedures(SOPs) are documented processes used in tablet formulation and production, and several techniques are used to evaluate tablet quality.[6] Pharmacopoeias specify some tests that are typically concerned with the content and in vivo release of active compounds, while non-compendia tests are known to be concerned with quality attributes and must be utilized in tablet quality review.

The dosage forms that have completed all stages of manufacture, including labeling and final container packaging, are referred to as finished products [4]. The final product must adhere to the FPQC test's acceptance limits and qualitative and quantitative features as well as test processes as outlined in the specification for the duration of its valid expiration date [5].

The quality attributes associated with the production process influence the final product's specification.

A proper specification for each aspect of the quality under study should be periodically developed during the development stage and during the manufacturing process validation.[9]

Certain IPQC and FPQC tests are carried out during or after the manufacturing process when the acceptance criteria (such as size, shape, weight, hardness, thickness, disintegration, dissolution, and other characteristics) are the same or less than the release requirement. These tests can be used as a basis for quality evaluation when they are incorporated into the specification [7].

Indian Pharmacopoeia (IP), British Pharmacopoeia (BP), United States Pharmacopoeia (USP), European Pharmacopoeia (PhEur), International Pharmacopoeia (PhInt), and Japanese Pharmacopoeia (JP) are just a few of the many pharmacopoeias found around the world.

. Since several pharmacopoeias have established various stated limitations, the value must fall within these limits to be considered compatible with the standards. The purpose of this study is to demonstrate the quality characteristics for pharmaceutical tablets in accordance with pharmacopoeias, which are a component of quality control tests for both in-process and final goods.

II. STANDARD TEST FOR THE DOSAGE FORM OF PHARMACEUTICAL TABLETS

At least 90% of medications taken orally, including tablets and capsules, are thought to significantly lower pharmaceutical errors in dose measurement when the patient takes the medication themselves [10].

The four tests—description, identification, assay, and impurity—are probably pertinent to the dosage form of tablets and other pharmaceutical goods.

2.1. Description: This test provides a qualitative account of how tablets seem as they are shown in a specification. The specification, for instance, shows the tablets as being round, white, biconvex, film-

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coated, and imprinted with the words "drug strength (Rx)" on one side [11].

2.2. Identification : Checking the identity of the active pharmaceutical ingredient (API) and identifying the substance or compounds that share a structure with those that are expected to be found in pharmaceutical tablets are the goals of an identification or identity test [11]. However, identification alone is not considered adequate by the British Pharmacopoeia 2014[12]

2.3. Assay This test, which is sometimes referred to as a content test, determines the potency or composition of the active medicinal substances found in the tablets. This technique is used as a stability-indicating test since it is specific and quantitative in identifying chemical changes over time [11].

2.4. impurity This test, which detects the presence of components other than API or excipients, is frequently referred to as a purity test and a stability-indicating test. Related substances that result from a chemical change in the drug substance that occurs during manufacturing and/or storage of the new drug product are the most common type of impurities that are calculated [11, 13]

III. IN PROCESS AND FINISHED PRODUCT QUALITY CONTROL TESTS FOR THE TABLET DOSAGE FORMS:

During the tablet-making process, in-vitro testing can regulate a number of characteristics, such as the granules' moisture content, size, drying loss, final mix flow, etc. Tablets' final product quality control tests include measurements (diameter, thickness), assay, content homogeneity, weight fluctuation, friability, active component content, hardness, disintegration, and dissolution tests, among others [14].

3.1. Non-compendial requirements for tablet quality control tests Many tests are frequently performed on tablets that are not covered by official pharmacopoeias and are determined by the product specifications provided by the manufacturer.

3.1.1. General appearance A number of characteristics, including the tablet's size and form, color, taste, texture, odor, and the readability of any identifying markings, can be evaluated to manage its overall look[15]

3.1.2. moisture content of Granules :in wet granulation are held together by bonds of a specific strength, primarily because of the moisture content of the particulate matter powder. Additionally, a certain percentage of moisture content affects the powder's flowability, compressibility, and size reduction. Granules that are overly dry, for instance, have a tendency to cap or laminate when tablets are compressed[15]

3.1.3. Size and shape: By evaluating the size and shape of tablets, their characteristics can be dimensionally depicted, tracked, and managed. [10]

3.1.4. Thickness :Thickness measurement is used to assess uniformity in production processes such as granulation, particle size, size distribution, powder mixing, etc. [10]. Tooling (such as die diameter, die internal volume, powder compressibility, force or pressure, etc.) during the compression process determines it. A micrometer or any other automated device can be used to intentionally measure the thickness of entity tablets [16]. To facilitate the packing process, the tablet's thickness, which is measured in millimeters (mm), should be kept within a range of ± 5% deviation of a standard [10].

3.1.5. Distinctive marker for identification: In addition to adding color, the pharmaceutical industry uses printing, engraving, and embossing as unique marking techniques. On tablets, these indications include the product code, medicine strength, firm name or logo, and so on [10].

3.1.6. Organoleptic characteristics: (taste, color, and odor) For quick identification and customer acceptability, many pharmaceutical companies color their pills. The distribution of colors should be uniform and free of mottling. When evaluating visual color, the sample's color is compared to the standard color. One indicator of stability could be the smell. For instance, the distinctive smell of acetic acid signals that aspirin tablets are degrading. Another factor that affects patient compliance is taste. For instance, a chewable tablet with a suitable taste improves patient compliance [10].

3.1.7. Hardness: Given that it influences the friability, solubility, and disintegration of tablets, hardness may be an important factor. In order to endure abrasion during handling, packaging, and transit, tablets require a specific level of hardness and resistance to friability. The hardness of tablets is influenced by the amount of pressure applied during compression, a feature of granulation. Therefore, it is crucial to regulate pressure in order to manage the hardness of a tablet. A multifunctional system or a hardness tester, such as the Pfizer, Erweka, Schleuniger, or Monsanto testers, are used to quantify hardness [10, 16]. The tablets are usually placed between two platens, one

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Volume 10, Issue 1 Jan - Feb 2025, pp: 1113-1120 www.ijprajournal.com ISSN: 2456-4494

of which is stationary while the other moves with sufficient force to shatter a tablet.

Fig. Monsanto Hardness Tester

- **Pharmacopoeial standards-based quality control test for tablet dosage forms**

1.Friability

The strength and durability of compressed and uncoated tablets can be evaluated by using a friabilator [16], primarily the Roche friabilator [10]. This test involves weighing, dedusting, and placing tablets with an average weight of < 650 mg and over 650 mg, a sample of 10 complete tablets, and a sample of 6.5 g of tablets, respectively, in a friabilator drum that rotates 100 times. The following formula is used to determine the percentage that represent the friability value:

Friability is equal to Wi × 100 (Wi − Wf).
where Wf is the total mass of tablets at the end and Wi is the total initial mass of the tablets

The test is often conducted just once, but it may be repeated again if there are issues interpreting the results or if the final weight loss exceeds the desired amount. The result is then expressed as the mean of the three tests. In addition to tablets that are cracked, chipped, or broken, the test is unacceptable if the weight loss of rolled tablets (after 100 revolutions) is greater than 1% [12, 17, 18].

Fig. Friability tester

2. Test of Weight Variation

This test, which weighs 20 tablets separately and determines the average mass, is applicable to both coated and uncoated tablets. If the weight of no more than two tablets deviates from the average weight by more than the percentage indicated in tables 3 and 4, and if the weight of no tablets varies by more than twice that percentage, then the requirements for weight variation are satisfied [12, 17, 18].
The following formula is used to calculate the test's outcome, which is expressed as a percentage:
Weight Variation = WA × 100 (WI − WA)
where WA is the average tablet weight and WI is the weight of each individual tablet.

As per USP the tablet complies with the test if not more than 2 of the individual masses deviate from the average mass by more than the percentage deviation as shown in Table 2 and none deviates by more than twice that percentage [22].

Table : USP limits for weight variation test for uncoated tablets

Average weight (mg)	Percentage Deviation (%)
130or less	10
130-324	7.5
More than 324	5

3.Content uniformity:

In order to ascertain if the quantity of drug from batch to batch and tablet to tablet falls within a specific range surrounding the label claim, USP/BP states that this test is based on the assessment of the individual content of drug substance(s) in ten randomly selected tablets [12, 17].

According to BP, a tablet is considered compliant if every single piece of content falls between 85 and 115% of the average content and none of them vary from that range. Calculate the individual contents of an extra 20 tablets if the content of one is in the ranges of 75% and 125% but outside of the range of 85% to 115%[12].

4.**Test of disintegration**

The purpose of this test is to ascertain if, when placed in a liquid medium under the specified experimental conditions, tablets will break down into smaller particles or constituent parts within the allotted time [12, 17, 18].

Six open-ended transparent tubes measuring 77.5±2.5 mm in length, 21.85±1.15 mm in internal diameter, and 1.9±0.9 mm in wall

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thickness make up the USP & BP disintegration equipment [12, 17]. Six open-ended clear tubes of 77.5±2.5 mm in length, 21.5 mm in internal diameter, and roughly 2.0 mm in wall thickness make up the IP disintegration apparatus [18]. At the bottom of the basket rack assembly, this seamless tube was secured to a 10-mesh screen. A single tablet is placed in each tube to measure the disintegration time, and the basket rack is set up in a suitable vessel, ideally a 1-liter beaker, with the wire mesh at least 15 mm below the liquid's surface when the assembly is in the outmost position. The liquid medium is kept at 37 ± 2 °C (unless the individual monograph specifies otherwise). and the upper open ends of the tubes stay above the liquid's surface when the assembly is in its lowest position since the wire mesh is at least 25 mm above the beaker's base. Avoid immersing the basket rack assembly's top in medium. The basket assembly holding the tablets is moved up and down 5.5±0.2 cm at a frequency of 28 to 32 cycles per minute using a typical motor-driven tool [12, 18]. The exam may also make use of perforated plastic discs. Place one tablet in each of the basket's six tubes. Perforated plastic discs may alternatively be used for the test if directed. If, during the allotted time, no residue is left on the 10-mesh screen, the tablets pass the test. They should be soft bulk without a discernibly solid core, if they are there [12, 18]. Twelve additional pills are used in the study if one or two of the six tablets do not dissolve. If at least 16 of the 18 tablets break apart, the test is considered to have been passed. British Pharmacopoeia BP and Indian Pharmacopoeia IP indicate specific tablet withdrawal periods as shown in following Tables

BP limits for Disintegration times for tablets

Categories of tablets	Disintegration Time (min)
Uncoated tablets	15
Coated tablets	60
Effervescent tablets	5
Soluble tablets	3
Dispersible tablets	3
Orodispersible tablet	3
Gastro-resistant tablets	60
Oral lyophilisates	3

IP limits for disintegration times of tablets

Categories of tablets	Disintegration Time(min)
Uncoated tablets	15
Coated tablets	60
Enteric coated tablets	60
Film coated tablets	30
Effervescent tablets	5
Soluble tablets	3
Dispersible tablets	3

Fig. Disintegration apparatus

5.**Dissolution**

The clear, inert cylindrical cylinder with a hemispherical bottom that may be covered and a 1L capacity is the basis of the BP, JP, or USP dissolving apparatus I (Basket apparatus) and apparatus II (Paddle apparatus). The only assembly difference between the two devices is the stirring element, where apparatus I uses a basket and apparatus II uses a paddle. However, in IP, this assembly is inverted, with apparatus I using a paddle and apparatus II using a basket.

Throughout the test, the temperature of the partially submerged vessel in a water bath is kept at 37±0.5°C [12, 17, 19].

A specified volume of dissolution medium (±1%) is added to the vessel of the specific apparatus to test dissolution, and the temperature is maintained at 37±0.5°C for the duration of the test. A single tablet is put within the device, and after a predetermined amount of time, a sample is taken from halfway between the surface of the dissolving medium and the top of a spinning basket or paddle, at least 1 centimeter from the vessel wall, being careful to remove air bubbles from the tablet

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surface. Fresh dissolving media is used to replace the aliquots that were removed for the designated number of sampling periods. As specified in the individual monograph, the analysis was carried out using an appropriate dissolving media and assay technique, and the test was repeated using extra tablets.

When using a buffered solution as a dissolving medium, the pH of the solution is adjusted to within 0.05 units of the specified pH. The specimens are removed within a tolerance of ±2% of the specified time in each case.[12,17,19]

Place the prescribed volume of the dissolving media (± 1 %) in the vessel of the designated apparatus for this test in accordance with BP and PhEur. Equilibrate the dissolving media to 37 ± 0.5 °C after assembling the equipment. Make sure there are no air bubbles on the tablet's surface when you insert it into the device. Run the device at the designated pace. Remove a specimen from a zone halfway between the top of the revolving basket or blade and the surface of the dissolving medium, at least 1 cm from the vessel wall, within the allotted time frame or at each of the times mentioned. Replace the aliquots taken out for analysis with equal amounts of brand-new dissolving medium at 37 °C when numerous sample intervals are specified, or adjust for the volume change in the computation if it can be demonstrated that replacing the medium is not required. Throughout the test, keep the vessel covered, and check the medium's temperature at the appropriate intervals. Follow the instructions in each specific monograph to conduct the analysis using an appropriate assay method. Do the test again using more tablets. Unless otherwise specified in the individual monograph, according to BP, USP, PhEur, JP and PhInt the requirements are met if the quantities of active ingredient dissolved from the tablets tested conform to the following acceptance criteria (Table) [20,21,22,23,24].

Table : BP, USP, PhEur, JP and PhInt acceptance criteria for dissolution test of tablet

Stage	Number of tablet tested	Acceptance Criteria
S1	6	Each unit is not less than Q+5%
S2	6	Average of 12 units (S1 + S2) is equal to or greater than Q, and no unit is less than Q – 15 %
S3	12	Average of 24 units (S1 + S2 + S3) is equal to or greater than Q, not more than 2 units are less than Q – 15 %, and no unit is less than Q – 25 %.

Continue testing through the 3 stages unless the results conform at either S1 or S2. The quantity Q, is the specified amount of dissolved active substance, expressed as a percentage of the labeled content; the 5 percent, 15 percent, and 25 percent values in the table are percentages of the labeled content so that these values and Q are in the same terms [13,14,15,18,19].

Fig. Dissolution apparatus

❑ **Moisture Permeation Test**

To guarantee that single-unit and unit dose containers are suitable for packaging tablets, the USP requires an assessment of their moisture

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permeability properties. By packing the dosage unit with a color-revealing desiccant pellet, exposing it to known relative humidity for a predetermined amount of time, and watching for color changes in the desiccant pellet, the degree and rate of moisture penetration are ascertained.

Any color shift signifies moisture absorption. The amount can be computed by weighing the pellets before and after the test.[22 ,25,26]

IV. CONCLUSION :

Various in-process and final product quality control tests based on various compendial and non-compendial criteria for quality attributes prior to their release into the market are briefly summarized in the current review.

To ensure the production of medications with higher efficacy and safety consistently from batch to batch, in-process quality tests are intended to evaluate issues that arise during manufacturing or to offer early warning for quality and to examine processes for a product. These in-process controls are necessary to ensure the product's quality, and by using in-process quality tests, we may reduce material, time, expense, and process repetition.

Although there are minor differences in quality control tests between the Indian, British, Japanese, European, international, and United States pharmacopoeias, the primary goal of all pharmacopoeias is to produce high-quality pharmaceuticals for human welfare.

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