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Review on Quality Control Tests for in Process and Finished Tablet Products

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ABSTRACT:

In order to categorize a Tablet as a drug of high quality, it must adhere to specific standards. The primary factors used to evaluate the quality of any tablet product include its safety, potency, effectiveness, stability, patient acceptance, and adherence to regulatory guidelines. The assessment of tablet quality must be undertaken during the development phase of the product. During the product's design and assembly, it is imperative to establish the physical, chemical, and biological parameters necessary to ensure compliance with quality requirements and the setting of quality objectives. The utilization of in-process quality control (IPQC) testing is crucial during production to guarantee the quality of the final product. These tests, conducted throughout the manufacturing process, enable the monitoring and adjustment of operations to ensure that the product aligns with specifications, ultimately resulting in tablets of excellent quality. The main aim of IPQC is to prevent or rectify errors at each stage of production, thus yielding an impeccable finished product. Once the manufacturing process concludes, finished product quality control (FPQC) tests, in accordance with the specifications outlined in the pharmacopoeia, are performed on the pharmaceutical tablets. Such tests are instrumental in assessing whether the quality parameters fall within acceptable limits. The purpose of this study is to provide IPQC and FPQC testing for pharmaceutical tablets in accordance with the pharmacopoeia guidelines.

KEYWORDS: Pharmaceutical tablets, Pharmacopoeia, In-process quality control (IPQC), Finished product quality control (FPQC), Specifications.

1. Introduction:

Quality is not an accident, but the result of deliberate artistry. In the pharmaceutical field, quality is the most important and sensitivity thing. The importance of pharmaceutical quality is well recognized through international cooperation and compliance with current FDA Good Manufacturing Practices (cGMP), specifically adapted for the new era. Ensuring pharmaceutical excellence requires implementing comprehensive safeguards to prevent errors at every stage of the manufacturing process.

Good Manufacturing Practices (GMP) recognizes manufacturing practices that provide the highest quality finished products while paying close attention to worker safety. GMP includes manufacturing processes and quality control QC. Quality control, an essential part of GMP, requires careful inspection of all production elements to detect and correct errors that occur at each stage of production. The goal of quality control is to prevent or correct defects throughout the manufacturing process to achieve a perfect product. It is important to emphasize that achieving quality results in the health sector requires collaboration. In general, the design and manufacturing process of a product, including the physical layout, location, ventilation, cleanliness, and hygiene of the manufacturing facility have a significant impact on product quality and product size.

Regular IPQC inspections are conducted throughout the manufacturing process to monitor and adjust manufacturing processes to ensure compliance with specific requirements. IPQC integrates environmental controls and tools as an integral part of an in-process control system. It is important that these inspections do not compromise the quality of the products. In-process testing helps detect problems early so that defective product packages can be corrected. However, once the archive is complete, your changes may not be available. Failure to comply with the requirements of the IPC constitutes a breach of contractual obligations and circumstances beyond our control. In the pharmaceutical industry, it is important to establish and follow standard operating procedures (SOPs) for IPQC and testing procedures.

Final Product Quality Control (FPQC) is performed after the manufacturing process to assess product reliability and quantity. It also includes the test procedures and acceptance criteria that the final product must follow throughout its useful life. The quality attributes of the final product are determined to define the necessary requirements, taking into account the production process. When developing and validating manufacturing processes, it is important to provide complete information on every aspect of quality control. Critical components should be closely monitored and tested as needed. When a product is launched, the marketing authorization applicants set the benchmarks so that the expected information remains accurate throughout its lifetime. These conclusions were drawn from the analysis of the data collected from the studied groups.

Drug standards are often referred to as pharmacopoeias. Indian Pharmacopoeia(IP), British Pharmacopoeia (BP), United States Pharmacopoeia (USP) , European Pharmacopoeia (PhEur), International Pharmacopoeia (PhInt) and Japanese Pharmacopoeia JP incorporate these standards and are widely recognized worldwide. These guidelines outline specific criteria that must be met to meet quality standards. The purpose of this study is to discuss the quality parameters of pharmaceutical tablets described in the pharmacopoeia. These parameters play an important role in ensuring quality during production and evaluating the final product.

2. General Test for Pharmaceutical Tablet Dosage Forms:

There are approximately 50% products are tablet formulations available on the market. Four evaluation tests have been carried out on tablets and tablet products.

2.1. Description:

This test is important for the requirements and descriptions of the pharmaceutical field. For example, the description of a tablet on a specification may read: white, round, biconvex, film-coated tablet, imprinted with „„Rx‟‟‟ on one side.

2.2. Identification:

The primary purpose of identification or proof of identity is to verify the identity of the active medical integration API contained in the medical platform. This test can distinguish between structurally very similar compounds.

2.3. Assay:

This test determines the potency and API content in the drug class and is called a potency test.

2.4. Impurities:

The purpose of this test is to determine the presence of ingredients and additives in pharmaceutical tablets that do not fall under the API of active pharmaceutical ingredients. The main impurities tested are termed impurities, which include impurities created during the synthesis of new drugs, API degradation products, or a combination of the two.

3. IPQC and FPQC Test for Pharmaceutical Tablets:

IPQC testing of pharmaceutical tablets was regulates by various physical parameters such as temperature, pressure, humidity, time, weight, particle size, hardness, loss on drying, residence time, color, simplicity and reliability. In contrast, FPQC tests for medical tablets are analytical in nature. IPQC and FPQC tests for tablets that meet the standards set by the Pharmacopoeia and cover areas such as content consistency, volume consistency, weight change, weakness test, determination of input active content, maturity assessment, segmentation analysis and recall evaluation.

3.1. Size and Shape:

The tablet's size and configuration can be monitor and managed, an attribute verified by the device during the compression process.

3.2. Color and Odor:

Many industries use color as an important method for quick identification and customer acceptance. But, this should be the same on the same floor, from floor to floor, from place to place. An odor coming from the medication stack may indicate an ongoing problem. E.g; Dissolved aspirin tablets produce an acetic acid odor characteristic of the drug. Vitamins have a unique smell. Taste is important to consumer acceptance of chewable tablets.

3.3. Thickness:

The performance of the tablet is exclusively influenced by its thickness, which can be evaluated by observing the dimensions of its various layers through a microscope. An alternative approach involves incorporating 5 or 10 layers into the seating and potentially utilizing a sliding scale to ascertain the overall thickness. Maintaining a sheet thickness within a deviation of ±5% from the standard deviation is crucial. Consequently, adjustments must be made to the thickness to guarantee efficient absorption. The thickness is presented in millimeters.

3.4. Unique Identification Markings:

Pharmaceutical companies use unique logos to mark boards and images featuring the company name, brand or product logo to ensure quick identification and association with a specific product.

3.5. Moisture Content of Granules:

The particles/granules must be strong enough to withstand handling and mixing without breaking, resulting in a fine powder. However, moisture plays an important role in achieving good therapeutic results by reducing the size and enveloping in several layers, presenting a perfect surface for perfect mixing.

3.6. Assay:

The incorporation of active pharmaceutical ingredients (APIs) into tablets requires the use of appropriate analytical methods during testing to ensure the creation of a quality final product.

3.7. Uniformity of Content:

To evaluate the effectiveness of the tablet, you need to monitor the amount of active ingredient in each tablet and in each different batch. To achieve this, a precise analytical method must be used according to the British Pharmacopoeia (BP), where the individual content of the active ingredient is determined for 10 randomly selected tablets. To meet the standards specified in BP, the individual capacity of each floor must be between 85% and 115% of the average capacity. If several parts of the content exceed these limits, or parts of the content fall outside the range of 75-125% of the average content, the board fails the test. If the individual content falls outside the range of 85% to 115% but remains within the range of 75% to 125%, the individual content of another 20 randomly selected panels will be determined. A board meets the test requirements if at least one component out of a total of 30 boards is in the 85-115% range and no component exceeds the performance limits. The average volume is 75 to 125%.

3.8. Uniformity of Mass:

This test applies to concrete and uncoated panels. 20 tablets will be selected at random and individually weighted according to BP; to determine the average weight. To meet the requirements described in table 1, especially in the second quarter, the collective must adhere to one of the concessions and send the maximum measurement of two individual books from the average volume.

Table 1: BP limits for uniformity of mass.

Average Mass (mg)	**Percentage Deviation (%)**
80 or less	10
More than 80 and less than 250	7.5
250 or more	5

3.9. Weight Variation Test:

The USP weight change test is an analytical procedure in which 20 tablets are weighed individually to determine the average weight. The weight of each pill is compared to the average weight. The results of the weight change test are presented as percentages.

The following formula is used

Weight Variation = (Iw - Aw)/Aw x 100%

where, Iw = Individual weight of tablet; Aw = Average weight of tablet.

According to the United States Pharmacopoeia (USP), a mass is considered good if it does not exceed two masses during the second trimester and deviates significantly from the average mass by the percentage specified in Table 2.

Table 2: USP limits for weight variation test for uncoated tablets.

Average Weight (mg)	**Percentage Deviation (%)**
130 or Less	10
130 – 324	7.5
More than 324	5

3.10. Content of Active Ingredients:

The purpose of carrying out these tests according to the International Pharmacopea IP is to determine the amount of active substance using the described measurement method and to estimate the dose of the active substance. . It's on every bill. Products must conform to the specified range of active ingredient content as indicated in the relevant literature. This range is determined by the need to use 20 tablets during use or other quantities specified in the

monograph. If you don't have 20 frames, you can use as little as 5 or more frames. However, to account for possible sampling error, the allowed difference is extended as shown in Table 3.

Table 3: IP limits for content of active ingredients.

Weight of Active Ingredients in Each Tablet	**Subtract from Lower Limit for Samples of**			**Add to the Upper Limit for Samples of**		
	15	**10**	**5**	**15**	**10**	**5**
0.12 g or less	0.2	0.7	1.6	0.3	0.8	1.8
More than 0.12 g But less than 0.3 g	0.2	0.5	1.2	0.3	0.6	1.5
0.3 g or more	0.1	0.2	0.8	0.2	0.4	1.0

As specified by the IP requirements Table 3 apply when the stated limits are between 90 and 110 % . For limits other than 90 to 110 percent, proportionately smaller or larger allowances should be made.

3.11. Hardness Test:

A quick testing tool, the Ketane tablet hardness tester is used to assess tablet hardness, especially when using a variation of the Monsanto hardness tester. The device consists of a cylindrical container containing a compression spring placed between two pistons. When the bottom piston hits the ground, the first measurement is taken. The threaded bolt is pressed against the upper piston, causing the plate to break. As the spring is compressed, the pointer moves on a calibrated scale inside the container to show the force of application. The force required to break is expressed in kilograms.

3.12. Friability Test:

Laboratory analysis of tablet friability requires the use of Roche friabilator. Take 20 tablets and put them in the machine, applying a rotation speed of 25 rpm for 4 minutes. The tablets are compressed and weighed again. The difference between the initial and final stresses is used to determine a percentage value that represents friability. It is determined by the following formula.

Friability = (Iw –Fw) Iw x100%

where, Iw = Total Initial weight of tablets; Fw = Total final weight of tablets.

As stated by USP if conventional compressed tablets that loss less than 0.5 % to 1 % (after 100 revolutions) of their weight are generally considered acceptable.

3.13. Disintegration Test:

The USP digester consists of six glass tubes, each 3 inches long, of open design, attached to a 10-inch screen at the bottom of the package rack assembly. To assess the digestion time, a plate was inserted into each tube and the kit was immersed in the indicated medium at a temperature of 37 ± 2°C. The plate should be 2.5 cm below the surface of the water and no more than 2.5 cm above the bottom of the glass. Using a standard motor running at a frequency of 28 to 32 revolutions per minute, the basket containing the dishes can easily move up and down 5 to 6 cm. For testing purposes, a compressed plastic disc can also be used and placed on the ground to give it a good effect. These discs may not have the high sensitivity required for testing, but they are good for sensitive surfaces. Use the tool for the specified time, typically 15 minutes for uncoated surfaces, if other conditions are acceptable.

The tablet passes the test if tablet disintegrates and all particles pass through the screen 10 in the specified time. If the balance is still intact, the structure should be the same and not too difficult. Tablet testing according to the United States Pharmacopoeia USP determines that all tablets will disintegrate. If 1 or 2 layers do not dissolve, repeat the test with the next 12 tablets. This arrangement is considered satisfactory if 16 of the 18 tablets tested disintegrate. British Pharmacopoeia BP and Indian Pharmacopoeia IP indicate specific tablet withdrawal periods as shown in Tables 4 and 5.

Tablet 4: BP limits for disintegration times of tablets

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

Tablet 5: 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

3.14. Dissolution Test:

The dissolution apparatus, referred to as the BP or USP apparatus, is commonly known as the basket apparatus. It consists of a transparent cylindrical container with a hemispherical base, which may be optionally covered, and is constructed from glass or other inert materials. This apparatus encompasses a motor, a metallic drive shaft, and a cylindrical basket. The container can be partially submerged in a suitably sized water bath or heated using a heating jacket. The purpose of the water bath or heating device is to maintain a steady temperature of 37 ± 0.5 °C within the container throughout the testing process, while simultaneously ensuring continuous and fluid movement of the bath liquid.

According to the guidelines prescribed by BP, the first part of the test consists of accurately loading the specified removal medium into the container of the instrument marked to ±1%. It is important to ensure that the device is properly mounted and that the melting medium is equilibrated to a temperature of 37 ± 0.5 °C. When placing the card in the device, be careful not to create air bubbles on the surface. The device must run at the specified speed. Samples should be taken at designated locations, or as directed, in the space between the surface of the solvent and the top of the rotary basket or screen. It is important to remove this sample at least 1 cm from the wall of the container. If they are selected several times, the part taken for analysis should be replaced with fresh medium at a temperature of 37 °C. However, if replacement is not required, volume changes should be taken into account when calculating results. The vessel must be completely covered for the duration of the test and the time and temperature must be monitored. Analyzes should be performed using appropriate analytical methods according to specific roles and guidelines. It is recommended that the test be repeated using additional tablets. If not specified on the individual sheets, compliance with the requirements written in BP, USP, PhEur, JP and PhInt is good if the amount of active ingredient is dissolved in the tested tablets and meets the acceptance criteria specified in table 6.

Table 6: BP, USP, PhEur, JP and PhInt acceptance criteria for dissolution test of tablet

Stage	Number of Tablet Tested	Acceptance Criteria
S_1	6	Each unit is not less than Q + 5 %.
S_2	6	Average of 12 units (S_1 + S_2) is equal to or greater than Q, and no unit is less than Q – 15 %.
S_3	12	Average of 24 units (S_1 + S_2 + S_3) 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 %.

1. If your results are S1 or S2, continue your assessment with step 3.

2. The Q represents the Quantity or amount soluble fraction of a specified substance and is expressed as a percentage of the specified content.

3. The percentages in the table, i.e., 5%, 15%, and 25%, are the same as those given, so they are equivalent to the Q term.

4. CONCLUSION:

The Pharmacopoeia sets standards for high-quality medicines. According to the records of the World Health Organization (WHO), about 140 independent countries, including African, European and international medicine and national authorities, adhere to these standards. This important study shows that although different pharmaceutical companies propose different IPQC and FPQC assessments for pharmaceutical products, the main goal of all pharmaceutical companies in the world is to produce the best pharmaceutical products to improve people's lives.

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