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

Aishwarya Nale, Sandhya shinde(Kadam), Vivekkumar Redasani
YSPM'S Yashoda Technical Campus, Faculty of Pharmacy, Wadhe, Satara – 415001

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ABSTRACT:
All Pharmaceutical industries endeavour to produce good quality products which are achieved by allowing in-process And finished product quality control approaches. In-process quality control is concepts that are carried out before, after And during production covering all steps, counting the establishment of specifications, sampling, relevant testing and Analytical clearance assuring that the intermediates, packaging materials and finished pharmaceutical tablets conform With approved specifications or standard for efficacy, safety and elegance which assure the consumer that the products Perform consistently and in a manner satisfactory for the purpose for which it is recommended. Quality control Highlights testing of products for defects which ease the producer to refuse the releases of products or carry out the Possible investigation to make pharmaceutical tablets perfect before released into the market. Since different Pharmacopoeias have set the diverse specified limits to some extent within which the value ought to fall with respect To be acquiescent as per the standards. Hence by comparing pharmacopoeias, an effort is made to convey the Harmonized limits so that the products should meet the requirements as specified in pharmacopoeias specification to Confirm the quality of pharmaceutical dosage form. The endeavour of this study is to compare various quality control Assessments for pharmaceutical tablets according to different pharmacopoeias standards.

Keywords: In-process quality control; Finished product quality control; Pharmaceutical tablets; Pharmacopoeia; Specification

I. INTRODUCTION

Quality is not an accident this is the result of intelligent effort.[1] The quality in the Pharmaceutical industry has become a very important and sensitive issue. Since the world has Gathered together to unite its practices, guides and the launching of the Food and Drug Administration (FDA) current good manufacturing practices (cGMP) for the 21st century –There has been a growing awareness for the significance of the quality of the pharmaceutical Products. In the pharmaceutical industry, it is essential for controlling the errors during the Every stage in production process since total quality of the product must be ensured according To compendia of drugs.[2]

Manufacturing practices which result in good quality finished products and has adequate Considerations for safety of the employees is recognized as GMP. GMP is concerned with Both production and quality control (QC).[3] QC is the part of GMP by which QC personnel Analyses the quality of all factors involved in production in order to eliminate errors at every Stage in production. The purposes of QC are to produce a perfect finished product by Preventing or eliminating errors at every stage in production. QC is a team work and we have To remember that quality must be built into a drug product during product and process design And it is influenced by the physical plant design, space, ventilation, cleanliness and sanitation During routine production.

[4]IPQC tests are performed at regular intervals (generally each 1 hr later) during the Manufacturing process.[5] The objectives of IPQC involve monitoring and alteration of the Manufacturing process if necessary with a vision to comply with the specifications. The Control of the environment or equipment may also be regarded as a part of in- process control (IPC). They should not carry any risk for the quality of product. In process testing enables Easier identification of problems. It sometime identifies a defective product batch that can be Corrected by rework, whereas once that batch has been completed, this may not be possible. Failure to meet IPC specification indicates either those procedures were not followed or some Factors were out of control.[6] Standard operating procedures (SOPs) should be defined and followed

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in the pharmaceutical business to describe IPQCs and tests.[7]

FPQCs are tests performed after the manufacturing process is completed to verify qualitative and quantitative attributes, as well as test methodologies and acceptable limitations to which the finished product must adhere throughout its valid shelf life.[8]

In order to define the requirements of the finished product, the quality characteristics related to the manufacturing process should be taken into account. An appropriate specification for each aspect of quality studied during the phase of development and during the validation of the manufacturing process should be determined. At least those aspects considered to be critical should be the object of specifications routinely verified. The specification limits of the finished product at the time of batch release are set by the marketing authorization applicant such that the specifications proposed at the end of shelf-life are guaranteed and are established on the basis of a critical detailed review of the data gathered from the batches analyzed[9].

Pharmacopoeias are called drugs standard.[10] There are various types of pharmacopoeia such as Indian Pharmacopoeia (IP), British Pharmacopoeia (BP), United States Pharmacopoeia(USP), European Pharmacopoeia (PhEur), International Pharmacopoeia (PhInt) and Japanese Pharmacopoeia (JP) in different parts of the world and they have laid down the specified limits within which the value should fall in order to be compliant as per the standards. The objective of this study is to show the quality parameters for pharmaceutical tablets according to pharmacopoeias that are part of in-process and finished product quality control tests.

Universal tests for pharmaceutical tablet :

The tablet dosage form accounts for approximately 50% of all dosage forms on the market.[11]There are four tests that are generally applicable to pharmaceutical tablets and other drug Products.

Description:

This test is often called appearance on a specification and is a qualitative description of the Pharmaceutical tablet. For example, the description of a tablet on a specification may read: White, round, biconvex, film-coated tablet, imprinted with „„Rx"" on one side.[12]

Identification:

The purpose of an identification or identity test is to verify the identity of the active Pharmaceutical ingredient (API) in the pharmaceutical tablet. This test should be able to Discriminate between compounds of closely related structures that are likely to be present.[12]

Assay:

This test determines the strength or content of the API in the pharmaceutical tablet and is Sometimes called a content test.[12]

Impurities:

This test determines the presence of any component that is not the API or an excipient of Pharmaceutical tablet. The most common type of impurities that are measured is related Substances, which are processed impurities from the new drug substance synthesis, Degradation products of the API, or both. [12]

IPQC AND FPQC TEST FOR PHARMACEUTICAL TABLETS:

Physical parameters of pharmaceutical tablets that are controlled by IPQC tests are temperature, pressure, moisture Content, time, weight, particle size, hardness, loss on drying, disintegration time, colour, compactness, integrity etc. FPQC test for pharmaceutical tablets are assay, uniformity of content, uniformity of mass, weight variation, Friability test, content of active ingredients, hardness test, disintegration test, dissolution test etc. IPQC and FPQC Test for pharmaceutical tablets according to pharmacopoeias are listed below:

Size and Shape:

The size and shape of the tablet can be dimensionally described monitored and controlled. It is determined by the Tooling during the compression process [11]

Colour and Odour:

Many pharmaceutical tablets use colour as a vital means of rapid identification and consumer acceptance. But it must Be uniform within a single tablet, from tablet to tablet and from lot to lot. The presence of an odour in a batch of Tablets could indicate a stability problem e.g. the characteristic odour of acetic acid in degrading aspirin tablets or Could be characteristic of the drugs e.g. vitamins have a characteristic odour. Taste is important in consumer Acceptance of chewable tablets [11]

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Thickness:

The thickness of a tablet is the only dimensional variable related to the process. Thickness of individual tablets may Be measured by a micrometer. Other techniques involve placing 5 or 10 tablets in a holding tray, where their total Thickness may be measured by a sliding calliper scale. Tablet thickness should be controlled within a ± 5 % variation Of a standard. Thickness must be controlled to facilitate packaging. It is expressed in mm [11].

Unique Identification Markings:

Pharmaceutical companies often use some type of unique markings on tablets in addition to colour, for rapid Identification of their product these markings utilize some form of embossing, engraving or printing of the company Name or symbol or a product code [11].

Moisture Content of Granules:

Granules should possess sufficient strength to withstand normal handling and mixing processes without breaking Down and producing large amounts of fine powder. On the other hand, some size reduction during compaction into Tablets is desirable to expose the areas of clean surface necessary for optimum bonding to take place so moisture Content is the very important factor for producing good pharmaceutical product [11].

Assay:

In a tablet an active ingredient is present which is called API. So to prepare the tablet assay has to be done by using Suitable analytical method to produce good finished product [13].

Uniformity of Content:

A physically sound tablet may not produce the desired effects. To evaluate a tablet potential for efficacy, the amount Of drug per tablet needs to be monitored from tablet to tablet and batch to batch. For this test according to BP using a Suitable analytical method, determine the individual contents of active substance(s) of 10 tablets taken at random [13].

The tablet complies with the test according to BP, if each individual content is between 85 percent and 115 percent Of the average content. The tablet fails to comply with the test if more than one individual content is outside these Limits or if one individual content is outside the limits of 75 percent to 125 percent of the average content. If one Individual content is outside the limits of 85 percent to 115 percent, but within the limits of 75 percent to 125 Percent, determine the individual contents of another 20 tablets taken at random. The tablet complies with the test if Not more than one of the individual contents of the 30 tablets is outside 85 perce
to 115 percent of the average Content and none is outside the limits of 75 percent to 125 percent of the average content [13].

Uniformity of Mass:

This test is applicable for uncoated and film coated tablets. For this test according to BP weigh individually 20 Tablets taken at random and determine the average mass. As per BP 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 1 And none deviates by more than twice that percentage [13].

Table 1: BP limits foruniformity of mass

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

Weight Variation Test:

According to the USP weight variation test is run by weighting 20 tablets individually calculating the average Weights and comparing the individual tablet weights to the average. The value of weight variation test is expressed In percentage. The following formula is used [15]:

Weight Variation = (Iw – Aw)/Aw □ 100%

where, Iw = Individual weight of tablet; Aw = Average weight of 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 [15].

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

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

Content of Active Ingredients:

For this test according to IP determine the amount of active ingredient(s) by the method described in the assay and Calculate the amount of active ingredient(s) per tablet. The result lies within the range for the content of active Ingredient(s) stated in the monograph. This range is based on the requirement that 20 tablets, or such other number As may be indicated in the monograph, are used in the assay. Where 20 tablets cannot be obtained, a smaller number, Which must not be less than 5, may be used, but to allow for sampling errors the tolerances are widened in Accordance with Table 3 [16].

Table 3. 1P limits for content of active ingredients

As specified by the IP requirements Table 3 apply when the stated limits are between 90 and 110 percent. For limits Other than 90 to 110 percent, proportionately smaller or larger allowances should be made [16].

Hardness Test

For this test one of the earliest testers was Kegan tablet hardness tester, which is a type of the Monsanto hardness Tester to evaluate tablet hardness tester. The tester consists of a barrel containing a compressible spring held between Two plungers. The lower plunger is placed in contact with the tablet and zero reading is taken. The upper plunger is Then forced against a spring by turning a threaded bolt until the tablet fractures. As the spring is compressed, a Pointer rides along a gauge in the barrel to indicate the force. The force of fracture is recorded in kilogram [17].

Friability Test

Friability of a tablet can determine in laboratory by Roche friabilator. For this test twenty tablets are weighed and Placed in the friabilator and then operated at 25 rpm for 4 minutes. The tablets are then dedusted and weighed. The Difference in the two weights is used to calculate friability and the value of friability is expressed in percentage. It is Determined by the following formula [15]:

Friability = (Iw – Fw)/Iw □ 100%

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 [15]

Disintegration Test

The USP disintegration apparatus consist of 6 glass tubes that are 3 inches long, open at the top, and held against a 10-mesh screen at the bottom end of the basket rack assembly. To test for disintegration time, one tablet is placed in Each tube and the basket rack is positioned in specified medium at 37 ± 2 °C such that tablet remains 2.5 cm below The surface of the liquid on their upward movement and descend not closer than 2.5 cm from the bottom of the Beaker. A standard motor driven device is used to move the basket assembly containing the tablets up and down Through distance of 5 to 6 cm at a frequency of 28 to 32 cycles per minute. Perforated plastic discs may also be used In the test. These are placed on the top of tablets and impart an abrasive action to the tablets. The discs may or maynot be meaningful or impart more sensitivity to the test, but they are useful for tablets that float. Operate the Apparatus for the specified time (15 minutes for uncoated tablet unless otherwise justified and authorized) [15].

The tablet complies with the test, if the tablets disintegrate, and all particles pass through the 10-mesh screen in the Time specified. If any residue remains, it must have a soft mass with no palpably firm core. The tablet complies with The test according to USP, if all of the tablets have disintegrated completely. If 1 or 2 tablets fail to disintegrate Completely, repeat the test on 12 additional tablets. The requirement is met if not less than 16 of the total of 18 Tablets tested are disintegrated [15]. The BP and IP limits for disintegration times of tablets are given in Table 4 and Table 5 respectively [13,16].

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Tablet 4: BP limits for disintegration times of tablets

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

Tablet 5: IP limit for disintegration of tablets

Categories of tablet	Disintegration time (min)
Uncoated tablet	15
Coated tablet	60
Enteric-coated tablet	60
Film coated tablet	30
Effervescent tablet	5
Soluble tablet	3
Dispersible tablet	3

Dissolution Test:

The BP or USP dissolution apparatus (Basket apparatus) consist of a cylindrical vessel with a hemispherical bottom, Which may be covered, made of glass or other inert, transparent material; a motor; a metallic drive shaft; and a Cylindrical basket. The vessel is partially immersed in a suitable water bath of any convenient size or heated by a Suitable device such as a heating jacket. The water bath or heating device permits holding the temperature inside the Vessel at 37 ± 0.5 °C during the test and keeping the bath fluid in constant, smooth motion [13,15].

For this test according to BP and PhEur place the stated volume of the dissolution medium (± 1 %) in the vessel of The specified apparatus. Assemble the apparatus, equilibrate the dissolution medium to 37 ± 0.5 °C. Place 1 tablet in The apparatus, taking care to exclude air bubbles from the surface of the tablet. Operate the apparatus at the specified Rate. Within the time interval specified, or at each of the times stated, withdraw a specimen from a zone midway Between the surface of the dissolution medium and the top of the rotating basket or blade, not less than 1 cm from The vessel wall. Where multiple sampling times are specified, replace the aliquots withdrawn for analysis with equal Volumes of fresh dissolution medium at 37 °C or, where it can be shown that replacement of the medium is not Necessary, correct for the volume change in the calculation. Keep the vessel covered for the duration of the test and Verify the temperature of the medium at suitable times. Perform the analysis using a suitable assay method as Directed in the individual monograph. Repeat the test with additional 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 6)[13,14,15,18,19].

Table 6: 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 12units (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%

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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 labelled content; the 5 percent, 15 percent, and 25 percent values in the table are percentages of the labelled content so that these values and Q are in the same Terms [13,14,15,18,19]

II. CONCLUSION:

Pharmacopoeias set up standards for superior quality pharmaceuticals. As listed by the WHO, 140 independent countries are at present employing some 30 national as well as the African, European and International Pharmacopoeias. From the present study it is clearly Demonstrated although various pharmacopoeias suggest various types of IPQC and FPQC Tests for pharmaceutical tablets, but the main purpose of the entire pharmacopoeias in the World is to produce good quality pharmaceuticals for human health.

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