IJNRD.ORG ISSN : 2456-4184
INTERNATIONAL JOURNAL OF NOVEL RESEARCH AND DEVELOPMENT (IJNRD) | IJNRD.ORG
An International Open Access, Peer-reviewed, Refereed Journal

COMPARATIVE STUDY OF IN-PROCESS AND FINISHED PRODUCT QUALITY CONTROL TEST OF IP,BP AND USP FOR TABLET.

1V.K.Suryawanshi, 2K.A Suryawanshi, 3S.R.Nikam, 4D.S.Bacchav 5P.B.Mairal

1Student, 2Student, 3Student, 4Student, 5Assistant Professor

Department Of Pharmaceutical Analysis

Dr.Babasaheb Ambedkar Technological University, Lonere, Raigad, India

Abstract:-

The present study deals with a brief summary of the evaluation of the quality requirements for finished products quality control and in-process products quality control. Tests with certain common dosage forms according to the Indian Pharmacopeia (IP), British Pharmacopeia (BP), & United States Pharmacopeia (USP).Total quality control relates to the ability to produce a quality products through a number of steps, involving an arrangement to minimize errors at every stage of the production process. To maintain that the finished product conforms to the compendial standards stated in the pharmacopoeias, in-process product testing is performed. The pharmaceutical company works to manufacture high-quality goods, which is achieved by permitting methods for completed product and in-process quality control .There is a significant difference because the final sample used for the finished product testing is actually an example of a significant batch. In the exchange for a value to be compliant with the standards, the pharmacopoeias have defined the prescribed range that the value may stand. The quality standards for pharmaceutical products are specified in various regulatory active ingredients toward the country. Except for a few properties, it was observed that the quality control tests are mostly equivalent. To ensure that the intermediates, packaging materials, and finished pharmaceutical tablets conform with approved specifications or standards for efficacy, safety, and elegance that ensure the consumer that the products Perform consistently and in a manner satisfactory, in-process quality control is a concept that is carried out before, after, and during production covering all steps, including the establishment of specifications, sampling, relevant testing, and analytical clearance. Quality control involves checking products for problems that make it easier for the manufacturer to hold back product releases or conduct potential research to produce optimum pharmaceutical tablets. before released into the market As the comparing pharmacopoeias, an attempt is made to convey the harmonized limitations so that the products should conform with the specification as given in the pharmacopoeias to ensure the quality of pharmaceutical dosage form. This study aims to compare various quality control methods evaluations of medication tablets in accordance with various pharmacopoeia standards.

Keywords:-Indian Pharmacopeia, British Pharmacopeia, United, States Pharmacopeia, Tablet Quality control Tests, Quality Control Tests.

Introduction:-

In pharmaceutical industry, Total product quality must be provided in the pharmaceutical industry in order to prevent the production of goods which does not meet the standards given by the Pharmacopoeias and The integration of the products or services to the specified requirements can be defined to as quality. The concentration of quality control is on based techniques for errors and communicating the results to management, that also decide to even further into or discard the release. The product's general quality is maintained by quality control tests conducted on both the work-in-progress and the finished products. Stringent quality control tests are used in the complete transaction process (in process and finished product quality control testing) to ensure products must be completely error-free before being started it on market.to manage the industrial production issues.Since quality is a broad concept, it should be ingrained in the product and without being tested for it [1]. Pharmaceutical production quality is become an important and sensitive topic. Since the world has come together to meld its methods, guidelines, and the introduction of the Food and Drug Administration's (FDA) current good manufacturing practises (cGMP) for the 21st century, there has been an increase in destructive impact of the quality of pharmaceuticals. Only when an units and facilities,& requirements defined quality requirements and guidelines is it considered "suitable use for" [2]. Quality is an intelligent action which assure that drugs and medicines may be suitable for their intended use based on their safety and efficacy, as thought on the label, or as upgraded or revealed by their compliance with requirements regarding identity, strength, purity, and other attributes [3]. The high level of quality and safety of the products are provided by Good Manufacturing Practices (GMP) conditions or measures. GMP unites production and quality control (QC) as one structure [4].The quality of the every area of manufacturing is evaluated by QC personnel as part of GMP in order to prevent errors at each production stage. The aim of quality control are to make a perfect product by reducing or eliminating errors at every stage of production. When producing drugs, quality must be included in.Establishing a process that is completed through proper spacing, ventilation, plant architecture, sanitation, and hygienic during scheduled product construction [5].

.It Is required to carry out the quality control test as given in various pharmacopoeias and guidelines [6] in order to confirm the uniformity of pharmaceutical dosage form quality. Quality control is described as "the operational approaches and actions that are useful to achieve standards for quality" by the International Standard of Organization (ISO). According to this definition, the quality control test could complete any function connected to quality control, management, improvement, or assurance [3].Instead of being part of the formal procedure that involves which are carried out before to release, in-process tests can be carried out while the drug substance or drug product is being manufactured. Before the manufacturing procedure is finished, inspections are made as part of in-process controls (IPC).

In order to ensure that the production control complies with the specifications, in-process controls monitor it and, if necessary, change it. Control over the environment and equipment also may be part of this In process materials should be evaluated during the manufacturing process for their physical characteristics and quality qualities. The quality control department will then approve or reject the materials based on the test results. Rejected To prevent their usage in manufacturing, in-process materials should be identified and regulated by an isolation system. In-process controls maintain a close watch on the production control and adjust it as necessary to make sure it conforms with the specifications. Control over the surrounding and the equipment may also be included. During the production process, in-process materials should be evaluated for their physical traits and chemical traits. Depending on the results of the tests, the quality control unit will next accept the materials. Rejected In-process materials should be recognized and controlled by an isolation design to prevent their use in manufacturing Certain IPQC and FPQC assessments are carried out during or after the manufacturing process, where the acceptance criterion is the same or less significant than the release requirement (for example, size, shape, weight, hardness, thickness, disintegration, dissolution, and other characteristics), which can also include the as a base for quality evaluation when included in the specification [8]. There are numerous pharmacopoeias used in various nations around the world, including the Indian Pharmacopoeia (IP), British Pharmacopoeia

(BP), Japanese Pharmacopoeia, European Pharmacopoeia, United States Pharmacopoeia, (USP) ,and International Pharmacopoeia (JP). Since many pharmacopoeias have produced the various stated limitations to some extent, the value should be within these limits in order to be compliant with the standards. This study was designed to establish the quality requirements for pharmaceutical tablets in reference with the pharmacopoeias, these are a part of the control tests both for in-process and finished products. Quality control and process control are the objectives of process control. The recording of measured values by group members is part of the regular definition of the word "in process control." The term "finished product controls" (FPC) relates to checks made on a finished product following the manufacturing process

regarding qualitative and quantitative characteristics, test procedures, and their approval limits, with which the finished product must comply for the duration of its regulatory shelf life. There is a requirement for the harmonized limit within which a product should be in order to meet the pharmacopoeia specifications of that region because the official pharmacopoeias are varied in various parts of the world. The study's objectives include contrasting and contrasting some common dosage forms as according different pharmacopoeias and conducting quality control tests on the various Pharmacopeias

2. Universal test for the dose form of pharmaceutical tablets:-

least 90% of medications taken orally, including tablet and capsules, are thought to significantly reduce medication errors in dose calculation when taken by the patient personally [12].

The four tests—Description, Identification, Assay, and Impurity—are probably applicable to tablets dosage form and other pharmaceutical products.

2.1. description:-

This is test provides a qualitative description of the tablets appear as they are described in a specification. As an example, the specification describes the tablets as white, round, biconvex, film-coated tablets with "drug strength (Rx)" written on a single side [13].

2.2. Identification:-

The purpose of an identification or identity test is to confirm the identity of the active pharmaceutical ingredient(s) (API) and to identify the compound(s) that are structurally similar to those that are expected to be found in pharmaceutical tablets. However, The British Pharmacopoeia 2014 does not consider identification to be the only form of definitive verification of identity [14].

2.3. Assay:-

This test, also referred to as a content test, determines the quantity or strength of the pharmaceutically active ingredients contained in the tablets. This technique can be used as a stability-indicating test since it is accurate and quantitative in detecting chemical changes over time [13].

2.4. Impurities:-

The most common type of impurities found in pharmaceutical products are related chemicals that result from a chemical change in the medication substance that occurs during production and/or storage [13, 15].

3. Quality control tests for the finished product and tablet dosage form: -

The moisture content of various parameters can be controlled by in-vitro testing for making tablets .Granules, granule size, moisture content, loss during drying, final mix flow, etc. Test for finished product Dimensions (thickness, diameter), assay, consistency of content, weight variation, friability test, and assay for tablets are some of the criteria Active ingredient content, hardness test, disintegration test, Dissolution tests etc. [16]

3.1. Quality control test for tablets: non-compendial standards:-

There are Frequent numbers tests are regularly applied on tablets that are not specified in official pharmacopoeias and instead are dependent on the product specifications set together by the manufacturer.

3.1.1. General appearance:-

The few elements, including the tablet's dimensions (size and shape), colour, odour, taste, texture, and disintegration Test :- Add a disc and a tablets into each test tube. Place the component in the beaker containing the prescribed liquid and run the device for the specified amount of time. Clear the liquid off the assembly. If every tablet has broken down, the test is considered successful.Repeat the test on 12 more tablets if one or two tablets fail to dissolve. At least 16 of the total 18 tablets must dissolve in order for the test to be considered successful. If the tablets stick to the disc and

the preparation being tested is ineffective, repeat the test but take the disc out. If all of the tablets in the repeat test disintegrate, the preparation fulfills the test.readability of any identifying markings, can be evaluated in order to regulate the general appearance of the tablet [12].

3.1.2. The moisture content is granule's:-

Because mostly to the moisture content in a powder of particulate materials, wet granulation binds granules together by the bonding of a specific strength. Therefore, a certain percentage of moisture content influences the powder is compressed, transported, and smaller in size. For instance, during tablet compression, too-dry granules have a tendency to cap or laminate [6].

3.1.3. Size and shape:-

By considering the shape and size of tablets, it is possible to dimensionally portray, monitor, and regulate the attributes of tablets. Manufacturing has a role in the compression process [12].

3.1.4. Thickness:-

Thickness measurements are used to assess uniformity in manufacturing processes such as granulation, particle size, size distribution, powder mixing, etc. [12]. During the compression process, it is determined by the tooling (e.g., die diameter, die internal volume, powder compressibility, force or pressure, etc.). A micrometre or any other accurate item of equipment can be used to determine the thickness of entity tablets [17].

3.1.5. Unique identifying marking:-

Pharmaceutical companies use embossing, engraving, or printing as well as colour to produce unique marks. On tablets, these marks may include the company name or logo, the product code, the medicine strength, the product name, etc. [12].

3.1.6 .Organoleptic characteristics (colour, odour, and taste):-

To allow rapid identifying and consumer acceptability, many pharmaceutical companies colour tablets. The distribution of colours should be homogeneous and mottling . Evaluation of visual colour contrasts the sample's colour with the reference colour. An indicator of stability could be the smell. For instance, the unusual odour of acetic acid signals the breakdown of aspirin tablets. Another factor that influences patient compliance is taste. For instance, a chewable tablet with a suitable taste increases patient compliance [12].The tablets are typically held between two platens, one of which is fixed and the other of which moves with sufficient force to break a tablet. Round and conventional tablets are packed (as a diametrical loading) across their diameter, where breakage occurs in plane [18]. Hardness is often measured by crushing strength, which must be more than 4 kg (or other arbitrary units) [17]

3.2. Pharmacopoeial standards quality control test for tablet dosage form: -

3.2.1. Friability :-

The strength and durability of a compressed and uncoated tablet can be measured using a friabilator [17], mostly the Roche friabilator [12]. For this test, tablets with an average weight between 650 mg and greater than 650 mg, a sample of 10 whole tablets, and an entire sample weighing approximately 6.5

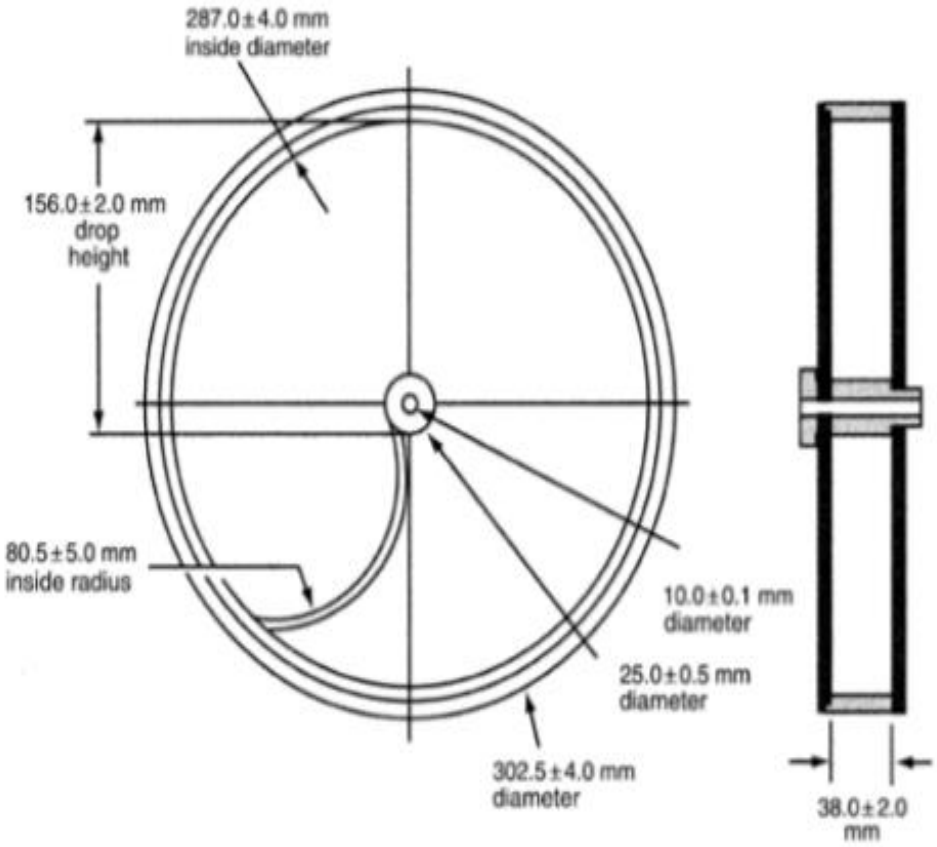
are weighed, dedusted, and placed in a friabilator drum, which is rotated 100 times.the percentage form of the friability rating is calculated using by the subsequent Formula

$$\text{Friability} = \frac{(\text{Wi} - \text{Wf})}{\text{Wi}} \times 100$$

Where;

Wi = Total initial mass of tablets.

Wf = Total Tablets final mass.



Tablet Friability Apparatus

The test is usually only performed once, but can be obtained once the result covers interpretation, or the final reduction is greater than the desired amount. The result is then stated as the mean of the three tests. In addition to tablets that are cracked, chipped, or broken, the test is invalid if there is a weight loss of more than 1% in dry (after 100 revolutions) tablets [14, 18, 19].

3.2.2. Disintegration test :-

Add a disc and a tablets into each test tube. Place the component in the beaker containing the prescribed liquid and run the device for the specified amount of time. Clear the liquid off the assembly. If every tablet has broken down, the test is considered successful.Repeat the test on 12 more tablets if one or two tablets fail to dissolve. At least 16 of the total 18 tablets must dissolve in order for the test to be considered successful.

If the tablets stick to the disc and the preparation being tested is ineffective, repeat the test but take the disc out. If all of the tablets in the repeat test disintegrate, the preparation fulfills the test.

3.2.3. Uniformity of dosage units:-

Any of the two methods—Content Uniformity or Weight Variation—can be used to present the uniformity of dosage units.

- **Weight variation test:-**

This test involves weighing 20 tablets individually and calculating the average mass for both coated and uncoated tablets. The weight of no more than two tablets may depart from the average weight by more than the percentages stated in tables 3 and 4, and no tablet's weight may vary by more than twice that percentage [14, 18, 19].

This test's result is calculated using the following formula and expressed as a percentage:

$$\text{Weight Variation} = \frac{(\text{WI} - \text{WA})}{\text{WA}} \times 100$$

Where;

WI = Individual tablet's weight

WA = Average tablet's weight

- **Uniformity of content:-**

If the preparation scores between 85 and 115 percent on each topic, it is acceptable. If more than one individual content exceeds these bounds or if one individual content exceeds the bounds of 75 to 125 percent of the average content, the preparation is not test-compliant.

Repeat the calculation using an additional 20 tablets if one content is outside the range of 75 to 125 percent but within the range of 85 to 115 percent of the average content.

When not enough than one of the individual contents of the 30-tablet sample is outside the range of 85 to 115 percent of the average content and no contents are outside the range of 75 to 125 percent of the average content, the preparation complies with the test.

3.2.4. Content of active ingredients:-

Calculate the amount of the active ingredient in each tablet using the assay's specified method to determine the amount of the active ingredient. The outcome is in line with the active component content reported in the monograph. This range is predicated on the need that 20 tablets be utilized in the assay, or any other number that may be specified in the monograph.A reduced number of tablets—not to be below than 5 be used in the absence of 20 if 20 can't be procured, however the tolerances are broadened in accordance with When the specified limitations are between 90 and 110 percent, the criteria of the apply. Limits outside of the 90–110 percent range should have proportionately smaller or bigger allowance.

3.2.5. Assay:-

An active ingredient, also known as API, can be present in tablets. Using an appropriate analytical approach, this test establishes the strength or content of the API expected to be present in the pharmaceutical tablet based on the strength specified on the label [19, 20]. Assay value is frequently determined by taking the average of each individual's content uniformity into account [18]. Content uniformity is determined using the same analytical process as that described in the assay test.

3.2.6. Dissolution:-

The BP, IP, or USP dissolution apparatus I (Basket apparatus) and apparatus II (Paddle apparatus) each have a 1L capacity and are composed of clear glass or an inert material. The bottom of the tank is hemispherical and may be covered. Only the stirring element, where apparatus I uses a basket and apparatus II a paddle, is different in the assembly of the two equipment are used in device II.

In IP, however, this construction is done in reverse, with apparatus I and II using a paddle and a basket, respectively. Throughout the test, the partially submerged vessel in a water bath is maintained at a temperature of 37 0.5 °C [14, 18, 20].

The test for dissolution, a predetermined volume of the dissolution medium (less than one percent) is added to the vessel of the specific equipment, which maintains a constant temperature of 370.5°C for the duration of the test. One tablet is inserted in the device, and the test is run for the allotted time interval with a sample being taken at least one centimetre (cm) from the vessel's wall, midway between the surface of the dissolution medium and the top of a revolving basket or paddle. Aliquots that are withdrawn after the designated number of sampling times are replaced with new dissolving media. Performed the analysis using an appropriate dissolve medium and assay technique as specified in the specific monograph, and the test is repeat with supplementary tablets.

Calculate the percentage of the indicated amount of the active component that has been dissolved in solution for each of the tested tablets. When two or more tablets are combined, calculate the amount of active component in solution present in each tablet for each test as a percentage of the specific quantity

Classification of dissolution apparatus in different pharmacopeias:

	I.P.	USP	B.P.	E.P.
Type 1	Paddle apparatus	Basket apparatus	Basket apparatus	Paddle apparatus
Type 2	Basket apparatus	Paddle apparatus	Paddle apparatus	Basket apparatus
Type 3		Reciprocating cylinder	Flow through cell apparatus	Flow through cell apparatus
Type 4		Flow through cell apparatus		
Type 5		Paddle over disk		
Type 6		cylinder		
Type 7		Reciprocating holder		

5

4. Conclusion:-

Based on the review above, it can be said that some conventional dosage forms were included by most of the in-process and finished product QC testing by IP, BP, and USP. Similarly, there was a difference. For products which are marketed globally, it is important to note that some tests are only available in certain pharmacopoeia. As a result, a significant amount of time, money, and manpower can be saved. The previous review article evaluates a number of final products quality control tests based on various compendial and non-compendial standards for quality assessment before to their release onto the market, in addition to various in-process quality control tests.

In-process quality testing is required to assess commodities issues or to provide early warnings for quality and evaluate procedures for a product in order to ensure the consistent production of medications with higher efficacy and safety from batch to batch. By using in-process quality tests, we may also reduce the amount of time, money, resources, and sequence of processes while still ensuring the product's quality.

Manufacturing high-quality pharmaceuticals for human use is the primary goal of all pharmacopoeias.With a few variation is quality control tests carried out in compliance with Indian pharmacopoeia and British Pharmacopoeia, including the American, European, Japanese, and European pharmacopoeias.

Acknowledgments:-

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