Research Article

In-Process and Finished Products Quality Control Tests for Sterile and Non Sterile Dosage Form

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ABSTRACT

In a pharmaceutical organization a quality control is a fundamental segment that refers to a process of striving to produce a product by a series of in process quality control test in order to eliminate or prevent error at any stage of production. Present study encophosis with a brief overview of comparative study of quality requirements for in process and finished product quality control test of sterile and non-sterile dosage form. Injectable occupy a considerable prominence in world market irrespective of diminishing growth in the pharmaceutical market for 2-3 years. The advancements in technology up-gradation and investments have provided immense growth opportunities for Injectable to emerge in the world's pharmaceutical industry in recent years. According to research report, "UK Injectable Market Outlook to 2017", the market is anticipated to grow at a rate of approximately 4.0% during 2011-2017. The increasing need of injectable for diseases like diabetes, infectious diseases and arthritis is primarily driving the market. A lot of investment is being done in research and development of Injectable in order to improve their medical outcomes. Different regulatory requirements of the respective countries demand products with different specific limits so this comparative study will help in meeting all the requirements of all the pharmacopoeias and later the regulatory requirements of that particular country. Present review highlights the basic types of injectable preparations and their quality control tests with their standards.

Keywords: Quality control, Injectable, Adsorption, Implants

INTRODUCTION

Quality is suitability of drugs for their intended use determined by their efficiency weighed against safety, according to label claim, or as promoted or publicized their conformity to specifications regarding identity, purity and other characteristics.

The International Standard of Organization (ISO) definition states that quality control is "the operational techniques and activities that are used to fulfill requirements for quality".

This definition could imply that any activity whether serving the improvement, control, management or assurance of quality could be a quality control activity.[1,2]

Injectable Preparations are also called as parenteral preparations. Injectable preparations are sterile preparations and are administered by injection, infusion or implantation.

An injection is an infusion method of putting fluid into the body, usually with a syringe and a hollow needle which is pierced through the skin to a sufficient depth for the material to be administered into the body.[3,4]

Steps involved in In Process Quality Control (IPQC).[5]

- Identify types of formulations manufacturing or going to manufacture, e.g. Tablet, Liquids, Parenteral, and Ointments etc.
- Identify which are the critical steps in the manufacturing of the product, where it will be necessary to check certain parameters to confirm that the process is in control.
- Identify the specifications of the parameters which will confirm the parameters are within control.
- Define the frequency of checking of parameter.
- Create monitoring and control records for all I.P.Q.C. process.
- Keep a provision for modification of process if required.
- The entire process is described and explained to the I.P.Q.C. workers and supervisors before implementing. Records of such IPQC training may be kept.

Sterile Products

Sterile products are the dosage forms of therapeutic agents that are free of viable microorganisms. Principally these include parenteral, ophthalmic and irrigational preparations.

Of these, parenteral products are unique dosage forms of drugs as they are injected through the skin or mucous membranes into the internal body compartments. As they have circumvented the highly efficient first line of body defense i.e., the skin mucous membranes, they must be free from microbial contamination and from toxic compartments as well as possess an exceptionally high level of purity.

All components and processes involved in the preparation of these products must be selected and designed to eliminate, as much as possible, contamination of all

types, whether physical, chemical or microbiological origin.[7]

The In-Process Quality Control system lays emphasis on the responsibility of manufacturer's processors in ensuring consistency in quality during all stages of production by adopting quality control drills and exercising control on raw materials and bought-out components, manufacturing process, packing and final testing. Finished product is product which has undergone all stages of production including packaging.

Quality control test is done for finished product to check the integrity of these products. Different pharmacopoeia gives specific limits according to the regulatory requirements of that particular region.[8]

Characterization of Injectables

Injectables are characterized for the following tests:

- Solubility & Excipient Compatibility
- Physiochemical Characterization of API
- Hygroscopicity Evaluation
- Plasma Compatibility Studies
- Aggregation Analysis by SEC (Peptides)
- Thermal Characterization
- Filter Compatibility Assessment
- Adsorption[9]

Types and Standard Tests of Injectables

1. Injection
2. Powder for injection or Infusion.
3. Intravenous Infusion
4. Extractable volume
5. Concentrated solutions for injections.
6. Implants[10]

Injections

Injections are sterile solutions, emulsions or suspensions prepared by dissolving emulsifying or suspending the active ingredients and other additives in water for injection or other suitable non aqueous vehicle or in mixture of two, if they are miscible.

Powder for injection or Infusion

Powder for injections are sterile solid substances (including freeze dried material) which are distributed in their final containers which, when shaken with the prescribed volume of the appropriate sterile liquid, rapidly form clear and practically particle-free solutions or uniform suspension.

Powders for injection (PIs) are a popular parenteral dosage form for drugs that cannot be marketed as ready-to-use injectables because of their instability in an aqueous environment. PIs are relatively simple with respect to formulation and process development. However, their performance and stability.

Intravenous Infusion

These are sterile aqueous solutions or emulsions with water as continuous phase. When a drug is infused intravenously at a constant rate, a plateau concentration will be reached progressively in the most frequently most of the cases follows first order kinetics. On starting the infusion, there is no drug in the body and therefore, no elimination.

The amount of drug in the body then rises, but as the drug concentration increases, so does the rate of elimination. Thus, the rate of elimination will keep rising until it matches the rate of infusion. The amount of drug in the body is then constant and is said to have reached a steady state or plateau.

Extractable Volume

Suspensions should be shaken before the contents are withdrawn. Oily injections may be warmed but should be cooled to 250 C before carrying out the test.

Containers is of two type single dose and multi dose containers which can be used for the according to BP, USP, EP and JP given in Table 1.

Table 1: No of containers to be used for the test as per to BP, USP, EP and JP

Volume of the Solution	No of Containers to be Used for the Test
≥ 10 ml	1
3-10 ml	3
< 3 ml	5

Concentrated Solutions for Injections

Concentrated solutions for injections are sterile solutions that are intended for administration by injection or by IV infusion only after dilution with suitable dilution with a suitable liquid. After dilutions these preparations should comply with the requirements of tests for injection or intravenous infusions as appropriate.

Implants

Implants are sterile solid preparations of size and shape for implantation into body tissues so as to release active ingredient over an extended period of time. An implant is a medical device manufactured to replace a missing biological structure, support a damaged biological structure, or enhance an existing biological structure. Medical implants are man-made devices, in contrast to a transplant, which is a transplanted biomedical tissue. The surface of implants that contact the body might be made of a biomedical material such as titanium, silicone or apatite depending on what is the most functional. In some cases implants contain electronics e.g. artificial pacemaker and cochlear implants. Some implants are

bioactive, such as subcutaneous drug delivery devices in the form of implantable pills or drug-eluting stents.[11]

MATERIALS AND METHODS

IPQC for Sterile Dosage Form

Sterile Dosage Form: These are the products which are manufactured using sterilization or aseptic processing conditions.

There are two types of sterile dosage forms

1. Parenteral preparation

2. Opthalmic formulations

The in-process quality control test includes the leakage and clarity testing. The quality control of finished product required the pyrogen and sterility testing.[12]

Leakage Test

Leakage test is employed to test the package integrity. Package integrity reflects its ability to keep the product in and to keep potential contamination out". It is because leakage occurs when a discontinuity exists in the wall of a package that can allow the passage of gas under pressure or concentration differential existing across the wall. Leakage test can be done by dye bath test.

Dye Bath Test

The test container is immersed in a dye bath. Vacuum and pressure is applied for some time. The container is removed from the dye bath and washed. The container is then inspected for the presence of dye either visually or by means of UV spectroscopy. The dye used may be of blue, green, yellowish-green color. The dye test can be optimized by use of a surfactant and or a low viscosity fluid in the dye solution to increase the capillary migration through the pores. The dye test is widely accepted in industry and is approved in drug use. The test is inexpensive and is requires no special equipment required for visual dye detection. However, the test is qualitative, destructive and slow. The test is used for ampoules and vials.

Clarity Test

Clarity testing is carried out to check the particulate matter in the sample. In this test transparent particles or white particles observed against the black background and the black or dark particles observed against the white background.

Pyrogen Test

Limulus Amebocyte Lysate (LAL) Test

The LAL Assay is an *in vitro* assay used to detect the presence and concentration of bacterial endotoxins in drugs and biological products. Endotoxins, which are a type of pyrogen, are lipopolysaccharides present in the cell walls of gram-negative bacteria. Pyrogens as a class are fever-inducing substances that can be harmful or even fatal if administered to humans above certain concentrations. This test is based upon the gelling property of an enzyme, the limulus amebocyte lysate extracted from the horse shoe crab, limulus polyphormus. The enzyme gels in the presence of bacterial endotoxin and the degree of gelling is related to the amount of endotoxin present. A no. of instrument is available for measuring the degree of gelling of enzyme. The test can be used for quantifying the amount bacterial endotoxin present and provide a better information regarding the quality of a product than rabbit pyrogen test which is more of a qualitative test.

Sterility Test

The tests for sterility are intended for detecting the presence of viable microorganism in pharmaceutical preparation that is designed to be sterile. The test is based on the principle that if micro-organism are placed in a medium that provide optimum condition of nutrition, moisture, PH, aeration, temperature, they can grow and their presence will be indicated by the presence of turbidity in clear medium. Test for sterility may be carried out by one of the following two methods.

Membrane Filtration Method

Use membrane filters having a nominal pore size not greater than 0.4µm whose effectiveness to retain microorganisms has been established. Cellulose nitrate filters, for example, are used for aqueous, oily, and weakly alcoholic solutions; and cellulose acetate filters, for example, are used for strongly alcoholic solutions. Specially adapted filters may be needed for certain products (e.g., for antibiotics). The technique described below assumes that membranes about 50 mm in diameter will be used. If filters of a different diameter are used, the volumes of the dilutions and the washings should be adjusted accordingly. The filtration apparatus and membrane are sterilized by appropriate means. The apparatus is designed so that the solution to be examined can be introduced and filtered under aseptic conditions: it permits the aseptic removal of the membrane for transfer to the medium, or it is suitable for carrying out the incubation after adding the medium to the apparatus itself. After filtration the preparation membrane is cut into two halves. One halve is transferred in to 100ml of culture medium meant for the growth of the bacteria and incubated at 30 to 35°C for not less than 7 days. The another halve is transferred to 100 ml of culture medium meant for fungi and incubated at 20 - 25 ^{o}C for not less than 7 days.

Direct Inoculation Method

Although international pharmacopoeias recommend using standard membrane filtration for sterility testing, there are certain products that are not filterable or deformable. These products are normally tested using direct inoculation. In this method, the test sample is added directly into the required media, ensuring that the amount of sample is below 10%. To comply with your different direct inoculation method requirements, we

offer sterility test media in various volumes, from 9mL tubes up to 75 mL bottles. In this method an aliquot quantity of the material being tested is drawn aseptically from the container and transferred to a vessel containing a measured quantity of a suitable culture medium. The culture is incubated at appropriate temperature for not less than 14 days. The culture medium is observed at periodic intervals during the incubation period and at the end to detect presence of any microbial growth.

Content Uniformity & Weight

Determine the content of the active ingredient of each of 10 containers taken at random. The preparation under examination complies with the test if the individual values thus obtained are all between 85 and 115 percent of the average value. The preparation under the examination fails to comply with the test if more than one individual value is outside the limits 85 to 115 percent of the average value or if any one individual value is outside the limits 75 to 125 percent of the average value. If one individual value is outside the limits 85 to 115 percent but within the limits 75 to 125 percent of the average value, repeat the determination using another 20 containers taken at random. The preparation under examination complies with the test if in the total sample of 30 containers not more than one individual value is outside the limits 85 to 115 percent and none is outside the limits 75 to 125 percent of the average value. Limits for uniformity of weight is given in Table 2.

Table 2: Limits for Uniformity of Weight

Pharmaceutical Formulation	Average Mass	Percentage Deviation (%)
Powders for parenteral use	More than 40 mg	10
Powders for eye drops	Less than 300 mg	10
Powders for eye lotions	300 mg or more	7.5

Extractable Volume

a) Single Dose Containers

Method I: Where the nominal volume does not exceed 5ml.

Use 6 containers, 5 for the tests and 1 for rinsing the syringe used. Using a syringe with appropriate capacity, rinse the syringe and withdraw as much as possible the contents of one of the containers reserved for the test and transfer, without emptying the needle, to a dry graduated cylinder of such capacity that the total combined volume to be measured occupies not less than 40% of the nominal volume of the cylinder.

Repeat the procedure until the contents of the 5 containers have been transferred and measure the volume.

The average content of the 5 containers is not less than the nominal volume and not more than 115% of the nominal volume. Alternatively the volume of contents in milliliter can be calculated as mass in grams divided by the density.

Method II: Where the nominal volume is more than 5ml.

Transfer the contents of not less than 3 containers separately to dry graduated cylinders such that the volume to be measured occupies not less than 40% of the nominal volume of the cylinder and measure the volume transferred. The contents of each container are not less than the nominal volume and not more than 110% of the nominal volume.

8. Particulate matter in injections

The preparations intended for parenteral use should be free from particulate matter and should be clear when inspected visually.

Two methods are described by USP according to the filled volume of the product to be tested. For large volume parenteral (LVP's), a filtration followed by microscopical examination procedure is used. For small volume parenterals (SVP's) a light obscuration based sensor containing electronic liquid-borne particle counter system is used. The USP standards are met if the LVP's under test contain NMT 50 particles per ml of 10µ m, and NMT 5 particles per ml of 25µm in an effective linear dimensional fashion. The USP standards are met if the SVP's under test contain NMT 10,000 particles per container of 10 µm, and NMT 1000 particles per container of 25µm in an effective spherical diameter.

Non-Sterile Product

1. Granules (starting materials)

2. Tablets (finished products)

3. Capsules

4. Liquid dosage form[13]

Granules

a) Appearance: The general appearance of a granule, its identity and general elegance is essential for components in manufacturing, for control of lot-to-lot uniformity and tablet-to-tablet uniformity. The control of general appearance involves the measurement of size, shape, color, presence or absorbance

b) Size and Shape:

(1) Sieving: Particle having the size range between 50 and 150 m are estimated by this method. In this method the size is expressed as d sieve which describes the diameter of a sphere that passes through the sieve aperture as the asymmetric article .The method directly gives the weight determination.

Method:

Standard sieves of different mesh numbers are available commercially as per the specification of IP and USP. The

sieves are arranged in nest with the coarsest at the top A sample 50 gm of the powder is placed on the sieve this sieve set is fixed to the mechanical shaker apparatus and shaken for the certain period of time (20) min.

The powder retained on each sieve is weighed it is expressed in terms of arithmetic or geometric mean of the two sieves.

(2) Sedimentation: Sedimentation method may be used over a size range of 1 to200 m in this method size is expressed as stokes diameter which describes the diameter of an equivalent sphere having the same rate of sedimentation as that of the symmetric particles Sedimentation of particles may be evaluated by different methods like E.g.: Andersen pipette method.

Andersen Pipette Method

Principle

The rate setting of particles in a suspension of emulsion may be obtained by stokes. However this equation can be extended to irregularly shaped particles of various sizes when the power is suspended in a vehicle initially the particles of large diameter settled due to heavy weigh after sometime particles of intermediate diameter finally the particles of smaller size settled. Hence the study involves the sampling during sedimentation at different time intervals.

Procedure

- Prepare 1-2 %suspension of powder in a suitable medium.
- A deflocculating agent can be added for uniform dispersion of the suspension.
- Transfer the suspension into the Anderson vessel.
- Place the stopper and a shake the vessel to distribute the suspension uniformly.
- Remove the stopper end the two way pipette and securely suspend the vessel in a constant temperature in a water bath.
- At different time intervals 10 ml samples are withdrawn using two way stop cork and collected in watch glass. Samples were evaporated and weighed.
- The weight of the amount of particles obtained in each time intervals is referred to as weight under size. The weighs are converted into cumulative weight under size.
- Particles diameter was calculated from stokes law with in (h) in equation being the height liquid above the lower end of the pipette at the time with drawing sample.

3) **Optical microscope:** Most direct method here the particles size and size distribution is determined by preparing a suspension and absorbing under, microscope.

c) Surface area: Surface area of the drug can have a significant effect upon the dissolution rate it is determined by Gas adsorption, Air permeability.

d) Bulk Density and Tapped Density:

Bulk Density: The bulk density of a powder is the ratio of the mass of an untapped powder sample and its volume including the contribution of inter particulate void volume.

$$\text{Bulk density} = \frac{\text{Mass of powder (W)}}{\text{bulk volume (Vb)}}$$

It is determined by 3 methods

Measurement in a Graduated Cylinder,

Measurement in a Graduated Cylinder

Measurement in a Vessel

Tap Density: The tapped density is an increased bulk density attained after mechanically tapping a container containing the powder sample.

$$\text{Tap density} = \frac{\text{Mass of powder (W)}}{\text{Tapped volume (Vt)}}$$

e) Angle of Repose (θ): The flow characteristics are determined by angle of repose, it is defined as maximum angle possible between the surface of a pile of the powder and horizontal planes,

$\theta = \text{Tan}^{-1}(h/r)$

h = height of pile

r = Radius of the base of pile

The lower the angle of repose the better the flow property Rough and irregular surface of the particles gives higher angle of repose. Limits for angle of repose is given in Table 3.

Table 3: Shows Angle of Repose

Angle of repose	Powder flow
< 25	Flow
25-30	Good
30-40	Passable
> 40	Very poor

f) Moisture Content: When there is high moisture content, then there will be greater risk of cohesion and adhesion. Moisture content is commonly determined by:

Loss on Drying

Mix and accurately weigh the substance to be

- If the test specimen is in the form or large crystals reduce the particles size to about 2mm by quickly crushing
- Weight and empty dried glass stopper shallow weighing bottle

- Put the test specimen in the bottle replace the cover and accurately weigh the bole and the contents
- By gentle sideways shaking distributed the test specimen as evenly as practicable deep of about 5mm generally more than 10 mm in case of bulky materials (w_1)
- Place the loaded bottle in the drying chamber removing the stopper end leaving it also in the chamber
- Dry the tests specimen at the temperature and for the time specified in monogram
- Upon opening the chamber close the bottle promptly and allow it to come to room temperature in desiccators' before weighing (w_2)
- The substance melts at a lower temperature then the specified for the determination of loss on drying maintain the bottle with it content for 1-2 hrs at a temperature at 5-10 degrees below the melting temperature than dry at the specified temperature
- When the specimen under test is capsules use a portion of mixed contents of fewer than 4 capsules If it is tablets use powder from not fewer than 4 tablets grind to a fine powder Where drying in a desiccators' is specified exercise particular care to ensure that the desiccant is kept fully effective by frequent replacement
- Other method employed for moisture content measurement is Karl fisher method

Compressibility index and type of flow of the formulated granules is given in Table 4.

Table 4: Shows compressibility index and Type of flow

Compressibility Index	Type of Flow
5-15	Excellent
12-16	Good
18-21	Fair
23-25	Poor
33-38	Very poor
>40	Extremely poor

g) Compressibility Index

It demonstrates the relation between the flow and compressibility of powder

$$\%\text{compressibility} = \frac{\text{Mass of powd (tapped density} - \text{poured density)}}{\text{tapped density}}$$

h) Hausner Ratio

Hausner predict the flow property of powder by using inter particle friction

$$\text{Hausner ratio} = \frac{\text{tapped density}}{\text{powder density}}$$

Tablets

a) Physical Appearance

The general appearance of a tablet, its identity and general elegance is essential for consumer acceptance, for control of lot-to-lot uniformity and tablet-to-tablet uniformity. The control of general appearance involves the measurement of size, shape, colour, presence or absence of odour, taste etc.

b) Weight Variation Test

Weigh individually 20 units selected at random and calculate the average weight. Not more than two of the individual weights deviate from the average weight by more than the percentage shown in the table and none deviates by more than twice that percentage.

c) Uniformity of Content

The test for uniformity of content of single-dose preparations is based on the assay of the individual contents of active substance(s) of a number of single-dose units to determine whether the individual contents are within limits set with reference to the average content of the sample[14].

Method

Determine the content of active ingredient(s) in each of 10 dosage units taken at random using the method given in the monograph or by any other suitable analytical method.

Acceptance limits for tablets, suspensions for injection and ophthalmic inserts:

The preparation complies with the test if each individual content is 85-115 % of avg content. The preparation 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 75-125 % of the average content. If one individual content is outside the limits of 85 to 115% of the average content but within the limits of 75 to 125%, repeat the determination using another 20 dosage units. The preparation complies with the test if not more than one of the individual contents of the total sample of 30 dosage units is outside 85 to 115 per cent of the average content and none is outside the limits of 75 to 125% of the average content.

d) Disintegration Test: Disintegration test is a measure of time required under a given set of conditions for a group of tablets to disintegrate into particles.

Apparatus

The apparatus consists of a basket-rack assembly, a 1-litre beaker, a thermostatic arrangement for heating the fluid and a mechanical device for raising and lowering the basket in the immersion fluid at a constant frequency rate. The basket rack assembly holds 6 plastic tubes, open at top and the bottom of tubes is covered with 10- mesh stainless steel wire screen. The basket rack is immersed in

a bath of suitable liquid, held at 37±2 °C. For compressed, uncoated tablets, testing fluid is usually water but sometimes monographs refer to use simulated gastric fluid. Tablets are placed in each of 6 cylinders along with plastic disc over the tablet if mentioned in monograph.

Through the use of a mechanical device, the rack moves up and down in the fluid at a specified rate, the volume of liquid is such that the wire mesh at its highest point is at least 25 mm below the surface of the liquid, and at its lower point is at least 25 mm above the bottom.

End point of the test is indicated when the tablets are completely disintegrated and any residue remaining is a soft mass with no palpably firm core. The preparation complies with the test if the time to reach this end point is below a given limit.

Limit

If 1 or 2 tablets fail to disintegrated, test is repeated using 12 tablets. of the 18 tablets tested, 16 must have disintegrated within given period of time.

e) Hardness Test

Hardness of the tablet also termed as its crushing strength. The hardness of the tablet may be defined as the compression force required breaking the tablet when such force is applied diametrically. The tablet is required to posse's sufficient hardness to resist breakage during the transport, storage or use. The hardness of a tablet is related to its disintegration and has more vital role to play in controlling the rate of drug release from the tablet.

(i) By Manual Testing: Manual testing method was employed previously. In this, method, the thumb acts as a fulcrum, while the tablet is held between the second and third hand fingers. When the pressure is applied the tablet which breaks with a sharp snap deemed to posses' sufficient hardness.

(ii) Monsanto Hardness tester method: The instrument measures the force required to break the tablet when the force generated by a coil spring is applied diametrically to the tablet.

(Iii) Pfizer Hardness Tester: Force required to break tablets recorded on dial and may be expressed in key pounds

Other devices:

- Strong-Cobb Hardness Tester
- Erweka Hardness Tester.
- Schleuniger or Heberlein Hardness Tester.

Acceptance criteria: A force of 4 kg/inch^2 is considered to be the minimum requirement for a satisfactory tablet.

f) Friability Test

The friability of a tablet may be defined as its resistance to shock and abrasion encountered during the process of manufacture, packing, transport and ultimately its usage. Friability in addition to hardness gives measure of tablets strength. It is determined through the use of a friabilator.

Method

A no. of tablets are weighed and placed in tumbling apparatus where they are exposed to rolling and repeated shocks resulting from free fall within the apparatus. After given no. of rotations, the tablets are weighed. Resistance to loss in weight indicates ability of tablet to withstand this type of wear. For tablets with an average weight of 0.65g or less take a sample of whole tablets corresponding to about 6.5g and for tablets with an average weight of more than 0.65 g take a sample of 10 whole tablets. De dusts the tablets carefully and weighs accurately the required number of tablets. Place the tablets in the drum and rotate it 100times.Remove the tablets, remove any loose dust from them and weigh them accurately.

Criteria

A maximum loss of weight (from a single test or from the mean of the three tests) not greater than 1.0% is acceptable for most tablets. If obviously cracked, chipped or broken tablets are present in the sample after tumbling, the sample fails the test. This test is applicable to compressed tablets and is intended to determine the physical strength of tablets.

Capsules

Capsules are solid dosage forms in which medicinal agents are enclosed in small shell of Gelatin. Capsule shells may be hard or soft, depending on their composition.[15]

Physical Appearance

The general of a capsule, its identity and general elegance is essential for consumer acceptance, for control of lot-to-lot uniformity and capsule uniformity. The control of general appearance involves the measurement of size, shape, color, presence or absence of odour, taste etc.

Weight Variation Test

Weigh an intact capsule. Open it without losing any part of the shell and remove the contents as completely as possible.

For soft gelatin capsules, wash the shell with a suitable solvent and keep aside until the odor of the solvent is not perceptible. Weigh the shell. The difference between the weighing gives the weight of the contents. Repeat the procedure with another 19 capsules.

Uniformity of Content

The preparation complies with the test if not more than one individual content is outside the limits of 85-115% of the average content and none is outside the limits of 75-125% of the average content. The preparation fails to comply with the test if more than three individual contents are outside the limits of 85-115% of the average

content or if one or more individual contents are outside the limits of 75-125 % of the avg. content.

If two or three individual contents are outside the limits of 85-115% of the average content but within the limits of 75-125%, repeat the determination using another 20 dosage units.

The preparation complies with the test if not more than 3individual contents of the total sample of 30 dosage units are outside the limits of 85-115% of the average content and none is outside the limits of 75-125 %of the average content.

Closing Length

The Acceptance criteria 0.2mm

Moisture Permeation Test

To assure the suitability of containers for packaging capsules, USP has started some rules and regulations. According those rules and regulations, the moisture permeating feature of capsules packaged in single unit containers is to be determined.

Procedure

For performing this test, one capsule is packaged along with the dehydrated pellets, which have the property of changing colour in the presence moisture.

The packaged capsule is then placed for a certain period of time in an atmosphere of known humidity.

Any change in the colour of dehydrated pellets reveals the absorption of moisture.

The weight of this capsule is then compared with the weights of the capsules under test.

The differences in the weights give the amount of moisture absorbed.

Liquid Dosage Forms

It is prepared by dissolving active ingredients or by suspending the drug (if drug is insoluble) or by incorporating the drug into one of the two phases of oil and water systems. Liquid dosage form comprises of solution, suspension and emulsion and a variety of preparation can be considered under each category.

These dosage form are categorized by their homogene, promote action and easy of Administration.

Liquid dosage forms are suitable for both internal and external use.

This is a general term used to describe a solution, suspension or emulsion in which the active ingredient is dissolved or dispersed in a suitable liquid vehicle.[16]

Liquid dosage forms are 2 types:

(i) Monophasic: a) Syrups, b) Elixirs, c) Tinctures etc.

(ii) Biphasic: a) Suspensions, b) Emulsions.

CONCLUSION

The objective of the current work was to compare in-process and finished products quality control tests for sterile and non-sterile dosage form.

By this we can minimize material, time, cost, processes repetition.

We can also get total details and properties of different dosage forms. We can develop the quality of products and minimize the repetitive usage of instruments, so we must conduct this IPQC test.

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