ejpmr, 2022, 9(8), 266-273

SJIF Impact Factor 6.222

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Review Article

ISSN 2394-3211

EJPMR

A REVIEW ON: QUALITY CONTROL TEST FOR SOFT GELATIN CAPSULE

Arya Mudgal[1], Payal Rani Chaudhary[*1], Shivani Rawal[1], Manisha Sharma[1] and Shaifi Tangri[2]

[1]Student Pharmd 5th Year, School of Pharmaceutical Sciences, Shri Guru Ram Rai University, Dehradun.
[2]Assistant Professor, School of Pharmaceutical Sciences, Shri Guru Ram Rai University, Dehradun.

***Corresponding Author: Payal Rani Chaudhary**

Student Pharmd 5th Year, School of Pharmaceutical Sciences, Shri Guru Ram Rai University, Dehradun.

Article Received on 14/06/2022 **Article Revised on 04/07/2022** **Article Accepted on 25/07/2022**

ABSTRACT

To provide the highest degree of patient satisfaction, pharmaceutical product quality is crucial. Safety, potency, efficacy, stability, patient acceptability, and regulatory compliance are the most crucial factors in determining a drug's dosage form quality. The quality, bioavailability, and optimum therapeutic action of pharmaceutical goods can be guaranteed by a variety of quality control measures. Because it is directly tied to the healthcare system, maintaining quality with ongoing facility improvements is crucial for the pharmaceutical businesses. A pharmaceutical capsule's quality must be planned from the beginning of the product development process. To eliminate error from every stage of production and maintain the final product's quality in accordance with the prescribed compendial standards, in-process quality control (IPQC) tests are conducted.

KEYWORDS: Capsule, gelatin, quality, control, process, test, product, safety, excipient, dissolution.

INTRODUCTION

Soft gelatin capsules are adopted in the pharmaceutical industry for a variety of strategic, technological, safety, and customer preference reasons. Pharmaceutical products are considered to be of high quality if they meet specifications or standards that have been established by authoritative compendia without any mistakes. Recent developments in soft gelatin capsules have been made to solve various problems with bioperformances (increased bioavailability & reduced plasma variability) by improving solubility and enhancing absorption techniques.[1]

Solid gelatin capsules with a liquid or semisolid interior are known as soft gelatin capsules. Gelatin, water, plasticizing agents, preservatives, colourants, and various excipients such flavouring and sweetening agents to improve palatability are the ingredients for SGC shells.[7]

The pharmaceutical company's quality control division is where the quality analyst tries to estimate the concentration of a particular ingredient in the sample.[7]

To assure the safety, quality, and efficacy of pharmaceutical development and manufacture, regulatory organisations are constantly upgrading their requirements.[8]

The European Medicines Agency carries out this duty in Europe (EMA). The Food and Drug Administration (FDA) and the Medicines and Healthcare Products Regulatory Agency (MHRA), respectively, are in charge of carrying out this duty in the UK and the USA.[9,10,11] The FDA has mandated that all drugs sold in the USA meet specific quality and purity requirements in addition to being safe and effective.[12] FDA regulations known as current good manufacturing practise (cGMP) and good manufacturing practise (GMP)

Universal test for pharmaceutical soft gelatin capsule

Of all the dosage forms available on the market, the capsule dosage form makes up about 10%. Pharmaceutical capsules and other drug items are subject to the following four tests.

1. Description

This test, which is a qualitative description of the pharmaceutical soft gelatin capsules, is frequently referred to as appearance on a Specification. For instance, the description of a capsule on a specification can read: "Rx" inscribed on cap, white cap, red body".[15]

2. Identification

Verifying the identity of the API in the soft gelatin capsule is the goal of an identification or identity test. This test ought to be able to distinguish between chemical compounds with similar structural relationships that are most likely to be present.[15]

3. Assay

This test, which is occasionally referred to as a content test[15], establishes the strength or content of the API in the pharmaceutical capsule.

4.Impurities
This test finds the existence of any component in a pharmaceutical soft gelatin capsule that isn't an excipient or an API. Related Substances, which are process impurities from the synthesis of novel medicinal substances, API degradation products, or both, are the most typical sort of impurities that are tested.[15]

5. Size and Shape
Soft gelatin capsules can be found in many different shapes, including spherical (0.05-5 ml), ovoid (0.05-7 ml), cylindrical (0.15-25 ml), tubes (0.5-0 ml), and pear (0.3-5 ml) among others.[16]

IPQC and FPQC tests for soft gelatin capsule
A number of quality control tests are carried out in the manufacturing and filling of soft gelatin capsules to guarantee that they are created in accordance with the official compendia and customary standards set by the industries over the years.

These tests are performed in three stages.
(a) in-process testing,
(b) finished product testing and
(c) shelf-life testing.

In process quality control test
Monitoring all product features that can have an impact on quality and preventing processing errors are the main goals of an IPQC system. From the procurement of raw materials to the release of completed dosage forms, IPQC is primarily concerned with giving an accurate, specific, and definitive description of the processes that will be used.[4] to identify deviations from the product's tolerance range so that quick corrective action can be performed. to quickly identify any irregularity and to specify the appropriate course of action. The auditing of the product's quality at various phases of production depends heavily on the in-process inspection during manufacturing.[4]

Temperature, pressure, relative humidity, particle size, colour, fill weight, shell weight, soft gel ribbon thickness, soft gel seal thickness, soft gel shell moisture level, soft gel hardness, disintegration time, and other physical characteristics of pharmaceutical soft gelatin capsules are controlled by IPQC tests. IPQC testing for process quality control are often carried out in the production area.[30] They shouldn't put the product's quality at risk.[30] Problem identification is made simpler by in-process testing. It occasionally discovers a batch of defective products that can be fixed through rework, whereas this may not be practicable once that batch has been finished.[30] Process control specifications that are not met either imply that procedures were not followed or that some factor(s) are out of control.[30]

IPQC tests are as follows
1. Appearance: Whether made in small or big quantities, capsules should have a consistent appearance. To find any issues with the integrity and look of the capsule, a visual or electronic inspection should be performed. Gross changes in appearance, such as hardening or softening, cracking, swelling, mottling, printing errors, or staining of the shell, are indicative of physical instability. Rejecting defective capsules is advised.[16]

2. Size and Shape: There are several different shapes of soft gel capsules, including spherical (0.05-5 ml), ovoid (0.05-7 ml), cylindrical (0.15- 25 ml), tubes (0.5-0 ml), and pear (0.3-5 ml).[16]

3. Disintegration Test: Six glass tubes, each measuring three inches in length and opening at the top, are used in the USP disintegration apparatus. These glass tubes are held against a 10-mesh screen at the bottom end of the basket rack assembly. One capsule is placed in each tube and the basket rack is set up in the designated medium at 37.2°C to test the disintegration time so that the capsules remain 2.5 cm below the liquid's surface on their upward movement and sink not closer than 2.5 cm from the bottom of the beaker. The basket assembly housing the capsules is moved up and down across a distance of 5 to 6 cm using a typical motor-driven device at a frequency of 28 to 32 cycles per minute. The exam may also make use of perforated plastic discs. These are affixed to the top of capsules and provide the capsules an abrasive effect. The discs may or may not be significant or increase the test's sensitivity, however they are helpful for floating capsules. Use the device for the allotted amount of time. If the capsules break apart and all particles pass through the 10-mesh screen within the allotted time, the capsule complies with the test. If there is any residue left, it must have a mushy mass and likely no hard core. If every capsule has entirely broken down, the capsule passes the test as determined by USP. Repeat the test on 12 more capsules if one or two of them fail to completely dissolve. If 16 or more of the 18 capsules tested disintegrate, the criteria has been met. Soft gelatin capsules have a 60- and 30-second disintegration time, respectively, according to IP and BP.[31]

4. Weight variation[5]: Before cutting and opening the capsules, weigh each one separately. Then, after cleaning with the appropriate solvent, remove the contents. Weigh each shell after letting the solvents drain from it at ambient temperature. Do the Net Content calculation.

Average Weight of Capsule	Percentage Deviation
Less than 300 mg	10
300 mg or more	7.5

5. Moisture permeation test: The dosage unit is packaged with a color-revealing desiccant pellet to reveal the degree and rate of moisture penetration. Set aside a certain amount of time to expose the packaged unit to a defined relative humidity. Check for colour changes in the desiccant pellet. Any alteration in hue suggests moisture absorption. Calculating the amount can be done

by measuring the pre-test weight and protest weight of the pellet.[31]

6. Bloom strength of gelatin: A test to determine a gel or gelatin's strength is called bloom. Oscar T. Bloom first created and patented the test in 1925. The test determines the weight in grammes that a particular plunger must have in order to depress the gel's surface by 4 mm without breaking it at a particular temperature. The term "bloom value" refers to the quantity, and the majority of gelatins range from 30 to 300 grammes. The mealting and gelling points of a gel are greater at higher bloom values, and their gelling periods are shorter.[31]

7.Content uniformity: Use the method described in the monograph or any other appropriate analytical approach with equal accuracy and precision to determine the amount of the active ingredient in each of 10 hard or soft capsules eaten at random. Use the following formula to determine the acceptance value (AV):M - X ⎪ + KS
Where: K = Acceptability constant; S = Sample standard deviation; M = Reference value; X = Mean of individual content (x1, x2,..., xn) expressed as percentage of the label claim.

If no more than one of the individual readings so obtained is outside the range of 85 to 115 percent of the average value and no value is beyond the range of 75 to 125 percent, the BP capsules pass the test. If more than three of the capsules' individual contents fall outside the range of 85 to 115 percent of the average content, or if one or more fall outside the range of 75 to 125 percent of the average content, the capsules fail the test. Repeat the calculation using an additional 20 capsules if 2 or 3 individual readings fall outside the range of 85 to 115 percent of the average values.

If, out of a total sample of 30 capsules, no more than 3 individual values go outside the range of 85 to 115 percent and none do so outside the range of 75 to 125 percent of the average value, the capsules pass the test.[31]

Monitoring parameters[36]
Some parameters need to be monitored and managed during the encapsulation of soft gelatin capsules.
a. The thickness and consistency of the gel ribbon.
b. At the time of encapsulation, soft gels seal thickness.
c. The weight of the fill in each capsule and how it varies from capsule to capsule.
d. The weight of the shell of the capsule and how it varies from capsule to capsule.
e. The capsule shell's moisture content both before and after drying.

Finished product quality control testing
When produced, capsules are put through a battery of tests in accordance with the regulatory standards and compendia requirements for unit dose capsule products. These evaluations confirm whether the product is suitable for commercialization.

These tests are as follows
1.Permeability and sealing
Soft gelatin capsules are visually inspected to check for physical integrity.
A compression probe with a diameter bigger than the capsule diameter can be used to measure seal strength. The force required to break the seal is measured with the seal positioned perpendicular to the probe.[2]

2.Potency and impurity content
Soft gelatin capsules are visually inspected to check for physical integrity.
A compression probe with a diameter bigger than the capsule diameter can be used to measure seal strength. The force required to break the seal is measured with the seal positioned perpendicular to the probe.[2]

3.Weight variation test
By measuring weight fluctuation or content consistency, the uniformity of dose units may be demonstrated.
The following weight variation test is used with soft gelatin capsules.
Count each of the 10 gelatin capsules.
Afterward, using a good, dry, clean cutting tool, cut and open the capsule (e.g., scissors or a sharp open blade)
Wash the substance out using an appropriate solvent (that dissolves the fill but not the shell) At room temperature, give the shells about 30 minutes to absorb the solvent. The individual washed shells were then weighed.
The active component in each capsule can be computed based on the formulation's percentage drug content, and the net contents are derived by subtracting those two amounts.[2]

4.Uniformity of Content
Only when the content is mentioned in the individual monographs and when the capsules fail the weight variation test is this test carried out. When the capsule is completely filled, this test shouldn't be done.
For nine (9) out of ten (10) dosage units evaluated, the amount of drug material found by assay is within the range of 85.0 percent to 115.0 percent of the label claim, with no unit falling beyond the range of 75.0 percent to 125.0 percent of the labelled drug content.[2]

Additional tests are necessary when two or three dose units fall beyond the intended range.
Use the method described in the monograph or any other appropriate analytical approach with equal accuracy and precision to determine the amount of the active ingredient in each of 10 hard or soft capsules eaten at random. Use the following formula to determine the acceptance value (AV).
Where, if M - X + KS
M is a reference number. X = Mean of each individual piece of material (x1, x2,..., xn) given as a proportion of

the label claim. K stands for the acceptance rate. Standard deviation of the sample[31]

5.Uniformity of Mass.
Weigh an intact capsule for this test. Remove the entire contents of the capsule while preserving as much of the shell as you can. A soft capsule's contents can be removed by washing the shell with ether or another suitable solvent and letting it stand until the solvent's odour is no longer detectable. the shell's weight. The difference between the weights is the weight of the contents. With an additional 19 capsules, repeat the procedure. the average mass to be determined. Not more than two of the individual masses differ from the average mass by more than the percentage deviation, according to IP, BP, PhEur, and PhInt capsules.[17,18,19,20]

6.Mass Variation Test
consistent with BP for soft capsules To determine the gross masses of 10 intact capsules, precisely weigh each capsule while taking care to maintain its unique identity. Then, using a clean, dry cutting tool like scissors or an open blade, cut open the capsules to release the contents, which should then be washed with a suitable solvent. Allow the occluded solvent to leave the shells at room temperature for about 30 minutes while taking steps to prevent moisture absorption or loss. Calculate the net contents by weighing each shell individually. Utilize the quantity of product taken from each capsule and the assay result to determine the amount of active ingredient in each capsule.

Use the formula below to determine the AV.[18]
The condition is satisfied, in accordance with BP and USP, if the acceptance value of 10 capsules is less than or equal to 15%. Test the following 20 capsules and determine the acceptance value if it is greater than 15%. If the ultimate acceptance value of the 30 capsules is less than or equal to 15% and no individual capsule content is calculated to be less than (1 - 25 0.01) M or greater than (1 + 25 0.01)M under mass variation or content uniformity, the standards have been met.[18,21]

7.Disintegration time test
This test shows that when placed in a liquid medium, capsules dissolve within the allotted time. To make sure that the medication material is completely available for disintegration and absorption from the gastrointestinal tract, soft gelatin capsules are assessed. The basket-rack assembly, which is filled with capsules, is repeatedly dropped 30 times per minute into a bath of fluid that is maintained at a temperature of 37 2 C. If no medication or shell pieces are present, the capsule passes the test.[2]

8.Dissolution test for capsules
A dissolution test is used to determine the pace and degree of medication disintegration from the capsule dosage form. This test offers a quality control method to guarantee that the drug release properties of various batches of the drug product are consistent.[2]

Processing for dissolution: In Tier 1, the test is run using the test method's typical dissolution medium. Testing proceeds directly to Tier 2, where enzymes are introduced to the dissolution medium, if the product violates Stage 3 criteria at any point in Tier 1.[37]

Methods for dissolution testing[39]
Two of the most widely excepted ways to perform dissolution testing are.
1. Paddle dissolution method
In this technique, the rotating shaft is fixed to a blade that is fastened at the end vertically. Typically, the drug is placed within the holding vessel and when it settles at the bottom, this blade is supposed to operate as a stirrer to mix the liquid inside holding vessel with the medication being tested. To start mixing, the rotating shaft is turned on.

In order to prevent the medication under test from adhering to the vessel walls and to make sure it stays below the spinning shaft, the drug is typically linked to a sinker. To avoid reacting with the drug sample it carries, this sinker is built of a non-reactive material.

2.Basket dissolution method
A separate device is at the revolving shaft's end in the basket dissolution method. The device is known as a basket. It is made of non-reactive mesh and has a cylindrical form to avoid any unintended chemical reactions that might change the outcome. To produce a homogenous solution, the mesh's pores enable the medicine to dissolve to travel from the basket into the holding vessel.

The substance under examination is initially placed within the basket, which is securely fastened to the rotating shaft's end. The motor is turned on and the shaft starts rotating the basket inside the vessel after the medication is safely in position.

Because the medications swell in water and may adhere to the walls of the dissolution vessel, the sticky drugs that contain HPMC or comparable chemicals as a binder are examined using a basket.

Which of these techniques will be utilised to evaluate the sample in the lab depends on its type, such as whether it is an emulsion, a coated capsule, or a non-coated pill. As a result, the type of dosage forms completely determines whether a paddle or basket is used for dissolution.

How is capsule dissolution affected by gelatin?
When the cross-linking took place, the dissolving rates of the capsule formulations were noticeably slowed. When gelatin is tested for water solubility, cross-linking produces membranes that are insoluble in water due to a bridge across the peptide backbone of the gelatin molecule. The Bloom strength and the dissolution rate have an inverse connection for a certain SGC. The physiochemical characteristics of the gelatin capsule

shells are altered by cross-linking, and this results in the formation of a water-insoluble film or pellicle around the gelatin capsule shell, on either the inside or exterior surfaces, or both (10–15). When the cross-linking took place, the rates of the capsule formulations' dissolution were dramatically slowed. Melting point, solubility, particle size, and chemical composition are other gelatin properties that can influence dissolution.[35]

3.Moisture content
Karl Fisher titrimetry is used to determine the water content of the entire capsule or just the contents in order to correlate water content with the degradation profile or drug-release properties of capsules.[2]

4.Moisture permeation test:
To ensure that single-unit and unit dose containers are suitable for packaging capsules, the USP mandates that their moisture-permeation properties be determined.

Packaging the dosage unit with a desiccant pellet that reveals colour, exposing the packaged unit to known relative humidity for a predetermined amount of time, watching the desiccant pellet for colour change (indicating absorption of moisture), and comparing the pre-test and post-test weight of the packaged unit are the methods used to determine the degree and rate of moisture penetration.[2,21,22,23]

5.Microbial content: Microbiological tests are used to check the capsules for the presence of bacteria and mould. These tests are often conducted by incubating the contents of the capsule in a growth medium and counting the colonies that form after a set amount of time.

The efficacy of this method for assessing microbial contamination depends on the choice of the growth medium, the length of the test, and the maintenance of aseptic conditions during the testing.[2]

Shelf life testing
These tests are commonly performed following predetermined storage times under predetermined settings. They aid in determining and confirming the medication product's stability and shelf life. The product's shelf life can last a long time under prescribed storage circumstances, hence accelerated storage is frequently used to estimate the product's shelf life.[3]

Stability Testing
The purpose of stability testing of capsules is to ascertain the intrinsic stability of the active drug molecule, the physicochemical stability of the active drug molecule in the finished drug product, and the impact of environmental factors (such as temperature, humidity, and light) on formulation components.[3] Stress testing, long-term stability testing, and accelerated stability testing are all used to identify the best storage conditions and the expected shelf life of a product.[3]

Stability testing categories
Real-time stability tests, accelerated stability tests, retained sample stability tests, and cyclic temperature stress tests are the four types of stability tests most frequently used.

Real-time stability test
Real-time stability tests involve monitoring a product while it is kept in recommended storage conditions for a certain amount of time (testimation) Real-time testing keeps the product in suggested storage conditions and keeps track of it until it doesn't meet the requirements. Real-time stability testing should normally be performed at intervals of 0, 3, 6, and 9 months during the first year, every 6 months during the following year, and once annually after that. In research on accelerated stability, the product is kept in high-stress circumstances (such as temperature and humidity). Product will eventually decline below its specification, given by the symbol t (specification), and we must ensure that it does not degrade below or to the same extent as test. Modeling the deterioration pattern will yield the expected value of t(specification). To reduce the chance of biases and the quantity of random error during data collection, good experimental design and procedures are required. The desired shelf life should be tested at intervals throughout, and testing must continue when the product no longer meets specifications. In order to capture lot-to-lot variation, a significant source of product variability, at least three lots of material must be employed in stability testing.[32,33,34]

Accelerated Stability Tests
A product is kept under elevated stress conditions during accelerated stability testing. A minimum of 0, 3, and 6 months shall pass through accelerated stability testing. Then, utilising established correlations between the acceleration factor and the degradation rate, degradation at the suggested storage conditions can be projected. Based on the degradation under each stress situation and known correlations between the acceleration factor and the degradation rate, degradation at suggested storage conditions may be anticipated. A product may be released based on accelerated stability data, but concurrent real-time testing is required to validate the predicted shelf life. Sometimes the anticipated stability's mistake is so great that the forecast is useless in and of itself. To minimise this inaccuracy, carefully plan your experiments. To lower prediction error, it is advised that numerous production lots be held at varied acceleration levels. A useful method for lowering error is to increase the number of levels.[32,33]

Retained sample stability testing: Every marketed product for which stability statistics are necessary follows this custom. Every marketed product that needs stability data undergoes retained sample stability testing as standard procedure. Cyclic temperature stress testing is created based on product knowledge to display potential market storage conditions. Stability samples are

chosen for this investigation with the intention of retaining them for at least one batch per year. It is advised to gather stability samples from two batches if there are more than 50 batches being marketed. Stability samples of every batch may be obtained at the time of the product's initial launch on the market; thereafter, this number may be reduced to merely 2 percent to 5 percent of marketed batches. In this study, the stability samples are evaluated at preset intervals; for example, if a product has a shelf life of five years, it is customary to test samples at three, six, nine, twelve, eighteen, twenty-four, thirty-six, forty-eight, and sixty months.[32,33]

Cyclic temperature stress testing

Cyclic temperature stress tests are created based on product knowledge to replicate potential market storage conditions. Due to the diurnal rhythm on earth, which the commercially available medications are most likely to undergo during storage, the cycle period is typically 24 hours. It is advised that the lowest and maximum temperatures for the cyclic stress testing be chosen product by product, taking into account things like the product's suggested storage temperatures and particular chemical and physical degradation qualities. Additionally, it is advised that the test should typically consist of 20 cycles.[32,33]

Validation

In an effort to raise the calibre of medications, two Food and Drug Administration (FDA) employees named Ted Byers and Bud Loftus initially introduced the idea of validation in the middle of the 1970s.[6]

Process validation gives production process controls flexibility and restrictions to achieve desired medicinal product quality while preventing undesired traits.[24] Process validation was described by the US Food and Drug Administration as "creating documented proof that gives high degree of assurance that a particular process will consistently generate a product satisfying its predetermined standards and quality characteristics.[25,26]"

Types Of Process Validation[27]

A) Prospective Process Validation: Prior to the process being employed for commercial purposes, the experimental plan known as the validation protocol is established (following the conclusion of the qualifying trials). There must be some degree of future experimentation in order to produce support data for validation.

B) Validation of the Concurrent Process: The Concurrent Process Validation gives concrete proof that the process is in a controlled condition during its actual execution. For concurrent process validation, important operations are tested in-process and/or watched over while each production batch is being manufactured.

C) Retrospective Process Validation: This refers to validation that is based on historical information obtained from the records of completed production batches and utilised as documented proof that the process has been under control.

D)Revalidation: Revalidation makes ensuring that alterations to the procedure and/or the processing environment, whether intended or not, do not have a detrimental impact on the characteristics of the product's quality.

Revalidation falls into two categories: >Revalidation after every change that affects the quality of the product >Periodic revalidation performed at predetermined intervals.

Importance of Process Validation[28]

Product quality is guaranteed, the process is optimised, the cost of product quality is decreased, and the number of product recalls from the market is limited. Since the process is under control, a thorough investigation is feasible.

Validation-Related Documents- Master plan for validation, SOPs, Validation Protocol, Validation Report.

Soft Gelatin Capsules[29]

A soft gel, also known as a soft gelatin capsule, has a solid outer shell that encloses a liquid or semi-solid interior (inner fill). The interior fill, the outer shell, or both may contain an active substance. The technique for making capsules is the same as for making tablets; the main distinction is that the granules are placed within the capsule shell rather than being compressed.

The following additional factors in the encapsulation process need to be validated.

A) Content of the capsule shell

-Determine whether the capsule's shell and its contents are compatible.

- Determine whether the formulation of the capsule is hygroscopic.

As an illustration, a hygroscopic formulation (API/excipients) may draw water from the capsule shell, which may impact the stability of the API.

B. Encapsulation Speed: To assess the encapsulation's operating range, the formulation should be encapsulated at a variety of rates.

C. Encapsulation: Just like compressing tablet dosage forms, encapsulation is a crucial step in the production of capsules. The materials to be encapsulated must have good flow characteristics and a stable density.

Packaging and storage of soft gelatin capsules[3]

The medication is typically dissolved or dispersed in oils or hydrophilic liquids and placed within soft gelatin capsules (i.e., fill liquid). The soft gelatin capsule's natural flexibility is caused by the presence of plasticizers and lingering moisture in the shell of the capsule. Therefore, compared to traditional tablets, the soft gelatin capsule is a more dynamic device. The fill liquid or the capsule shell may absorb ambient moisture. While the plasticizer or leftover water in the gelatin shell may theoretically migrate into the fill, the medicine or

fill liquid may migrate into the capsule shell. Soft gelatin capsules may leak volatile substances into the atmosphere. When creating a shelf life stability programme for soft gelatin capsules, several factors must be taken into account.

It is crucial to preserve stability when the suggested storage conditions are listed on the label, which happens in the majority of cases. Empty capsule shells should typically be stored at a temperature of 15 to 25 °C and a relative humidity of between 35 and 65 %. During the encapsulation process, this condition is intended to reduce moisture absorption or loss and the ensuing changes in physical dimensions. There are a few recommendations that can be used to assess the storage requirements and duration of study needed for particular formulations of soft gelatin capsules, even though there are no clear guidelines for stability testing of soft gelatin capsules.

According to the recommendations, soft gelatin capsules should be tested for their appearance (including brittleness), colour, and odour of their contents, as well as their assay, degradation products, dissolution, and microbial content. They should also be tested for pH, leakage, and pellicle formation. Additionally, the fill medium needs to be checked for cloudiness and precipitation. A drug product should generally be assessed under storage circumstances (with suitable tolerances) that test its thermal stability, and if necessary, its susceptibility to moisture or potential for solvent loss. Drug products should be stored at a lower temperature if a certain product is shown to be heat sensitive; this lower temperature condition will eventually replace the designated long-term storage temperature.

Rejected material : In order to prevent their usage in manufacturing or processing processes for which they are inappropriate, rejected in-process materials must be recognised and controlled.[4]

New QCT for soft gelatin capsules

Testing qualitative physical attributes (QPAT) is a new technique that has been tried out and refined.Using artesunate SGC produced during scale-up testing, the QPAT method was created. The media for the dissolving testing experiment were phosphate buffer (pH 7.2, 1.5 percent CTAB) and water because there was no acceptable biorelevant rectal fluid mentioned in the literature. After testing many commonly used surfactants in dissolution media at various concentrations utilising saturation solubility experiments and dissolution trials, CTAB at a concentration of 1.5 percent was chosen. The entire dissolution of artesunate SGC typically takes place in 15 minutes.[38]

Future perspective

Soft gelatin capsules have become much more popular in recent years as a means of creating and manufacturing medications. The quick development of capsule dosage form is most likely to blame for this. Better patient compliance, product recognition, and product distinction are all made possible by the variety of sizes available, the beautiful design of the capsule, and printing directly onto the capsule.

Soft gelatin capsules come in a variety of sizes to allow for flexible dosing. The tasteless gelatin casing helps cover up unpleasant medication tastes and odours. They are an advantageous choice when creating poorly water-soluble pharmaceuticals since they can be used to encapsulate lipid solutions, fish oil, suspensions, or paste-like formulations. Compared to distribution as a tablet or powder, this will inevitably result in higher absorption of the active component. For the oral delivery of poorly water soluble chemicals, there is growing interest in the creation of soft gelatin capsules (soft gel) dosage forms (BCS class II or class IV).

With a concentrate on the advancements and difficulties of soft gelatin capsule formulation for oral administration for increased solubility and as a technique to enhance absorption, there are establishments and an ongoing development of the production technology for liquid fill capsules. Future applications for the delivery of oral medications are built on the basis of these elements. The components, procedures, and associated technology for this adaptable dosage form will keep getting better thanks to the efforts of the capsule industry.

CONCLUSION

The pharmaceutical industry has adopted quality control to monitor the uniformity of the product's quality and its production on a small- and large-scale basis. Testing for quality control identifies product flaws and errors. The responsibility of the quality executive is to oversee the results of the quality testing and then release the products for sale. Since QPAT has received WHO approval, it can be used for routine quality control.

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