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CAPSULES: TYPES, MANUFACTURING, FORMULATION, QUALITY CONTROL TESTS, PACKAGING AND STORAGE, INSTRUMENTS-A OVERVIEW ARTICLE

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ABSTRACT

Capsules are solid preparations containing either a soft or hard soluble shell for the drug or excipient. Typically made of gelatin or another suitable polymeric material, the sell produces a straight forward, tasteless, odorless, elegant, and simple dosage form that does not require a secondary coating step. at all medicinal dosage forms, the capsule in solid form has never been the subject of research. In order to accomplish modified drug release, this review incorporates more recent trends in the outer layer of capsules, capsule fill material, a capsule sealing technique, and various capsule systems. When making capsules, the gelatin solution is processed with the help of preservatives and surfactants. Water, which serves as a plasticizing agent for the gelatin coating and is necessary for the function of empty capsules, is present in a significant quantity. The basis of hard capsules is often composed of plasticizer and water. Additionally, the base may include sugars, colours, flavours, and preservatives. The animal source of gelatin can be a problem for certain consumers such as vegetarians or vegans and religious or ethnic groups, Since unmodified gelatin is prone to cross linking when in contact with aldehydes, solubility problems might be expected with certain fill formulations. The non-gelatin capsule shells are made up of such as Starch, HPMC, PVA, and Alginate.

KEYWORDS: Capsule, Gelatin, Manufacturing, Formulation, Quality control test, Pacaging and storage, Instrument.

INTRODUCTION

The Latin word "capsula," which means a small box or container, is the origin of the word "capsule." The term is used in a variety of scientific fields, including anatomy, where it is used to describe a membrane that surrounds something, botany, where it is used to describe fruits, and astrophysics, where it is used to describe a spacecraft.[1] The term "capsule" has been used in the pharmacy to describe both a glass ampule and the protective cap that covers a medicine bottle's stopper. In recent times, the term "capsule" has primarily been used to refer to solid dosage forms, which are containers containing a medicine. They fall into one of two main categories: hard capsules (two pieces) or soft capsules (one piece), depending on whether glycerol or another plasticizer makes them flexible and soft. There has been a soft gel dosage form for a long time. Soft gels first appeared in the 19th century. Numerous improvements have been made to the production of these soft capsules since then.[2] Manufacturing soft gel still necessitates specialized expertise and equipment, both of which are only provided by a small number of businesses to pharmaceutical clients.

Despite the advancements in soft gel manufacturing, the soft gel dosage form has largely remained unchanged over time. Consequently, the technology lost its patent protection, which is a disadvantage in the age of pharmaceutical life-cycle management. As a result, Banner has developed new soft gel varieties that not only provide additional patent protection for the compounds they deliver but also provide distinct advantages over standard soft gel. Formulations have steadily increased in popularity ever since the invention of the Soft Capsule Making Machine in the 1970s, with rapid advancements in recent years. This could be demonstrated by the emergency of more than 560 sets of transfer-mode Soft Capsule Making Machines, which produce up to 60 billion pills annually (or more than 3600 different drugs) worldwide.[3] Any substance that, when consumed, alters an organism's physiology or psychology is considered a drug.

In most cases, drugs are distinct from foods and substances that support nutrition. Inhalation, injection, smoking, ingestion, absorption through a patch on the skin, or dissolution under the tongue are all methods of drug consumption.[4] A drug is a chemical substance with a known structure that has a biological effect when given to a living organism in pharmacology. A chemical substance that is used to treat, cure, prevent, or diagnose a disease or to promote well-being is referred to as a pharmaceutical drug. It is also referred to as a medication or medicine. Generally tranquilizes were acquired through extraction from therapeutic plants, yet all at once more as of late likewise by natural union. For chronic disorders, pharmaceutical drugs may be used for a short time or frequently.[5]

DOSAGE FORM

Dosage form are pharmaceutical drug products in the form in which they are advertised for use. They contain a particular mix of active ingredients and inactive components (excipients), are arranged in a particular way (like a capsule shell, for instance), and are divided into a specific dose. The pharmaceutical formulation of a drug product's constituent drug substance(s) and any blends involved can also be referred to as a dosage form without taking into account other aspects (such as how it is ultimately configured as a consumable product like a capsule, patch, etc.). There are a variety of dosage forms to choose from, each with its own set of properties and advantages. There are numerous liquid, solid, and semisolid dosage forms among these. Pill, tablet, or capsule, drink, or syrup, as well as numerous natural or herbal forms like plants or foods of some kind, are all common dosage forms. Particularly, the dosage form of the drug in question determines the route of administration (ROA) for drug delivery. The liquid form of a dose of a chemical compound used as a drug or medication intended for administration or consumption is known as a liquid dosage form.[6]

CAPSULE

Containers are characterized as unit strong measurement type of medicaments accessible as little holders (shells) made up of gelatin encasing precisely estimated drug substances. The Latin word capsula, which means a small container, is the origin of the word capsule. Capsules play an important role in drug development. Due to their superior manufacturing process to that of other dosage forms, they are frequently regarded as the primary oral dosage form. When gelatin comes into contact with water, it breaks down, allowing the medication to completely dissipate. The capsule shells can also be made with polyvinyl alcohol, methyl cellulose, denatured gelatin, or gelatin alone.[7] There are primarily two kinds of capsules. capsules with hard shells that contain dry, powdered ingredients or miniature pellets made by extrusion or spheronization, for example. There are two halves to these: a "body" with a smaller diameter that is filled and then sealed with a "cap" with a larger diameter. Aqueous solutions of gelling agents, such as animal protein (primarily gelatin) or plant polysaccharides or their derivatives (such as carrageenans and modified forms of starch and cellulose), are used to make both of these categories of capsules. The hardness of the capsule can be decreased by adding plasticizers like sorbitol or glycerin to the gelling agent solution.[8] In scholarly articles, there are a variety of capsule types, which are as follows: the capsules made of hard and soft gelatin, Hydroxypropylmethyl cellulose (HPMC), polyvinyl alcohol (PVA), and starch. These are the gelatinous and non-gelatinous capsules, respectively.[9]

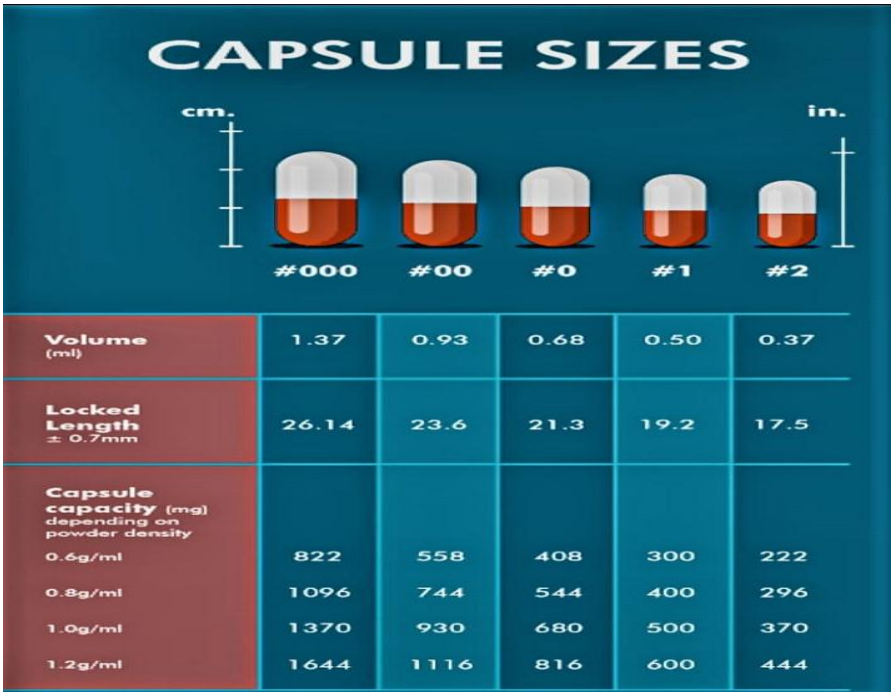

Figure:1

ADVANTAGES OF CAPSULES

Capsules are tasteless, odorless and can easily be administered.

Combination of powders we can use There are attractive in appearance.The drugs having un-pleasant odor and taste are enclosed in a tasteless shell

They can be filled quickly and conveniently.

Physician can change the dose and combination of drug according to patient requirement.They are economical.

They are easy to handle and carry.The ready solubility of gelatin at gastric pH provides rapid release of medication in the stomach. Packaged and shipped by manufacturers at lower cost less breakage than liquid forms.

DISADVANTAGES OF CAPSULES

Capsules are not suitable for liquids that dissolve gelatin, such as aqueous or hydro or hydro alcoholic solutions.

The concentrated solutions which require previous dilution are unsuitable for capsules because if administered as such lead to irritation into stomach.

Not useful for efflorescent or deliquescent materials. Efflorescent cause capsules to soften & Deliquescent may dry the capsule shell to brittleness.

DEVELOPMENT THE FORMULATION AND SELECTION OF CAPSULE SIZE

The goal is to prepare a capsule with accurate dosage, good bioavailability, easy to fill and production, stability and elegance. In dry formulation the active and inactive components must be blended thoroughly to ensure a uniform powder. This can be achieved by size reduction, and effective blending. A diluent as filler may be added to the formulation to produce the proper capsule fill volume. Lactose, microcrystalline cellulose and starch are commonly used diluents. Apart from providing bulk these materials provide cohesion to the powders.

GELATIN CAPSULES

This category of capsules is basically made from gelatin; they can either be soft or hard gelatin capsules.

SOFT GELATIN CAPSULE

Figure:2

Aspects broader Soft gelatin capsules were initially created in the 19th century to cover up the bad taste and smell of drugs. Today, they are used in a variety of industries, including cosmetics, health and nutrition products, pharmaceuticals, and even recreational goods like paint balls.[10]

BASIC COMPONENTS OF SOFT GELATIN CAPSULE SHELL

the various components of the soft gelatin capsule shell are as follows:

1. Gelatin

The primary component of a soft gelatin capsule shell is gelatin, just like it is in hard gelatin capsule shells. Depending on the liquid fill matrix, there are numerous gelatin shell formulations to choose from. Type B alkali- or base-processed gelatin is the most common type, accounting for 40 percent of the wet molten gel mass. Gelatin processed with acid type A can also be used. The choice of gelatin grade and the level of plasticizer present in the gelatin shell influence the product's properties.

2. Plasticising agents

Plasticizing agents are added in a soft gelatin capsule formulation to ensure adequate flexibility. They interact with gelatin chains to reduce the glass transition temperature (Tg) of the gelatin shell and/or promotes the retention of moisture (hygroscopicity). The most common plasticizer used for soft gelatin capsules is glycerol. Sorbitol, mannitol, and polypropylene glycol can also be used in combination with glycerol.

3. Water

The wet gel formulation typically contains 30-40% water, which is essential for the capsule's flexibility both in the finished product and during the manufacturing process (to facilitate production). The viscosity of the particular grade of gelatin used determines the desired water content of the gelatin solution used to produce a soft gelatin capsule shell. It typically contains 0.7 to 1.3 parts water for every part dry gelatin.

4. Preservative

Preservatives are frequently added to the gelatin solution to stop mold and bacteria from growing there during storage. Preservatives like potassium sorbate and methyl, ethyl, and propyl hydroxybenzoate are two examples that are frequently used.

5. Colorant and/or opacifier

For the purpose of encapsulating a photosensitive drug, a colorant (such as soluble dyes, insoluble pigments, or lakes) and/or an opacifier (such as titanium dioxide) may be added to the shell for both aesthetic purposes and to

limit light penetration. Typically, the color of the capsule's shell is chosen to be darker than its contents.

6. Other excipients[11]

Flavoring agents and sweeteners are two other, less frequently used excipients that can be used to improve palatability. Enteric release characteristics are imparted through the use of acid-resistant polymers. They can also be used to make soft gelatin capsules that are easy to chew. To stop the chemical degradation of oxidation-sensitive drugs that are catalyzed by free metals in gelatin, like iron, a chelating agent like ethylene diamine tetracetic acid (EDTA) can be added.

Hard gelatin capsule

Figure:3

A general fact is that most capsule goods are made of hard gelatin capsules. There are two shells that make up hard gelatin capsules: the capsule body and a cap that is shorter. The capsule body's open end is snugly covered by the cap. Gelatin, sugar, and water are used to make the basic hard gelatin capsule shells. They are transparent, tasteless, and colorless.[12] In the pharmaceutical industry, two-piece capsules have been used for nearly a century. Gelatin has been chosen as the main material for these capsules due to its excellent property as a gelatinizer. Nevertheless, gelatin is one of the animal-derived proteins; As a result, it is chemically unstable and may cause transmissible spongiform encephalopathy (TSE).[13] Hard gelatin capsules are composed of two halves, termed the cap and the body. During manufacture of the dosage form, the formulation is filled into the body (using a range of different mechanical techniques) and the cap is pushed into place. The two halves of the capsule are joined, the cap overlapping with the body.

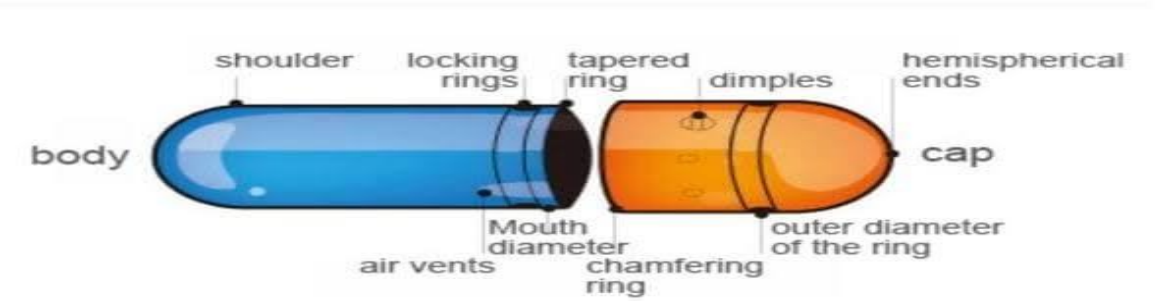

Figure:4

BASIC COMPONENT OF HARD GELATIN CAPSULES

1. Gelatin

The most well-known and widely used material for making hard capsule shells is gelatin. A mixture of purified protein fractions obtained through irreversible hydrolytic extraction of animal skin, white connective tissue, and bone collagen is referred to as this generic term.

2. Plasticizer

Gelatin is infused with plasticizers to soften the polymer and make it less rigid. Glycerin and polyhydric alcohol are two typical examples of plasticizers. Gelatin naturally contains water, which is an effective plasticizer.

3. Colourants

Hard gelatin capsules are typically colored to both enhance their aesthetic properties and serve as a means of product identification. The colorants used must be compliant with the regulations of the nations where the product will be sold. Synthetic dyes like azo dyes and xanthene dyes are two examples of common capsule colorants. Pigments made of iron oxide are also used.

4. Opacifying agents

To make clear gelatin opaque, pacifiers like titanium dioxide can be added. Capsules that are opaque can be used to conceal the contents or protect against light.

5. Preservatives

To make clear gelatin opaque, pacifiers like titanium dioxide can be added. Capsules that are opaque can be used to conceal the contents or protect against light.[14]

Capsule size

The length, diameter, and capacity of empty gelatin capsules can be varied. The quantity of fill material that will be encapsulated determines the size that will be utilized. The extent to which the fill can be packed into a capsule shell is largely determined by its bulk density and compressibility. Commercially available empty capsules for human consumption range in size from 0 (the largest) to 5 (the smallest). For veterinary use, larger capsules are available.

DEVELOPMENT THE FORMULATION AND SELECTION OF CAPSULE SIZE

The objective is to make a capsule that has a precise dosage, good bioavailability, is simple to fill and make, is stable, and looks good. In order to produce a uniform powder in dry formulation, the active and inactive components must be thoroughly blended. Effective blending and reducing the size make this possible. The formulation can be filled with a diluent to achieve the right capsule fill volume. Diluents like lactose, microcrystalline cellulose, and starch are frequently used. These materials give the powders cohesion in addition to adding bulk. Deteriorating specialists are likewise included the plan to work with the separation and dispersion of the case content.[15]

PREPARATION OF DUO CAP

The drug: carrier complex melt of drug prepared was solubilized in tetra glycol to give a final drug concentration of 3 % (m/m) and further sonicated for 1 h. (7) Ionotropic gelation technique was used to prepare the drug alginate sustained releasing beads. The batches, BFC-1 to BFC-3 were prepared with sodium alginate alone, BFC-4 to BFC-6 were prepared with HPMC, BFC-7 to BFC- 9 were prepared with chitosan and BFC-10 to BFC-12 were prepared with pectin in different proportions. Similarly, BFC-4 to BFC-6 were prepared using fixed concentration of sodium alginate and different concentrations of HPMC. (9) The batches, BFC-7 to BFC-9 were prepared using fixed concentration of sodium alginate and different concentrations of chitosan, as follows: The mixture of drug and sodium alginate dispersion was dropped through a syringe with a needle of size no.18 into 100 mL of chitosan solution containing 5 % calcium chloride (Chitosan dissolved in 10 mL of 5 % (w/v) acetic acid) and stirred at 100 rpm. Similarly, BFC-10 to BFC-12 were prepared using fixed concentration of sodium alginate and different concentrations of pectin.pecial leak proof capsules for both smaller and bigger size was used in this formulation. To prepare a novel capsule in-a-capsule technology the prepared optimized sustained release beads equivalent to 8 mg of drug were filled in size 2 hard gelatin capsule and was sealed with 15 % (m/m) warm gelatin solution.[16][17] This prepared sustained release smaller capsule was filled into a bigger capsule body size 0 which was further filled with the liquid dispersion of drug equivalent to 3.25 mg as loading dose using medicine droppers.[18]

EVALUATION OF CAPSULES

Weight variation test Each of the ten capsules was weighed, and the contents were taken out. Each of the empty capsules was weighed, and the net weight of the contents was determined by subtracting it from the total. The following formula was used to determine the percentage of weight variation Weight variation = (Weight of capsule-Average weight) ×100 Average weight of capsules Weight variation should not be more than 7.5%.[19]

Disintegration test

The capsules were placed in the basket rack assembly, which is immersed in a 37°C fluid at a thermostatically controlled temperature 30 times per minute. The capsules should completely decompose into a soft mass with no discernible firm core and no gelatin shell fragments to pass the test. The test should be repeated with an additional 12 capsules if one or two capsules fail. Then, at least 16 of the 18 capsules tested should completely decompose.

Dissolution studies

The disintegrated solid solute is transformed into a solution through the process of dissolution. The time it takes for a certain percentage of the drug in capsules to dissolve under certain conditions is the goal of the test. A USP Type II (paddle) dissolution apparatus at 50 rpm was used to measure the drug's release. As the dissolution medium, 900 milliliters of 0.1N hydrochloric solution acid were kept at a temperature of 37.5 0.5°C. To stay out of capsule flotation 14, a sinker was used. The examples were drawn at 5, 10, 15 30 and 45 mints and equivalent measure of new medium were supplanted to keep up with the sink conditions. The percentage of the drug that was released was determined by analyzing the withdrawn samples.

Table 1: Effect of Temperature and Humidity on Capsule shell Temperature.

Temperature	Humidity	Effect on capsule shell
21-24°C	60%	softer, tackier and bloated
Greater than 24°C	Greater than 45%	More rapid and pronounced effects – unprotected capsules melt and fuse together

Stability studies

The ability of particular formulations in a particular container to remain within its physical, chemical, therapeutic, and toxicological specifications has been defined as stability of the drug. The objective of stability testing is to demonstrate how a drug substance or drug

product's quality changes over time in response to a variety of environmental factors, such as temperature, humidity, and so on. The accelerated condition (40 2°C / 75 5% RH) and the long-term condition (25 2°C / 60 5% RH) were the storage conditions used for stability studies. The capsules were induction sealed with adsorbent cotton 26-29 in HDPE containers with a count of 30.[20]

Table 2: Test conditions for accelerated physical stability tests for capsule dosage forms Test conditions.

Accelerated physical stability	Observation
80 % RH at room temperature in an open container.	Capsules are observed periodically for 2 weeks; both gross and subtle effects of the storage conditions are noted and recorded. The control capsule should not be affected
40○ C C in an open container.	
40○C C in a closed container (glass bottle with tight screw-cap)	Except at the 80% RH station.

PACKAGING AND STORAGE OF HARD GELATIN CAPSULES

Finished hard gelatin capsules normally contain an equilibrium moisture content of 13 to 16%. This moisture is critical to the physical properties of the shells since at lower moisture contents (<12%), shells become too brittle and may crack when exposed to the appropriate stress. It is therefore important to avoid extremes of temperature and to maintain a relative humidity of 40 to 60% when handling and storing capsules. The bulk of the moisture in capsule shells is physically bound, and it can readily transfer between the shell andts contents, depending on their relative hygroscopicity. The removal of moisture from the shell could be sufficient to cause splitting or cracking, as has been reported for the deliquescent materials potassium acetate and sodium cromoglycate. It may be useful to first equilibrate the shell and its contents to the same relative humidity within the acceptable range before filling. Another problem that has received substantial attention in recent years is the loss of water solubility of shells, apparently because of sufficient exposure to high humidity and temperature or to exposure to trace aldehydes.[21]

PACKAGING AND STORAGE OF SOFT GELATIN CAPSULES

Soft gelatin capsules generally contain the medicament dissolved or dispersed in oils or hydrophilic liquids (i.e., fill liquid). The inherent flexibility of the soft gelatin capsule is due to the presence of plasticizers and residual moisture in the capsule shell. The drug or fill liquid may migrate into the capsule shell, while the plasticizer or residual water in the gelatin shell can potentially migrate into the fill. It is these characteristics that must be considered when designing a shelf life stability program for soft gelatin capsules. In most instances, the recommended storage conditions are stated on the label in which case it is imperative to maintain stability. While there is no strict guidance for stability testing of soft gelatin capsules, there are a couple of guidelines available that will help evaluate the storage conditions and length of study required for specific formulations of soft gelatin capsules. The guidelines indicate that testing of soft gelatin capsules should be evaluated in terms of appearance (including brittleness), color, and odor of content, assay, degradation products, dissolution, microbial content, pH, leakage, and pellicle formation.[22]

SUPPORT EQUIPMENT FOR ROTARY DIE SOFT GELATIN ENCAPSULATION MACHINE

i. Softgel Polisher

It consists of blankets and electric parts.You will use the Softgel polisher to give soft gelatin a smooth and shiny finish that appeals to the eye.

Figure:5

ii. Softgel Pulverizer

You will use it to recycle capsules that are not of the right shape or do not qualify for sale.It assists in saving costs and limiting waste.

Figure:6

iii. Softgel Sorting Machine
You can use it for sorting the Softgel pills and capsules. It will sort the soft gelatin capsules according to the diameter and other parameters.

Figure:7

iv. Inspection Machine
It assists in the inspection and elimination of all the negative aspects of the soft gelatin capsules. It assists in eliminating coarse chips and dust.

Figure:8

v. Medicine Mixing Tank
It consists of three layers including inner layer jacket, insulation jacket, and SUS 304 stainless steel. You can use it to thoroughly mix the active ingredients of the medicine.

Figure:9

vi. Gelatin Melting Systems
You will use this machine for melting gelatin at a faster rate than that of the encapsulation machine.

Figure:10

vii. Moving Gelatin Melting Tank
It consists of a glue melting technology for melting gelatin. It can control the melting temperature of the system thus maintaining constant melting rates.

Figure:11

viii. Gelatin Service Tank
You will use the gelatin service tank for providing extra services to gelatin.

Figure:12

ix. Medicine Service Tank
You can use it in the provision of extra services to the medicine you intend to mix. It will assist in maintaining right pressure and temperature among others.

Figure:13

x. Vacuum Mixer

It allows you to mix all the necessary ingredients in a vacuum. This allows very minimal interference from other ingredients in the environment.

Figure:14

xi. Colloid Mill

You can use the colloid mill for emulsification, homogenizing, and mixing of different types of emulsions and semi-liquids.

Figure:15

xii. Drying Trays

With the help of the drying trays, you can move Softgel capsules from the tumble dryer. It will assist you in transporting capsules to the drying tunnels.

Figure:16

Of course, you will also need a tumble dryer. It is a critical aspect of rotary die process soft gelatin capsules manufacturing.

Figure:17

xiii. Softgel Tooling

The component assists in shaping of the capsules to the shape you desire. It consists of different shapes that will match the shape of capsule you desire.

Figure :18

Softgel tooling system With that in mind, we will proceed to the last section of this guide.[23]

HARD GELATIN CAPSULES FILLING PROCESS

It goes without saying that the hard gelatin or hard shell gelatin capsule filling process is not possible without a machine. There is a wide array of equipment available ranging from small scale manual filling to intermediate level, semi-automatic and fully automatic large scale

machines. They can also be hand-filled and compounding pharmacy is an example of that.

Powder Formulation Filling in Hard Gelatin Capsules

Hard gelatin capsules can also be filled manually using hands for research purposes. Place the powder on a clean paper or porcelain plate and press the open end of the capsule downward till the time it is filled. Now place the cap to close the capsule. In any small scale manufacturing unit, hard gelatin capsules are filled manually using a hand operated machine. Hand operated capsule filling machines come in a variety of capacities ranging from 24 to 300 capsules. You can also produce about 200 to 2000 capsules per hour by focusing a bit more on efficiency. In short there are three major different types of capsule filling machines uses to fill empty hard gelatin capsules.

Manual Capsule Filling Machines

The manual capsule filling machine is a great, affordable option for small to medium-sized batches. Numerous sectors, including the production of pharmaceutical, herbal, nutritional supplement, and herbal goods, use this 300-hole machine. Hard gelatin capsules containing powders and granules are filled and sealed using an Adinath manual capsule filling machine. Due to the fact that it has a bed with 300 holes and a tray with the same number, this machine is also known as a 300 hole capsule filling machine. Additionally, the machine has a lever, a pressing plate with a rubber cap, and a pin plate. Depending on the machine's size and model, a large number of capsules can be filled every hour without any problem from the equipment. Additionally, it can handle capsules of different sizes, ranging from 00 to 5, using multiple machines and interchangeable parts.

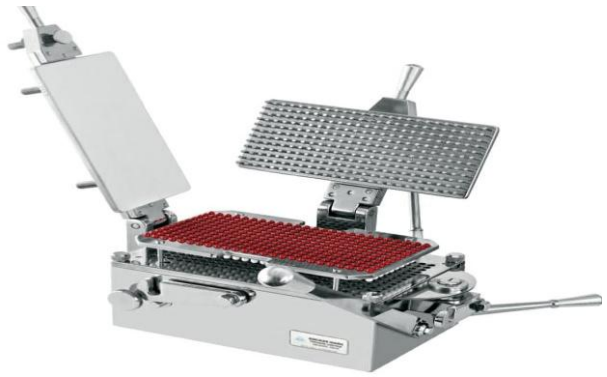

Figure:19

Semi Automatic Capsule Filling Machines

Modern pharmaceutical operations that require precise manufacturing techniques are perfect for applications requiring the ASCF Series Semi Automatic Capsule Filling Machine. The Semi Auto capsule filling machine provides a higher level of automation when compared to a manual capsule filling machine, ensuring improved filling weight accuracy. This semi automatic capsule filler can be used to fill capsules of different sizes with powders, granules, or pellets. The façade of the GMP-compliant semi-automatic capsule filling machine is built entirely of stainless steel. Depending on the size of the capsule and the operator's skill level, the machine may generate large volumes ranging from 25000 to 45000 capsules per hour. It performs online sorting and polishing activities, which eliminates the need for storage for filled capsules and operator requirements for polishing purposes.

Figure:20

Automatic Capsule Filling Machines

The most cutting-edge hard capsule filling equipment designed to increase production quality and speed is the fully automatic capsule filling machine. The machine complies with current cGMP regulations. It is a well-versed variant with new, advanced loading and considerably better electronic. The equipment can handle capsules from any global suppliers thanks to its separating system. We provide a fully automatic capsule filling machine that is made to dispense powder, pellets, and granular substances into firm gelatin capsules. Our automatic capsule filler is a high-quality performer. It can be trusted to accurately fill empty gelatin capsules. It's quite simple to use this completely automated capsule filling machine. It has a smooth operation and is simple to maintain and clean. Large scale manufacturing units have a number of machines at their disposal. These machines are semi-automatic as well as automatic and you can expect huge production capacities ranging between 3000 to 1,50,000 per hour. You must know that in large scale units the filling process depends on one of these two dosing devices- dosing disk/tamping device or dosator device.

Figure:21

CONCLUSION

Because of the aforementioned premises, capsules are solid preparations containing either a soft or hard soluble shell for the drug substance or excipient. The shell, which is typically made of gelatin or another suitable polymeric material, produces a straightforward, tasteless, odorless, elegant, and simple dosage form that does not require a secondary coating step. Contingent upon the arrangement of the case shell, cases might be named either hard or delicate container, with delicate cases having an adaptable, plasticizedgelatin film. The shells may be made up of two pieces that are cylinders with one end closed; the shorter piece, which is referred to as the "cap," and the longer piece, which is referred to as the "body," or they may be made up of a single piece. Hard-shell capsules and soft-shell capsules, respectively, are common names for the two-piece and one-piece capsules.

Dry powders, semisolids, nonaqueous liquids, and other dosage forms, such as beads, mini-tablets, and even mini capsules most of which are intended for oral administration—can all be stuffed into capsules. There are additionally specialty applications such as cases that can be stacked into dry-powdered inhalers, add reagents as a feature of a symptomatic unit, and incidentally delicate shell containers planned for rectal or vaginal addition as suppositories. Additionally, new developments have led to the discovery of non-gelatin capsules that lack gelatin as a shell-forming ingredient. Under this class of casesare the HPMC, PVA and starch cases. The fundamental components of these capsules, regardless of the type, include, but are not limited to: gelatin, plasticizer, colorants, opacifying specialists, additives, water, thickening specialists, enhancing specialists, improving specialists, and so forth.

A dip-coating process is used to produce hard gelatin capsules. This process involves preparing the gelatin solution (dipping solution), dip-coating it on metal pins (moulds), rotating the dip-coated pins, drying the gelatin-coated pins, stripping and trimming, joining the trimmed capsule shell, and printing. Likewise, the essential moves toward filling hard gelatin containers incorporate; fixing the capsules, separating the bodies from the caps, dosing the fill material, replacing the caps and closing the capsule shells, and ejecting the filled capsules. Other processes include locking and sealing, polishing, and brushing. On the other hand, softgels are produced utilizing the following techniques; plate method, rotary die method, reciprocating die method, accogel method, and seamless method. Filling and manufacturing of the soft gelatin take place simultaneously.

In-process testing, shelf-life testing, and finished product testing are all part of the quality control process.

Soft gelatin capsule drug products undergo in-process quality control tests at predetermined intervals during product manufacturing, which include; Gel ribbon thickness and uniformity across the ribbon, softgel seal thickness at encapsulation, capsule fill weight and variation from capsule to capsule, capsule shell weight and variation from capsule to capsule, and capsule shell moisture before and after drying The most important in-process tests for hard gelatin capsules are visual inspection, fill weight, and fill-weight uniformity. Additionally, the following are the finished product quality control tests for capsule drug products: potency and impurity content, permeability and sealing, weight variation test, weight variation test for hard gelatin capsules, weight variation test for soft gelatin capsules, uniformity of content, capsule disintegration time test, capsule dissolution test, moisture content, moisture permeation test, and microbial content While capsule stability is tested during the shelf-life test, Filleted capsules are packaged with the primary intention of preventing contamination and moisture loss during long-term storage. They are packed in a blister of plastic, a strip of aluminum foil, glass, or a variety of other materials to keep the capsules from being exposed to excessive humidity. However, long-term storage necessitates maintaining the appropriate temperature and humidity levels.[24]

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