

# SOFT GELATIN CAPSULE

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# Soft gelatin capsule

## DEFINITION:-

soft Gelatin capsules are one piece, hermetically sealed, soft gelatin shells containing a liquid, a suspension, or a semisolid.

The Nomenclature for this dosage form has now been changed to soft gel .

They have long been preferred dosage form for those, taking Health & Nutritional supplements.

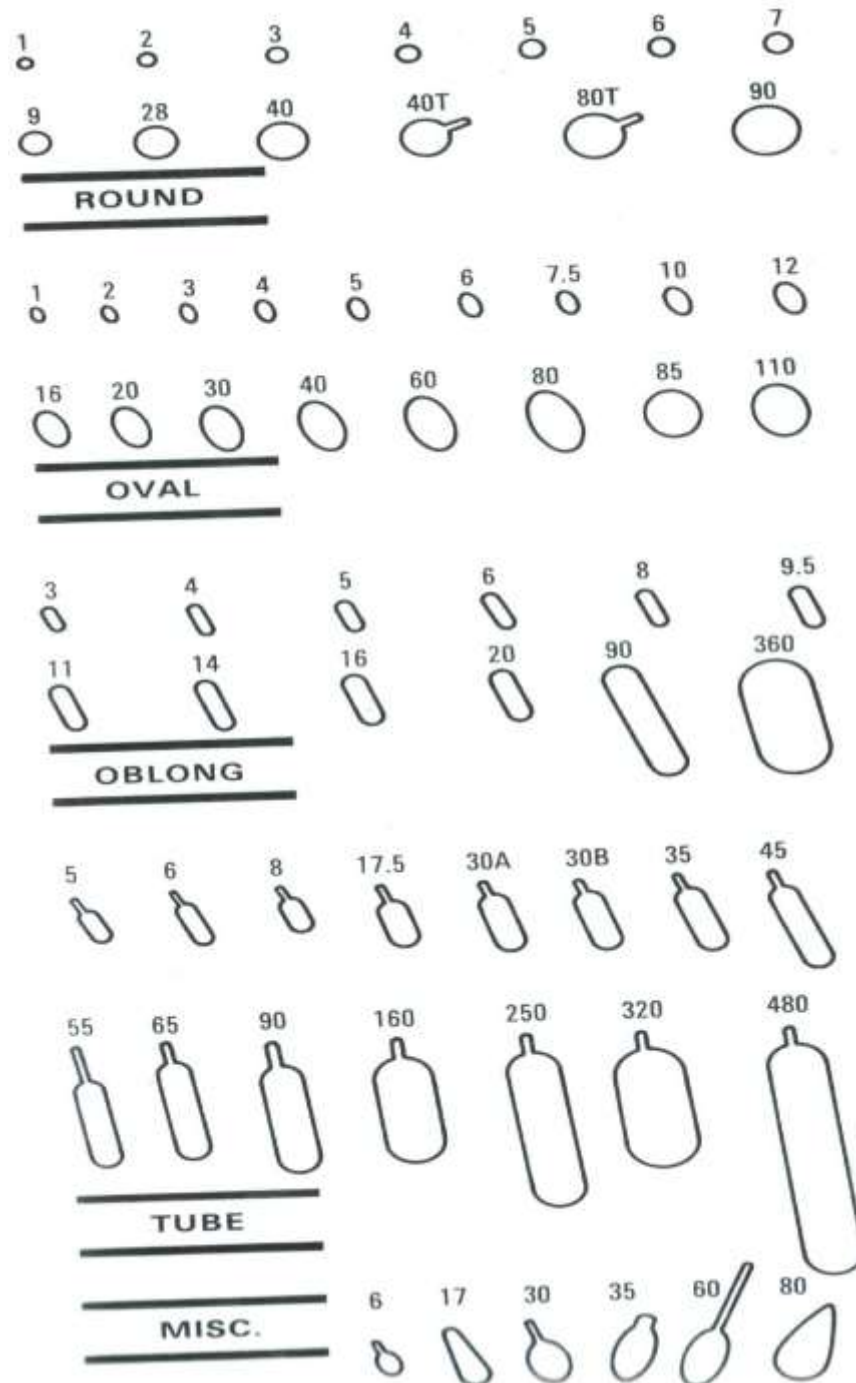
# ADVANTEGES

- ▶ Easy to administer
- ▶ Easy to Manufacture
- ▶ Liquids can be encapsulated ( non water soluble)
- ▶ Small to large sizes possible
- ▶ Elegance
- ▶ Portability
- ▶ Odour and taste masking
- ▶ Ready availability of drug hence faster action.
- ▶ Specialised dosage forms can be made e.g. chewable, extended release, captabs etc.
- ▶ Can be used for ophthalmic preparations e.g. aplicaps, vaginal / rectal suppositories

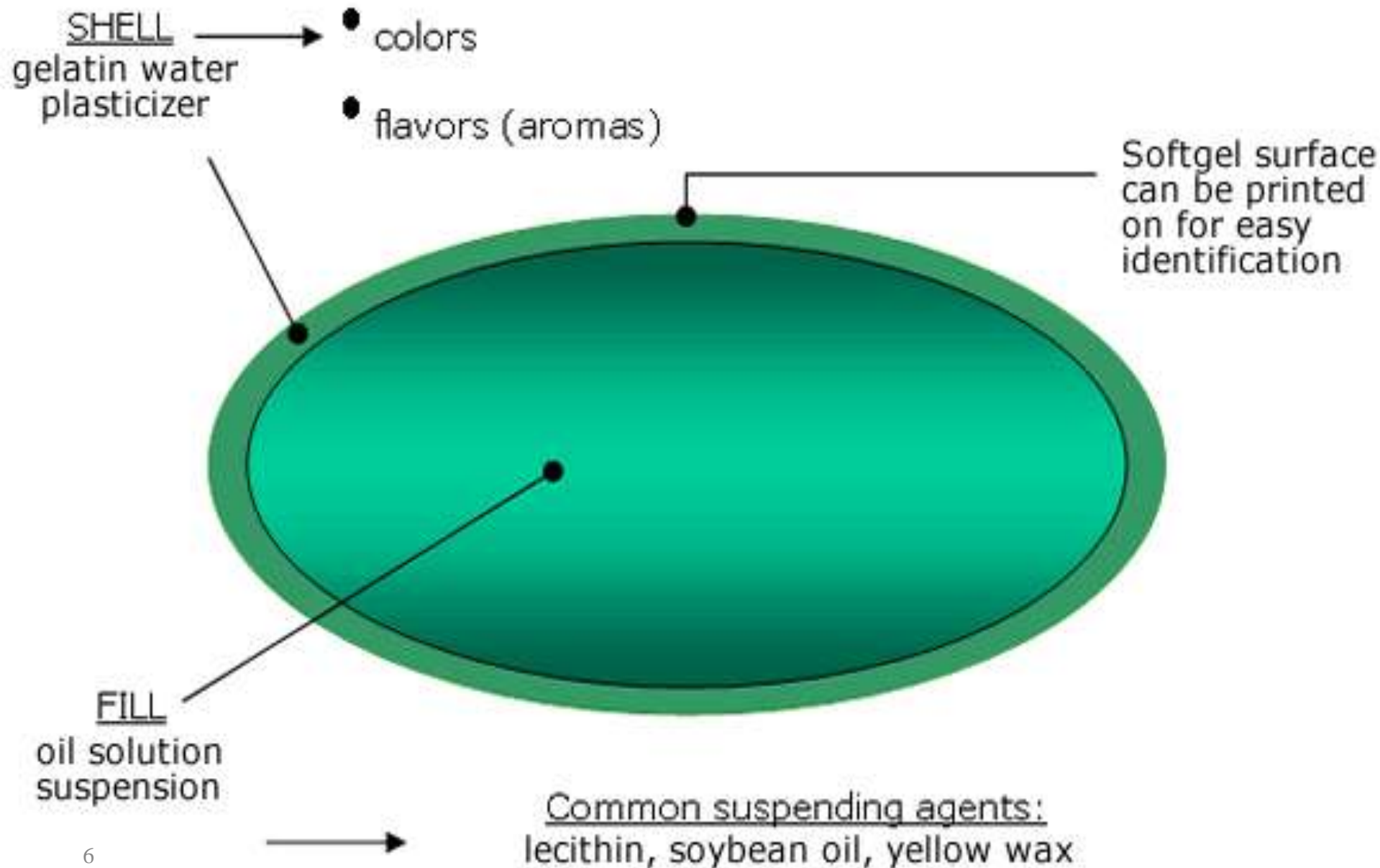
# DISADVANTAGES

- ▶ Water soluble material are difficult to incorporate
- ▶ Highly Moisture sensitive
- ▶ Efflorescent material cannot be incorporated, they may cause softening / leaching
- ▶ Deliquescent materials cannot be incorporated, they may cause hardening or brittle capsules.

# Shapes of Capsules -



# Anatomy of a Softgel



# CAPSULE SHELL

The capsule shell is basically composed of Gelatin, a plasticizer & water, it may contain additional ingredients such as preservative, coloring & opacifying agents, flavorings, sugars, acids & medicaments to achieve desired effects.

**GELATIN:**-Obtain from partial hydrolysis of collagen derived from the skin, connective tissue & Bones of animals.      may have viscosity of 38 mpa

Bloom strength:-150-250

cost of gelatin  $\propto$  Bloom strength

# IMPORTANT SPECIFICATIONS OF GELATIN

**Bloom or gel strength:** It is a measure of cohesive strength of cross-linkage that occurs between molecules and is proportion to the molecular weight of gelatin.

Bloom is determined by measuring the weight in grams required to move a plastic plunger of 0.5 inches in diameter, 4mm into a 62/3% gelatin that has held at 10°C for 17 hrs.

The unit of bloom is grams and it is between 150-250g



**Viscosity:** Is determined on a 62/3% gelatin of water at 60°C and it is a measure of the molecular chain length.

Standard used: 25-45 milli poise.

**Iron content:** Iron is always present in raw gelatin, and its concentration usually depends on the iron content of the large quantities of water used in its manufacture .

amount should not exceed 15ppm.

# Capsule shell

WATER:-n.m.t. 45% w/w •

The ratio by weight of water to dry gelatin can vary •  
from 0.7 to 1.3(water) to 1.0(dry gelatin) depending on  
the viscosity of the gelatin being used.

PLASTICIZER:-Used to make the soft gel shell elastic •  
& pliable.

Ratio used is between 0.3 to 1.8 for soft to hard shell •  
on dry basis.

E.g. glycerin , sorbitol •

COLOUR used in shell has to be darker than •  
colour of encapsulating material

colours may be natural or synthetic.

OPACIFIER, usually titanium dioxide, may be •  
added to produce an opaque shell ,when the  
fill formulation is a Suspension or to prevent  
photo degradation of light sensitive fill  
ingredients. Conc. Of opacifier may be up to  
0.5%

Chelating Agents:- Iron is always present in raw ➤  
gelatin, & should not contain iron more than 15  
ppm

Additionally chelating agent may be used for •  
preventing the reaction of iron with materials or  
colours.

## FILL FORMULATION

To dispense active compounds formulated as:

- 1) Liquids
- 2) Semisolids
- 3) Suspensions
- 4) Dry powders

They are formulated such that:

- (i) Smallest possible capsule, consistent with maximum amount of ingredient and it is physically stable.
- (ii) Therapeutically effective.
- (iii) Production efficiency.

## 1) LIQUIDS:

### (i) Water miscible liquids:

- PEG-400, polysorbates (non-ionic surfactants).
- 5-10% of propylene glycol, ethanol, glycerin.

### (ii) Water immiscible liquids:

- Vegetable oils, esters, ethers.
- Aliphatic & Aromatic chlorinated hydrocarbons.

### (iii) Liquids which can't be incorporated:

- Ethyl alcohol, aldehydes
- Water- in more than 5% of total formulation
- Liquids with extremes of pH, emulsions.

## 2) SUSPENSIONS:

- Suspending agents.

### (i) For water miscible vehicles:

- Solid glycol ester.
- High molecular weight PEGs.

### (ii) For water immiscible vehicles:

- Paraffin wax.
- Bees wax.
- Hydrogenated vegetable oils





# METHOD OF MANUFACTURING

Soft gelatin capsules are manufactured by four methods:

- 1) PLATE PRESS METHOD
- 2) ROTARY DIE PROCESS
- 3) ACCOGEL PROCESS
- 4) BUBBLE METHOD





# Gelatin Mass Manufacture

The gel is prepared in a 300-litre stainless steel vessel.



Gelatin powder is mixed with water and glycerine.

Heating ↓ Stirring

The molten gelatin mass is formed.



It is decanted into 200-kg mobile vessels.

Turbine mixing ↓

where colours and flavours can be added.



It ensures consistency of gelatin mass.



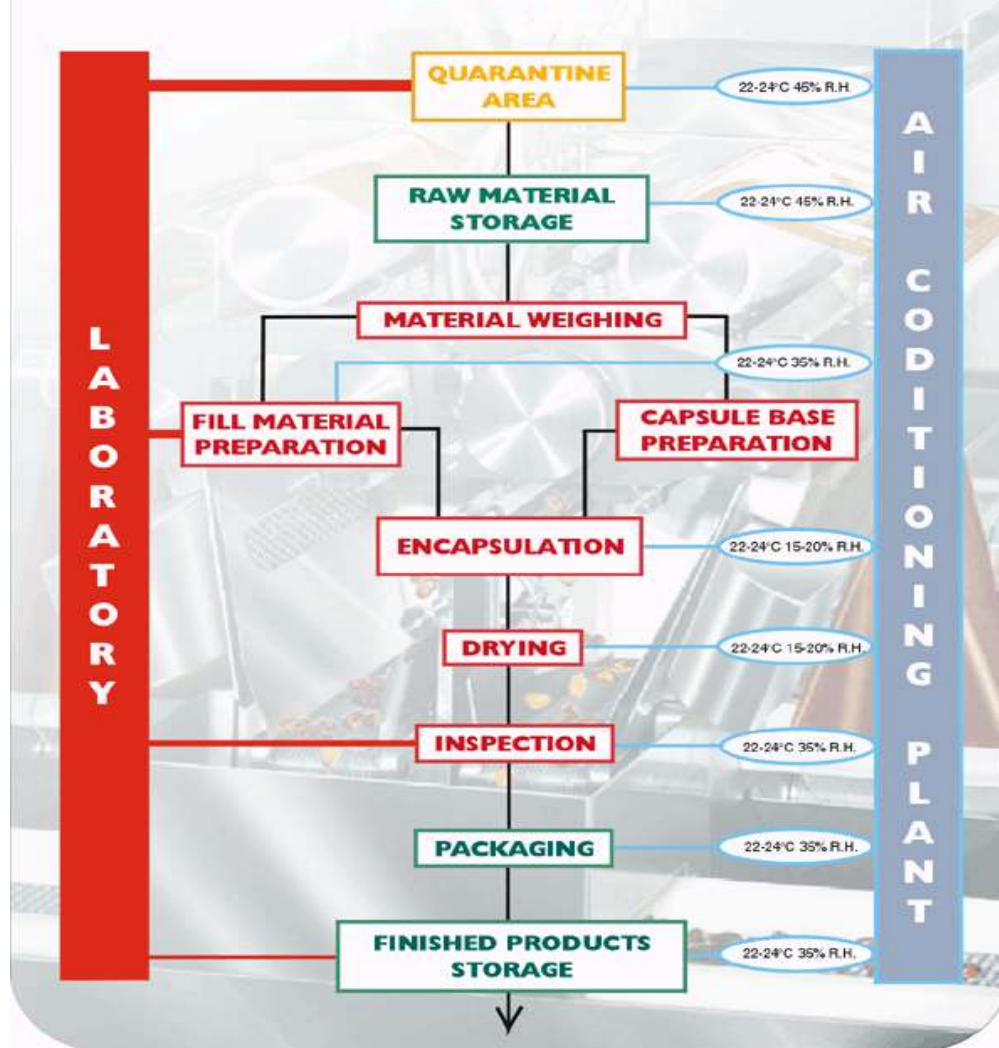
This mass is kept at a constant temperature until it is needed for the next stage of the process.

Solids that are not Sufficiently soluble in liquids or in combination of liquids are capsulated as Suspension.

Suspending agents used are

Lecithin, Soyabean oil, yellow wax.

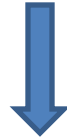
# ENCAPSULATING PLANT LAYOUT



# Manufacturing process

## Encapsulation •

The gel and fill mobile vessels are then taken to the encapsulation bays.



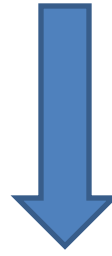
Where each encapsulation machine is segregated in individual bays.



The molten gel is pumped to the machine.



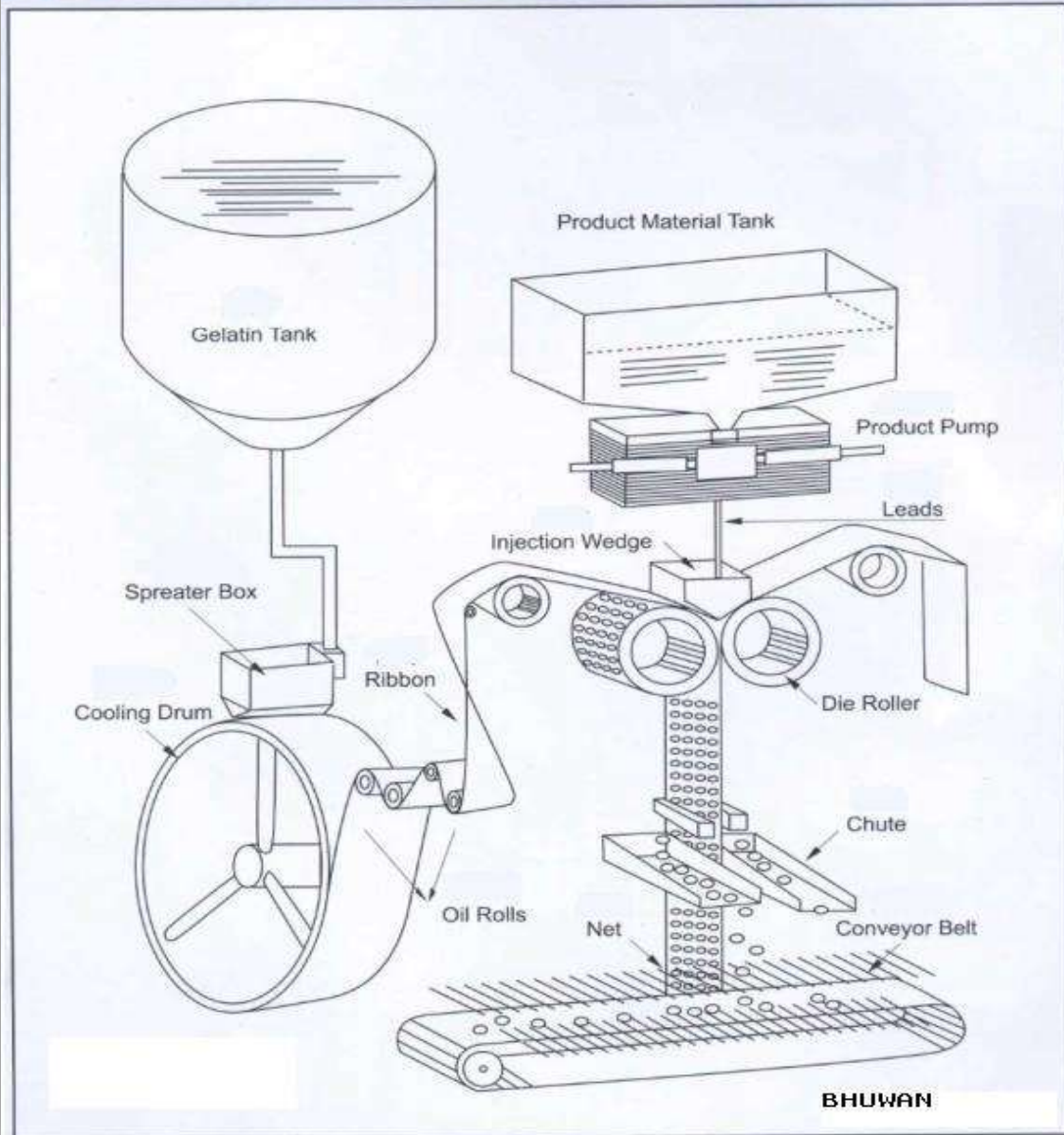
Two thin ribbons of gel are formed, one either side of the machine.



These ribbons then pass over a series of rollers and over a set of dies that determine the size and shape of the capsules

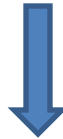
# ROTARY DIE ENCAPSULATING MACHINE

ROTARY DIE ENCAPSULATING MACHINE FOR SOFT GELATIN CAPSULE



# Capsule Manufacturing

## Encapsulation



**Tumble Drying :-** Dry, sterile air is forced across the tumbler and removes the moisture from the outer surface of the capsules.



**Supplemental Drying (curing):-** After the tumbler dryers, the soft capsules are placed on special trays for final drying in the drying room. For a period up to 48 hrs.



Sizing:- Automatic capsule sizing machine eliminates undersized and oversized capsules.



Inspection:- includes visual inspection to check malformed, damaged or improperly filled capsules.



Packaging:- capsule may be packaged in glass or plastic containers or may be strip-packaged, so long as such packaging involves tight closures & plastics having a low moisture vapor transfer rate.

# PRODUCT QUALITY CONSIDERATIONS

## 1-Ingredient specifications •

all ingredients of a soft gel are controlled and tested to ensure compliance with pharmacopoeial specifications.

E.g. Impurities such as aldehydes & peroxides ➤ which may be present in polyethylene glycols. Presence of high levels of these impurities gives rise to cross-linking of the gelatin polymer, leading to insolubilization through further polymerization.

## 2-In-process testing

During the encapsulation process the four most important tests are:-

The gel ribbon thickness;

Soft gel seal thickness at the time of encapsulation;

Fill matrix weight & capsule shell weight;

Soft gel shell moisture level and soft gel hardness at the end of the drying stage.a

# Finished product testing

These normally includes

- Capsule appearance,
- active ingredient assay & related substances assay
- Fill weight
- Content uniformity and
- Microbiological testing.

# VEGICAPS SOFT CAPSULES

- Vegicaps® Soft capsules are an alternative animal free capsule. The shell is made from seaweed extract and gluten free starch, and contains no modified sugars or artificial ingredients. The shell can be clear or coloured and there is a wide range of shapes, sizes and colours available.

An alternative to gelatin for those who prefer an •  
animal free product

Those with a level of concern about animal- •  
derived products

Vegetarians •

Those with religious or cultural restrictions •

Consumers looking for the most natural •  
alternative.

## **Benefits of Vegicaps® Soft capsules •**

Free of all animal derivatives – no pork or beef content. •

Easy to swallow •

Soft •

Natural •

Perception of a healthier product •

Plant based shell •

Low shell odour. •



THANK YOU

