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APPARATUS AND PROCESS FOR ENCAPSULATING CAPSULES OR TWO DOSAGES FILL WITHIN ONE CAPSULE CONTAINING THREE RIBBONS

Supriya Ahinave*

Scientist, Olive Healthcare 197/2 Athiyawad Dabhel Village Nani Daman, Daman, India.

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***Corresponding Author**
Supriya Ahinave
Scientist, Olive Healthcare
197/2 Athiyawad Dabhel
Village Nani Daman,
Daman, India.

ABSTRACT

The present invention provides an apparatus and process for making softgel capsules having incorporated therein two dosage forms selected from the group consisting of paste, liquid, dispersion, suspension, Sustained release dosage forms, immediate release dosage forms, extended release dosage forms and Zero order release dosage forms, said apparatus comprising : (a) three spreader boxes; (b) three casting drums; (c) a pair of rotary dies having means for Suction; (d) a liquid fill system connected with separate hoppers; (e) segment which divides into two parts, one ribbon is passing into these segment, which having two partition two different type of medicament fills which attached into the two different hoppers. (f) A wedge for heating gelatine ribbons and feeding said fill; and (g) two hoppers having said separate dosage forms, channel guides for transporting two different dosage forms which fill medicament into the softgel capsules both side pocket formed in the rotary dies.

DESC: This invention relates to methods and apparatus for the production of soft gelatin capsules containing internally two parts having three ribbons.

The capsules of the invention are now well established as a means for providing a variety of liquid products Such as drugs and dietary Supplements in a readily ingestible form especially when two drugs are not compatible with each other.

This invention further relates to softgels (or soft gelatin capsules) containing one or two medicaments fills into one capsule and to a process and apparatus for the manufacture

thereof. The present invention also relates to a gelatin capsule of the Soft type containing multiple active ingredients or the like, and more particularly to a novel gelatin capsule capable of containing two medicines or dietary Supplement as the content separated from each other, and its manufacturing method and manufacturing apparatus. The present invention also relates generally to a method and apparatus for forming capsules containing two parts because of three ribbons a measured amount of not compatible medicinal and more particularly to a method and apparatus for forming capsules. The method and apparatus of the present invention are particularly useful in connection with forming pharmaceutical product of softgel capsules having two parts which containing any two different types of dosage forms in one capsule, Such as for example medicines, Immediate release, sustained release, clear liquid, suspensions, paste, clear liquids and like which are not compatible with each other.

The present invention further relates to encapsulation machines and, more particularly, to soft encapsulation machines which make three Soft gelatin ribbons which forming two parts of capsules which contains two different types of medicament dosage form.

The invention is particularly useful for making formulations wherein two active ingredients are not compatible with each other but it is desirable to administer them in the same dosage form i.e., a capsule containing two type of medicine dosage form within a capsule.

SUMMARY OF THE INVENTION

The present invention responds specifically to the long-felt need theretofore unmet by the prior art, and especially with a view to overcoming the inherent inadequacies of combination of pharmaceuticals that are not compatible for oral delivery to mammals. The composition is a pharmaceutical combination i.e., a capsule containing two different type of dosage providing the convenience and reliability of oral administration, while providing near simultaneous delivery in vivo of incompatible substances. The composition is shelf stable when formulated.

The foregoing, and other advantages of the present invention, are realized in one aspect thereof in an oral pharmaceutical composition that is a combination of incompatible active ingredients. The composition comprises a double soft capsule which includes one pharmaceutical in a first capsule which is enclosed second soft capsule also containing a

second active ingredient. The Soft capsules are preferably made of gelatin. The active ingredients may be combined with acceptable grade carriers.

In another aspect, the invention is a method of simultaneously delivering incompatible compounds to mammals in vivo. Such delivery is achieved by administering orally to a mammal a double soft capsule containing a first Substance in a first capsule, which is enclosed with a second Substance, incompatible with the first Substance, in a second larger soft capsule. In another embodiment, this invention provides a method for preparing shelf-stable compositions of incompatible substances, which includes the use of multiple capsules of variable composition. Such method is accomplished manually or by the apparatus of the invention further described below.

As used herein, the term “incompatible' is meant to refer to substances which deleteriously react with one another when combined in desired levels or concentrations.

The invention also provides an apparatus for making soft gel capsules having two parts therein two different type dosage forms selected from the group consisting of Sustained release dosage forms, immediate release dosage forms, extended release dosage forms and Zero order release dosage forms, said apparatus comprising: (a) three spreader boxes; (b) two hoppers; (c) three casting drums; (d) a pair of rotary dies having means for Suction; (e) Segment which having middle section to transfer the third ribbon and both side dosing holes which separately attached by both hoppers; (f) a liquid fill system; dosing tubes which attached by two hopers and both side of segment; (g) a wedge for heating gelatin ribbons and feeding said fill.

The instant invention also provides a method for making softgel capsules having two different type of dosage forms which is separated by third ribbon, (a) three casting drum with three spreader boxes; (b) passing two films through a pair of rotary dies and third one in the segment; (c) feeding Smaller dosage forms into pockets using dosing tubes which separately attached by two hoppers; (d) filling pockets with a medicine formulation through segment with both sides of third ribbon; and (e) forming said capsule by sealing the pockets together.

A material fill mechanism is used to supply the fill material that is encapsulated within the soft capsules. When the fill material is a liquid, such as a liquid medication the fill mechanism includes a two separately hoppers which having separately dosing tubes which

connected by the segment having two parts. One ribbon is pass through in the segment which having systematically partition. One part is connected with one hopper and another part of segment which connected second hopper bye dosing tubes. Bothe hopper containing different medicament like

Sr.No	Hopper 1	Hopper 2
1	Clear Liquid	Clear Liquid
2	Suspension	Clear Liquid
3	Sustained Release	Immediate Release
4	Paste	Clear Liquid

The invention is also a process for making a softgel capsule having two different type of medicament, (a) feeding film sheets between a first die roll and a second die roll and third one is in the segment which having to space; (b) Designing the segment having divided into the two parts, Having separate dosing which is from two sides of middle ribbon, (c) arranging the two hoppers for two different types of medicaments. Hoppers connected bye segments one side each. (d)Machine having three casting drums including three spreader boxes and casting rollers.

The invention further provides softgel capsules two different types of medicines or two different types of Active Pharmaceutical Ingredients fills in one capsule having two pockets or two partitions at a same time.

The instant invention also provides a softgel capsule having one is immediate release dose and other is sustained release dose presence in one single capsule. (a) one side of the capsule contains Dutasteride fast release and the other side Tamsulosin Hydrochloride dosage form which is sustained release; (b) one side of the capsule contains Paracetamol suspension and the other side Ibuprofen clear liquid dosage form; and (c) one side of the capsule contains Paracetamol suspension and the other side Paracetamol clear liquid dosage form.

CLAIMS: 1. The art of the encapsulation has been known for many years, particularly for the production of unit dosage forms containing various pharmaceutical products. Normally, Such as pharmaceutical capsules are composed of gelatin or some modification thereof, which is fabricated essentially into two different forms, namely, the so-called hard gelatin capsule and the Soft gelatin capsule.

It is also known that conventional soft gelatin capsules are a preferred from of administration for medicaments and similar products; especially liquids, pastes, Solids dispersed in liquids, or dry solids. Soft gelatin capsules also possess particular advantages for Substances which require total protection from air and light, because the gelatin is completely sealed around the contents. An important example is for the encapsulation of vitamins, which has resulted in a high degree of stability thereof.

Hard gelatin capsules are also known in the art, and are generally formed from two distinct parts, namely the “cap' and the “body, fitting one into the other so as to form the complete capsule. The cap and the body are manufactured by the same process consisting of immersing in a gelatin Solution the end of a mandrel whose form corresponds to the inner volume of the cap or of the body, then withdrawing the mandrel from the solution and letting the layer of gelatin thus deposited dry, which is then removed like a glove finger. Hard shell capsules so formed have problems of leakage and do not provide adequate protection from air and light.

Soft gelatin capsules, now more commonly known as Soft gels, have been well known and widely used for many years. Softgels generally comprise an outer shell primarily made of gelatin, a plasticizer, and water, and a fill contained within the shell. The fill may be selected from any of a wide variety of substances that are compatible with the gelatin shell. Softgels are widely used in the pharmaceutical industry as an oral dosage form containing many different types of pharmaceutical and vitamin products. In addition to use as an oral dosage form for drugs and vitamins, soft gelatin capsules or softgels are also designed for use as Suppositories for rectal or vaginal use. Other uses are for topical and ophthalmic preparations and the like. The cosmetic industry also uses softgels as a specialized package for various types of perfumes, oils, shampoos, skin creams and the like. Softgels are available in a great variety of sizes and shapes, including round shapes, oval shapes, oblong shapes, tube shapes and other special types of shapes such as stars. The finished capsules or softgels can be made in a variety of colors. Also, opacifier may be added to the shell.

With the new claim and process, process for making softgel capsules includes the step wherein the gelatin shell and the fill material come together to form Softgel capsules. It takes place in a closed environment called clean room where the relative humidity is around 20%. The gelatin shell and fill material are brought together simultaneously in the encapsulation machine. The process is basically performed as follows: a pump delivers the warm gelatin over three chilled drums which are located at both opposite sides of the machine and third is

behind the machine which will be twisted using guiding rollers, through a spreader box that sits over each drum. The warm liquid gelatin flows over the drums and this transforms the liquid gelatin into two solid ribbons of gel. The left and right ribbons pass over rollers which feed them through two die rolls. These die rolls determine the shape and size of softgels and cut the Softgel shell from the ribbons as they turn around. Simultaneously, a sensitive and high accuracy positive displacement pump delivers the fill material into a heated wedge which sits between rotary dies. This wedge injects the fill material into the die cavities between ribbons just right before the die rolls cut the ribbons and seal the two halves together. Warm just formed softgels slide gently through a chute onto a conveyor belt which carries them to the tumble dryer where cooling and drying process takes place. In more specific detail, typical soft encapsulation machines form at least two flexible gelatin sheets or ribbons by cooling molten gelatin on separate drums then lubricating and guiding the sheets into communication with each other over co acting dies while simultaneously dispensing a desired quantity of fill material between the sheets in synch with cavities in the outer surfaces of the dies to produce soft capsules. The encapsulation machines typically utilize gearing to control the relative rotations of the various components and fill mechanisms to synchronize the operation of these various components. The synchronization of these various components, however, can vary depending upon a variety of factors, Such as the particular dies used, the number of cavities and the size of the cavities on the dies, and the type of material used to form the sheets. To change the synchronization of the various components, mechanical gears are required to be changed to obtain the desired ratios and synchronization of these components. The changing of gears, however, is time intensive. Additionally, the use of mechanical gears provides finite gear ratios which limit the synchronization of the various components to the mechanical gears that are available. Thus, it would be advantageous to provide a capsule machine wherein the synchronization and rates at which the various components operate can be altered without the necessity of changing gears. Additionally, it would be advantageous if the synchronization between the various components can be infinite to thereby allow more precise synchronization between the various components. It would also be advantageous to allow various components, such as the fill mechanism, to be adjusted independently of the other components while the machine is running to allow for adjustments of the timing of fill material inserted into each of the soft capsules. It would also be advantageous to eliminate the use of casting drums in the making of softgel capsules.

During the operation of the capsule making machine, the contact between the adjacent dies can be adjusted by the operator of the capsule making machine. Typically, the operator is able to move one of the dies closer to the other die so that the pressure or force exerted on the sheets passing between the adjacent dies can be adjusted. Such adjustments, typically are mechanical adjustments made by fluid actuators, such as pneumatic cylinders. The operator is able to adjust the pneumatic pressure thereby altering the force the dies exertion one another and on the sheets. This adjustability allows an operator to customize the pressure to ensure that quality soft capsules are produced. However, the dies are susceptible to premature failure and/or wear when the pressure or force between the two dies is more than that required to produce acceptable soft capsules. Thus, it would be advantageous to monitor/record the pressure applied to the dies so that quality capsules are produced without inducing excessive wear or premature wear on the dies.