Compressed Coated Tablet: A Review

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***Abstract*-The number of products based on novel drug delivery systems has grown dramatically in recent years, and it is anticipated that this trend will continue. When it comes to dose forms, tablets are more relevant and convenient than other types. Tablet dosage form innovation yields a product with greater medication selectivity for medical treatment. Drug delivery technologies have advanced to such an extent in recent years. This article aims to list some of the drug delivery technologies that have been most effectively marketed. The innovation in tablet systems, or tablets in tablet systems, is the main topic of this review. The transformation of an existing therapeutic molecule from its conventional form into the stated technology can lead to improvements in patient compliance, safety, and efficacy.**

***KEY WORDS* -New drug delivery system, Tablet, safety, efficacy.**

I . INTRODUCTION

Because of its ease of use, affordability, and sophistication, the tablet is the most widely utilized dosage form out of all those that are now available. Coating processes determine the aesthetic qualities, such as texture, color, mouthfeel, and taste masking. Although there are some limitations or drawbacks to this coating technology, a compressed coated tablet is one of the finest substitutes.[1]

In addition to providing the medication with chemical and physical protection, coating also alters the drug's release characteristics. In the 1800s, modern pharmaceutical coating, or sugar coating, was used to cover up the harsh taste. There are significant limitations and drawbacks to sugar coating. It requires a lengthy processing time, often up to seven days, and requires multiple steps (sealing, subcoating, smoothing, coloring, polishing, etc.) that demand a professional operator. Other issues with it include an unautomated coating process, weight gain, and a sugar solution that is prone to bacterial growth, all of which prompted the development of alternative coating methods. Film coating significantly shortened the manufacturing time needed for sugar coating. Abbott Laboratories introduced the first film-coated tablet to the market in 1954. The film coating revolutionizes coating technology the fastest, provides batch-to-batch consistency in formulation development, may be used with a variety of dosage forms, and allows for simple process automation and control. Both the organic and aqueous-based polymeric solutions were simple to utilize in the film coating process, but they each have drawbacks. The flammability, toxicity, solvent residue in the film, and expense of the organic solvents used for film coating are some of the disadvantages of these solvents. The need for heat and a longer drying time in the case of aqueous film coating significantly raise the overall cost of manufacturing and represent a drawback.[2]

In a patent from 1896, Noyes was the one who initially described the compression coating method. One of the greatest options for creating a novel coating technique in the creation of a new medication delivery system is compression coating. In the pharmaceutical industry, it has been applied to several projects, including the development of programmable, colon-specific, pulsatile, and modified release. As per the diverse literature that is now accessible, press coating technology is employed in the creation of tablets such as compress coating tablets, like glipizide tablets that are intended to accomplish zero-order release.[3]

As an alternative coating method, tablet or compress coating is introduced to address the issues with film or sugar coating. It was among the first methods of solvent-free coating and is also known as a dry coating or press coating. An exterior coating shell and an inside drug core make up the two main components of a tablet, also known as a compression-coated tablet. Encircling the inner core, the outer layer primarily regulates the stability, medication release, and film coating strength.[4]

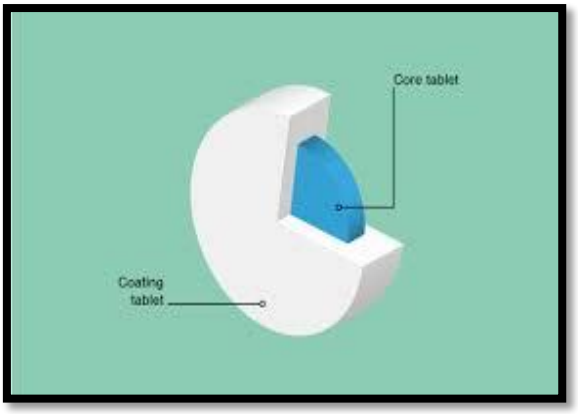

Fig 1. Compressed Coated Tablet

II. ADVANTAGES OF COMPRESSION COATING TECHNOLOGY [5]

- It is possible to separate incompatible material in the core and outer shell.
- It will be used to create a modified release product (such a delayed release product)

- Two distinct medicine tablets have the ability to target two distinct sections of the gastrointestinal tract.
- Press coating of the coating layer and core can eliminate the requirement for a separate tablet coating process.
- It is a solventless coating, so it is not hazardous to the environment.
- If a time interval is created in the release of concurrently delivered drugs, pharmacokinetic interactions (drug–drug) can be prevented in tablet dosage form.
- The Tablet in Tablet dosage form gives protection to the hygroscopic or thermo-liable drug.
- It is possible to produce both the immediate and sustained release effects of a distinct pharmacological combination or a similar drug in a single tablet dose form.

III. CHALLENGES RELATED TOCOMPRSSION COATING TECHNOLOGY [6]

- The cross-contamination possibility between the layers.
- There is a disparity in the elastic modulus between the adjacent layers. The large elastic modulus ratio between adjacent layers results in an insufficient layer adhesion and comparatively poor interfacial strength.
- Over time, maintain the device's chemical and physical integrity while storing it can provide issues.
- Due to the large tablet size, it creates a swallowing problem.
- The variation in coating efficiency when the system's core tablet is not positioned in the middle.

IV. MANUFACTURING PROCESS OF COMPRESSED COATED TABLET

As far as solid oral dose forms go, tablets are the most widely used and practical option. There are many different kinds of tablets. One sort of tablet is called a modified release dosage form, and because it has so many benefits, it is more significant in drug therapy. The compression coating technology is currently the best substitute for the bilayer tablet formulation for the incompatible drug when developing modified released products. Using specially made tableting machinery, granular materials are compressed around a prefabricated tablet core.
compression coating is also known as tablet in tablet or solvent-free–coating technique.

The two components of the compressed coated tablet dosage form are the inner core and the outer layer. A somewhat smaller tool than that used to prepare the exterior coat was used to prepare the internal core, which is a little tablet. Following the production of the internal tablet core, it is positioned in the center of another die that is somewhat filled with coating powder and larger than the core tablet. The remaining coating powder is then added to the top of the core tablet and compressed, creating a tablet inside a tablet. This procedure causes an issue where the core tablet may tilt when being transferred onto a different die. In order to provide a product with an instant release, the coat usually dissolves readily when taken orally and is water soluble. The compressed coated tablet can be used to create repeat action tablets by releasing the drug's initial dose first via the outer layer and then through the inner core later. The risk of overdose toxicity is indicated by the repeat action tablet in tablet dosage form, as the drug is rapidly released from the core tablet and reaches radically different blood levels.[3]

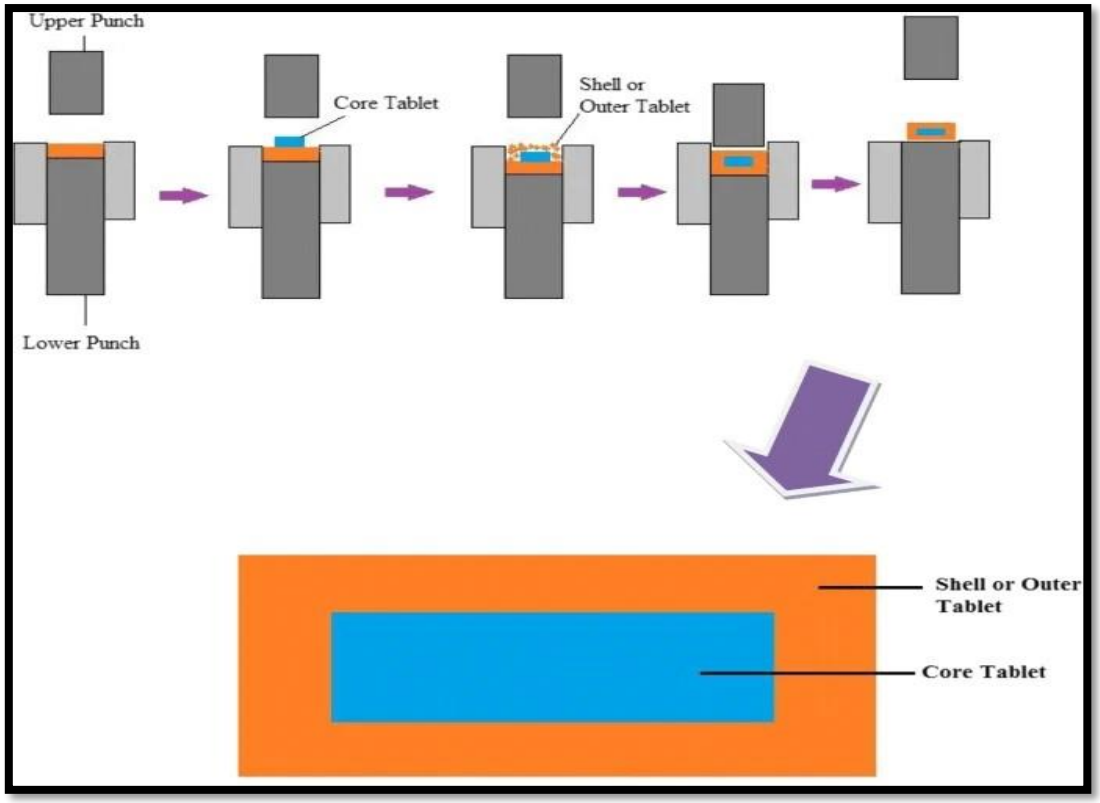

Fig 2. Manufacturing Steps of Compressed Coated Tablet

Hariharan and Gupta have also documented an additional technique for producing compressed coated tablets or tablets made from tablets. The core does not need to form independently when using this strategy. The core and coated tablets are produced simultaneously by the redesigned three-layer tablet machine. One side of the press is used to make the core tablet, and it is subsequently moved to the other side for coating. This coating technique forms an exterior layer of a coating mix in the shape of a cup first, followed by the trapping of core material and the formation of an additional outer coating layer on top. Beads, granules, microspheres, pure drug crystals, or drug-excipient mixtures can make up the core.[7]

The use of an IR spectrophotometric hydraulic press in tablet manufacture was documented by Lin et al. Production of tablets on a big scale is not a good fit for this press. The manual process needed to create a dry coated tablet is described by the author. First, fill the die with coating powder. Next, place the core tablet in the middle. Finally, apply compression force. The coating powder's thickness and particle size have an impact on the dissolving lag time, which can last anywhere from one to twenty hours. Smaller particles allow for longer lag times.[8]

V. EVALUATION OF COMPRESSED COATED TABLET [9-12]

The following quality control tests should carried out on compression coated tablet.

General Appearance

1. Size and Shape

Mechanical Strength of Tablet

1. Hardness
2. Friability

Content Uniformity

1. Weight variation test
2. Disintegration test
3. Dissolution test

General Appearance
The tablets distinctiveness and elegance are crucial for customer acceptability. The regulation of general appearance includes the measuring of size, shape, taste, color, odor, and other factors.

Size and shape
The dimensions and forms of a tablet may be precisely specified and regulated. The thickness of a tablet might vary. The tablet's thickness may be measured using a vernier caliper or another measuring equipment. The tablet thickness must be maintained within a variance of +/- 5% from the standard value.

Mechanical Strength of Tablet
The mechanical strength of tablet is determine mainly of by two tests as follow

Hardness
The tablet needs a certain level of hardness to endure mechanical vibrations during handling, manufacturing, packaging, and shipment. The tablet crushing strength, sometimes referred to as tablet hardness, is a measure of the tablet's resistance to breaking under pressure.

Friability
The determination of tablet friability may be conducted using a Roche friabilator in a laboratory setting. The Roche friabilator comprises a plastic chamber that rotates at a speed of 25 revolutions per minute. Tablets are released from a height of 6 inches inside the friabilator chamber, which is operated for a total of 100 revolutions. The tablets have been recalibrated. The permissible weight reduction of the pill to meet the criteria is below 0.1 to 0.5%.

Content Uniformity
A random selection of 30 pills was conducted. Among the 30 tablets, a total of 10 tablets were individually assessed for content consistency. The result is considered acceptable if 9 out of the 10 tablets have a drug content between 85% and 115%, and the remaining tablet has a drug content between 75% and 125%. If the requirement is not satisfied, the remaining 20 pills will be separately analyzed.

Weight variation test (U.S.P.)
This test involves individually weighing 20 tablets, calculating the average weight, then comparing the weight of each tablet to the average weight. If the number of pills outside the % limit does not exceed 2, then the result is considered acceptable.

Disintegration test
The disintegration test is conducted using a U.S.P. equipment specifically designed for disintegration testing. The apparatus has six glass tubes, each measuring 3 inches in length, with a #10 opening at the bottom and an open top. To conduct a disintegration test, insert one tablet in each tube and set the basket in a beaker containing water, simulated gastric fluid, or simulated intestinal fluid at a temperature of 37+/-2oC.
The basket, holding the tablets, undergoes vertical oscillation within a range of 5-6 cm at a frequency of 28-32 cycles per minute. To keep the tablets from floating during an exam, one may place perforated plastic discs on each tablet. As per the tests, the tablet should break down completely and all the particles of the broken tablet must pass through a #10 mesh located at the bottom of the tubes. If any remnants of the tablet are left, they should be in the form of a soft mass. The disintegration time required for uncoated tablets is 5-30 minutes, whereas for coated tablets it is 1-2 hours. The disintegration test is conducted specifically for the outer layer of the tablet when the tablet is formulated using the tablet-in-tablet technology and the outer layer is designed for quick release.

Dissolution test
Apparatus-1 (Basket type)
A little wire mesh basket affixed to the lower end of the shaft linked to a motor with adjustable speed. The motor was calibrated to rotate at a predetermined velocity. A solitary tablet is inserted into a basket and submerged in a dissolving liquid, as stated in the monograph, inside a 1000ml flask. The flask is kept at a constant temperature of 37+/-0.5oC using a temperature-controlled bath. The fluid is periodically extracted to ascertain the quantity of medication released in the solutions.
Apparatus-2 (Paddle type)
This apparatus is identical to apparatus-1, with the exception that the basket has been replaced with a paddle. Prior to commencing the test, it is permissible for the pill to descend to the bottom of the flask. The U.S.P. specifies the dissolving test's medium and volume, the kind of equipment used, the rpm of the shaft, and the time limit for the test.

CONCLUSION

The tablet is formulated in a tablet dosage form, with the core tablet containing an active component that is released in a sustained manner, and the outer layer releasing the medication immediately. This tablet has the capability to release both soluble and insoluble pharmaceuticals at a constant pace in a dissolving medium. Drugs that have a high water solubility may be decreased while maintaining the same effectiveness. The occurrence of issues such as frequent dosage, medication interactions, and burst impact may be minimized. No medication combination exhibits any interactions.

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