

# A REVIEW OF DUOCAP: THE CAPSULE IN CAPSULE TECHNOLOGY

Samta.S.Khillare<sup>1</sup>, S.A.Waghmare<sup>2</sup>, Dr. Hemant Kamble<sup>3</sup>, Mamata ankush pavale<sup>4</sup>

<sup>1</sup>Dept of pharmaceuticals

<sup>2</sup>CEO

<sup>3</sup>Principle

<sup>1, 2, 3, 4</sup> Loknete shri Dadapatil pharate collage of pharmacy

Mandavgan pharate Tal – Shirur District – Pune, Maharashtra, India.

**Abstract-** *The study of newer technology of capsule in solid dosage form among all pharmaceutical dosage forms is presented in this article. This review covers newer trends in capsule shell, capsule fill material, capsule sealing technique, and different capsule systems to achieve modified drug release, encapsulation of various types of materials, and for modified applications such as drug mapping for clinical evaluation. This can be accomplished via capsule shell or dosage filling in.*

*There are capsule dosage forms. This article primarily focuses on the advancement of capsule technology. The goal of this study is to reduce the frequency of dosing or to increase the efficacy of the drug by targeting it at the site of action, lowering the dose required, or providing uniform drug delivery.*

**Keywords-** Capsules, Chew caps, Duo caps, Hard Gelatin Capsule, Soft Gelatin Capsule, Vegetarian capsules

## I. INTRODUCTION

The term "capsule" comes from the Latin word "capsula," which means a small box or container. The term appears in a variety of scientific disciplines, including anatomy as an enclosing membrane and botany as a descriptive word for fruit, as well as astrophysics as a space vehicle. 1 In pharmacy, the term capsule has been used to describe a glass ampule as well as the name of a protective cap that goes over the stopper of a bottle of medicine. In recent years, the term capsule has primarily been used to describe solid dosage forms that consist of a container filled with a medicinal substance. They are classified into two types: hard capsules (two pieces) and soft capsules (one piece) based on the presence of glycerol or another plasticizer. Soft gel dosage forms have been around for a long time. The first soft gels appeared in the nineteenth century. Many advancements have been made in the production of these soft capsules since then. 2 Soft gel manufacturing still necessitates specialised skills

and equipment that only a few companies can provide to pharmaceutical clients.

Despite advancements in soft gel manufacturing, the soft gel as a dosage form has remained largely unchanged over the years. As a result, the technology's patent protection was lost, which is a disadvantage in the age of pharmaceutical life-cycle management. As a result, Banner has created new soft gel variants that not only provide distinct advantages over standard soft gel, but also provide additional benefits, but they also give the compounds they deliver additional patent protection.

Since the introduction of the Soft Capsule Making Machine in the 1970s, formulations have grown in popularity, with rapid advancements in recent years. This could be illustrated by the global emergency of more than 560 sets of Soft Capsule Making Machine with transfer mode, capable of producing up to 60 billion pills per year (i.e. more than 3600 different types of drugs).<sup>3</sup> Currently, more than 30 manufacturers use over 60 sets of advanced machines to produce more than 40 different types of soft capsules. 4 Soft gels' ability to improve bioavailability makes them not only the preferred dosage form for new chemical entities with low oral bioavailability, but they can also be used to reformulate existing drugs.

### Drug Candidates for Duo Cap

- Drugs with low bioavailability, such as digoxin, Ibuprofen and vitamins are examples of drugs with low melting points.
- Drugs with a low dose but a high potency. Drugs that have a consistent content.
- Drugs with critical stability, such as the antibiotic Vancomycin hydrochloride
- Sustained-release drugs, for example, Gelucire
- Drugs that have a short half-life. Specifically, penicillin G
- Drugs with a relatively short half-life. Diazepam, for example.

- Sulphonamides are examples of drugs that require high doses.
- Drugs with a high level of plasma protein binding.

#### Drug used for Duo Cap

- Digoxin
- Ibuprofen
- Vancomycin
- Gelucire
- Penicillin G
- Diazepam
- Sulphonamides
- Phenytoin
- Furosemide.
- Nimesulide
- Paracetamol
- Diclofenac

#### Preparation of Duo Cap

The capsule-in-a-capsule formulation is divided into two phases: immediate and sustained release. The immediate and sustained releasing doses were discovered to be approximately 3.24 mg and 8 mg, respectively. 6 PEG 4000 or PEG 6000 accurately weighed amounts were placed in an aluminium pan on a water bath and melted at 60°C with constant stirring with a glass agitator. At this temperature, fusion took 20 minutes. To ensure homogeneity, an accurately weighed amount of drug in a 1:1 drug:carrier ratio was incorporated into the melted carrier while stirring. The mixture was heated until it formed a clear, homogeneous melt. The prepared drug: carrier complex melt was solubilized in tetra glycol to a final drug concentration of 3% (m/m) and sonicated for 1 hour. The drug alginate sustained releasing beads were prepared using the ionotropic gelation technique. There were twelve different batches of beads tested.

were made with a fixed concentration of sodium alginate and varying concentrations of pectin. This formulation made use of special leak proof capsules in both smaller and larger sizes. To create a novel capsule within a capsule Using optimised sustained release beads equivalent to 8 mg of drug, size 2 hard gelatin capsules were filled. was sealed with a warm gelatin solution containing 15% (m/m).

This prepared sustained release smaller capsule was filled into a larger capsule body size 0 with a liquid dispersion of drug equivalent to 3.25 mg as a loading dose using medicine droppers. The larger capsule was also sealed with 15% (m/m) warm gelatin solution after being closed with a

cap. The filled capsules were kept at room temperature until they were tested.

#### Advantages

- Increased time within the Therapeutic Window due to lower peak plasma concentration and hollower slope
- Has kinetics similar to IV infusion, with the ease of a tablet
- Reduce dosing frequency
- Improve patient compliance
- Reduce gastric irritation and side effects
- Possible to enhance the bioavailability
- Alleviate the risk of dose dumping
- Reduce fluctuation in circulation drug level
- Avoidance of night time dosing
- More uniform effect
- Increased the rate of absorption of drugs
- Increased bioavailability of drugs
- Decreased variability of plasmatic drugs
- Patient compliance and consumer preference
- Safety for potent and cytotoxic drug
- Dose uniformity of low-dose drugs
- Product stability

#### Disadvantages

- If a toxic dose is administered, it will remain toxic for an extended period of time.
- Titration of the patient takes a long time.
- Strong first pass effect by remaining below the metabolising threshold
- Saturation point of enzymes
- A significant risk of dose dumping (failed delivery device) exists.
- immediate administration rigid dosing schedule
- Tablets cannot usually be split.
- High production costs
- Heat and moisture sensitivity
- Dietary constraints.

#### Evaluation of Capsules

##### Weight variation test

Ten capsules were individually weighed and the contents were removed. The emptied capsules were individually weighed and the net weight of the contents was calculated by subtraction and the percent weight variation was calculated by using the following formula:

Weight variation =  $(\text{Weight of capsule} - \text{Average weight}) \times 100$   
 Average weight of capsules /  
 Weight variation should not be more than 7.5 %

### Lock length

Ten individual capsules were taken from the formulation trial batch and the lock length was manually measured using vernier callipers, with an average of ten capsules noted.

### Disintegration

The capsules were placed in the basket rack assembly, which is immersed in a thermostatically controlled fluid at 37°C 30 times per minute. To pass the test, the capsules must disintegrate completely into a soft mass with no palpably firm core and no gelatin shell fragments. If one or two capsules fail, the test should be repeated on the remaining 12 capsules. Then, at least 16 of the total of 18 capsules tested must completely disintegrate.

### Dissolution research

Dissolution is the conversion of a disintegrated solid solute into solution. The test determines how long it takes for a specific percentage of the drug in capsules to dissolve under certain conditions. The drug release was measured using a USP Type II dissolution apparatus (paddle) at 50 rpm. The dissolution medium consisted of 900 ml of 0.1N hydrochloric solution acid, which was kept at 37.5 ± 0.5°C. To prevent capsule flotation, a sinker was used. To maintain the sink conditions, samples were drawn at 5, 10, 15, 30, and 45 mins, and an equal amount of fresh medium was replaced. The percentage of drug released was determined by analysing the withdrawn samples.

### Stability Studies

Stability of the drug has been defined as the ability of particular formulations, in a specific container, to remain within its physical, chemical, therapeutic and toxicological specification. The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors, such as temperature, humidity etc. The storage conditions for stability studies were accelerated Condition (40 ± 2°C / 75 ± 5 % RH) and Long term condition (25 ± 2°C / 60 ± 5 % RH). The capsules were packed as 30's count in HDPE containers, induction sealed with adsorbent cotton.

### Application

This technology is useful for GI diseases such as GI cancers.

Crohn's disease and acid reflux are both symptoms of Crohn's disease. It can also be used to treat diabetes.

Targeted release via magnet aids drug uptake and bioavailability without damaging intestinal tissues. Magnetic localization of chemotherapeutics at the site of GI tumours, which are simultaneously visible on X-ray after intravenous administration of radio opaque contrast, would allow for localised dosing while minimising systemic side effects.

It allows for the controlled release of drugs to specific sites in the GI tract in a quick, cost-effective, and convenient manner. It can be used to quickly design and complete a study in either a preclinical (animal model) or clinical setting.

### III. CONCLUSION

Based on the findings of this study, one can conclude that the capsule-in-capsule technology known as DUO CAP is a more recent invention. One formulation can provide both sustained and immediate release patterns. This reduces dosing frequency or increases drug effectiveness by localization at the site of action, lowering the dose required, or providing uniform drug delivery. Drugs that are poorly soluble, have a high potency, have a short half-life, and For the same formulation, large doses are very much applicable. The formulation of capsules contains two phases: immediate and sustained release. The immediate and continuous release. The doses were found to be approximately 3.24 mg and 8 mg, respectively. In this preparation, PEG 4000 or 6000 is used.

In addition to sodium alginate, calcium chloride, and pectin are used. This preparation provides numerous benefits, including reduced dose frequency, improved patient compliance, and the dual effect of controlled and sustained release. Widely used in GI cancer, Chron's disease, and acid reflux. It can also be used to quickly design and complete a study in either a preclinical (animal model) or clinical setting.

### REFERENCES

- [1] Paresh M, Ansari A, Patel S, Khinchi MP, Agrawal D, Sharma N A Review on Recent Advancement in Capsule Formulation. American Journal of Pharmtech Research 2013; 3: 1-14.
- [2] Khan AW, Ahmed MG, Ramesh B. Formulation and Evaluation of Novel Sustained Release Capsules of

- Terbutaline Sulphate. *Int. Res. J. Pharm* 2011; 2(1): 249-55.
- [3] Kathpalia H, Sharma K, Doshi G. Recent trends in Hard Gelatin capsule delivery System. *Journal of Advanced Pharmacy Education N Research* 2014; 4(2): 165-77.
- [4] Rabadiya B, Rabadiya P. A Review: Capsule Shell Material from Gelatin to Non Animal Origin Material. *International Journal of Pharmaceutical Research and Bio-Science* 2013; (3): 42-71.
- [5] Tiwari S, Patil S. Patented Technology in Soft Gelatin Capsule: A Review. *International Journal of Research and Reviews in Pharmacy and Applied science* 2(3): 491-512.
- [6] Cole ET. Liquid filled and sealed hard gelatin capsules. *Capsugel Library* 1999; 92: 1-12.
- [7] Kumar K, Raveendranath V, Leela M, Dorababu N, Hussain Z. Design and evaluation of pantoprazole Delay release capsules. *An International Journal of Advances in Pharmaceutical Sciences* 2010; 1(2): 213-20.
- [8] Rahman AA, Khidr SH, Samy EM, Sayed MA. Enhancement of the Dissolution Rate of Glipizide Capsules Using Fenugreek as Natural Additive. *Unique Journal of Pharmaceutical and Biological Sciences* 2014; 2(1): 1-8.
- [9] Vachhani SR, Patel JJ, Patel D, Prajapati ST and Patel CN. Formulation and in-vitro evaluation of floating capsules of Loratadine. *Journal of Chemical and Pharmaceutical Research* 2010; 2(2): 57-64.
- [10] Srinivas L, Lohithasu D, Madhupriya D, Siddhartha N and Tejaswi N. Formulation and evaluation of ibuprofen pulsion cap technique for controlled release. *Scholar Research Library* 2013; 5(1): 60-68.
- [11] Srividya B, Sowmya CC, Surya, Reddy P. Capsules And It' S Technology: An Overview. *International Journal of Pharmaceutics and Drug Analysis* 2014; 2(9): 727-33.
- [12] Rao AS, Nayeemuddin M, Hadi MA. Formulation and evaluation of a novel capsule-in-a-capsule technology for biphasic delivery of lornoxicam in the treatment of migraine. *International Journal of Pharmaceutical and Biomedical Research* 2013; 4(3): 170-76.
- [13] Chandana N, Gopinath H, Bhowmik D, Williamkeri I, Reddy AT. Modified Release Dosage Forms. *Journal of Chemical and Pharmaceutical Sciences* 2013; 6(1): 13-21.