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Formulation and Evaluation of Different Polymer-Coated Spherules from Granules

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Abstract: ***A novel spheronization technique is reported here for forming spherules from granules using FDA-approved excipients and common pharmaceutical unit operations. Aspirin is used as a drug to check stability during the process. Spherules are made by "bed coating during sliding" (BCDS) of granules. The spherules provide an opportunity to modify their surface properties by polymer film coating. It improves the functional properties such as appearance, drug release, and integrity of particles during the processing of spherules. Spherules with two size ranges (sieves no 22 and 44) are compared. These spherules are further coated with polymers to show the adaptability of the process. Microscopical evaluation reveals that several edges (90° and 45°) are less for spherules compared to granules. The angle of Repose and packing parameters appeared excellent. Different polymer coating drugs give different release profiles as per the properties of the polymeric drugs. This is a versatile platform delivery system for developing advanced drug delivery systems (ADDS). However, the stability of aspirin is affected by the wet process may be because aspirin is a hydrolytically labile drug. Granules and pellets are not necessarily spherical. Coated spherules can also be an option for coating as against to coating the tablet.***

Keywords: Spherules, Granulation, fluidized bed drying (FBD), Bed coating during sliding (BCDS).

I. INTRODUCTION

Spheronization is the maximum extensively used technique for producing spherules (spherical-formed particles). Which produces spherules with excessive drug loading potential and higher waft homes compared to granules and pellets. This is because, in granules and pellets, the shape is not necessarily spherical. [1] The spherules, in addition, provide an opportunity to modify their surface properties by polymer film coating. Surface coatings improve the functional properties such as appearance, drug release, and integrity of particles during the processing of spherules. As compared to granules, spherules have a low surface area to volume ratio so less amount of coating solution is required.

Spheronization is generally done with fluidized bed drying (FBD), where the droplets are dried in air under circulation to produce spherules with irregular shapes and surface roughness due to rapid drying. Thus, opportunity techniques are required that may be followed in small and massive strategies to supply uniform spherules.

Granulation may be performed via way of means of the sieving technique observed via way of means of sizing. Low-cost production of spherules can be achieved by wet granulation followed by "bed coating during sliding (BCDS)" as these processes can be engineered to regular pharmaceutical unit operations and scaled up. The spheronization by BCDS can lead to uniform-sized particles as the polishing of coated starch particles to granules happens during sliding, which can lead to the conversion of granules to spherules. The spherules may be surface-changed via way of means of polymer film coating. Polymers with one-of-a-kind physical properties may be used for that purpose. Ethyl cellulose (EC), is a cellulose-derived polymer, drastically applied in sustained-release formulations. Hydroxypropyl methylcellulose (HPMC) absorbs gastric fluid and swells to form a gel, hydration of this gel leads to erosion and release of the drug into the external environment. HPMC is used to modify drug-release properties from particles. Eudragit is a PH-sensitive anionic copolymer of methacrylic acid and methyl acrylate. Eudragit S 100 is soluble at a pH above 7 and is used for colon targeting and taste masking. Eudragit coating provides pH-dependent drug release. During coating color and appearance of the spherules are changed using appropriate colors and excipients. While this process appears affordable and accessible for small- and large-scale processes, it can lead to as well. [2] For example, the wet process can affect the stability of drug molecules.

In the current study, the effect of wet granulation, BCDS, and polymer coating on the stability of aspirin is analyzed. The granules, spherules, and covered spherules are efficiently prepared; however, the stability of aspirin is affected. Ethylcellulose-coated sustained-release aspirin spherules for treating COVID-19, applicable for emergencies. Cellulosic derivatives like ethyl cellulose (EC) [2], hydroxyl propyl methyl cellulose, and carboxy methyl cellulose used alone or in combination with other macromolecules

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are widely explored for drug delivery applications. **[3]** It is desirable to evaluate and analyze the role of these macromolecules in the design of the drug reservoir and rate-controlling membrane for producing the required delivery profile of the drug. Asprin has the triple results of inhibiting virus replication, anticoagulant, and anti-inflammatory properties; it is now being attempted for the prevention of COVID-19-associated cardiac complications. Spherules are being explored as a multi-particulate provider for numerous Sustained released (SR) drug delivery technologies. They are being Coated with rate-controlling polymer film coatings to provide Sustained-release spherules. For growing spherules, we developed a unique bed-coating-during-sliding (BCDS) technique to put together spherules from granules. This may be transformed into a "bed coating during the rolling process" (BCDR) for coating the drug reservoir with the rate-controlling membrane.

In this technique at some stage in the conversion of granules to coated spherules, the impaired coating film is because of the rolling of the spherules, so the coating technique needs To be taken into consideration as BCDR.

ASPIRIN: Aspirin is a class of Salicylates, [4, 5] Nonsteroidal COX Inhibitors of Nonsteroidal Anti-Inflammatory Drugs.

Aspirin belongs to the class of NSAIDs having analgesic, and antipyretic. Anti-inflammatory, Anti-platelet activity at symmetric standard dose.

They also are referred to as non-narcotic, nonopioid, or aspirin-like analgesics.

Polymer Names (Cellulose Derivative)	Description
Ethyle cellulose	Ethyl cellulose is a semi-synthetic hydrophobic polymer that is currently being used as a sustained-release (SR) coating in various SR and controlled-release (CR) formulations.
Hydroxyl propyl methyl cellulose (PMC) & Carboxy methyl cellulose (CMC)	Cellulose-PMC and Carboxy methyl cellulose-CMC used alone or in combination with other macro-molecules are widely explored for drug delivery applications.
Methylcellulose	Widely employed as a thickening agent in aspirin formulation.

Table: List of Cellulose Derivative polymer for Spherule formulation.

A. Advantages

1) To improve the flow property of material.
2) Coating of granules can help in achieving the controlled release of the drug.
3) Coating of granules can help in manufacturing [1] multiple drug tablets as the coated granules cannot interact with each other.
4) Coating of granules also helps in protection, masking the taste and odor of the drug.
5) Enteric coating of the granules can help to achieve the target drug delivery.
6) Some drug that causes GI irritation can also be coated with polymer to decrease GI irritation.

B. Disadvantages

1) It is very difficult to achieve a uniform coating of the granules.
2) It is difficult to achieve a smooth coating on the surface of each granule.
3) It is possible that the coating may break during the compression process.
4) Some coating solutions may [2] cause problems with the drug.
5) The coating layer may break or crack during the drying.
6) Moisture entrapment may take place during the granule coating process.

II. CONCLUSION

In conclusion, the formulation and evaluation of different polymer-coated spherules from granules, particularly focusing on Aspirin-loaded spherules, have been successfully achieved using the bed coating during sliding (BCDS) process.

The resulting spherules and coated spherules exhibit smooth spherical shapes with maximum obtuse angles, indicating successful spheroidization. Moreover, their excellent flow properties enhance manufacturing fidelity, ensuring consistency and reliability in production processes. This review underscores the potential of BCDS for the development of controlled drug release formulations, offering a promising avenue for future research and applications in pharmaceutical industries.

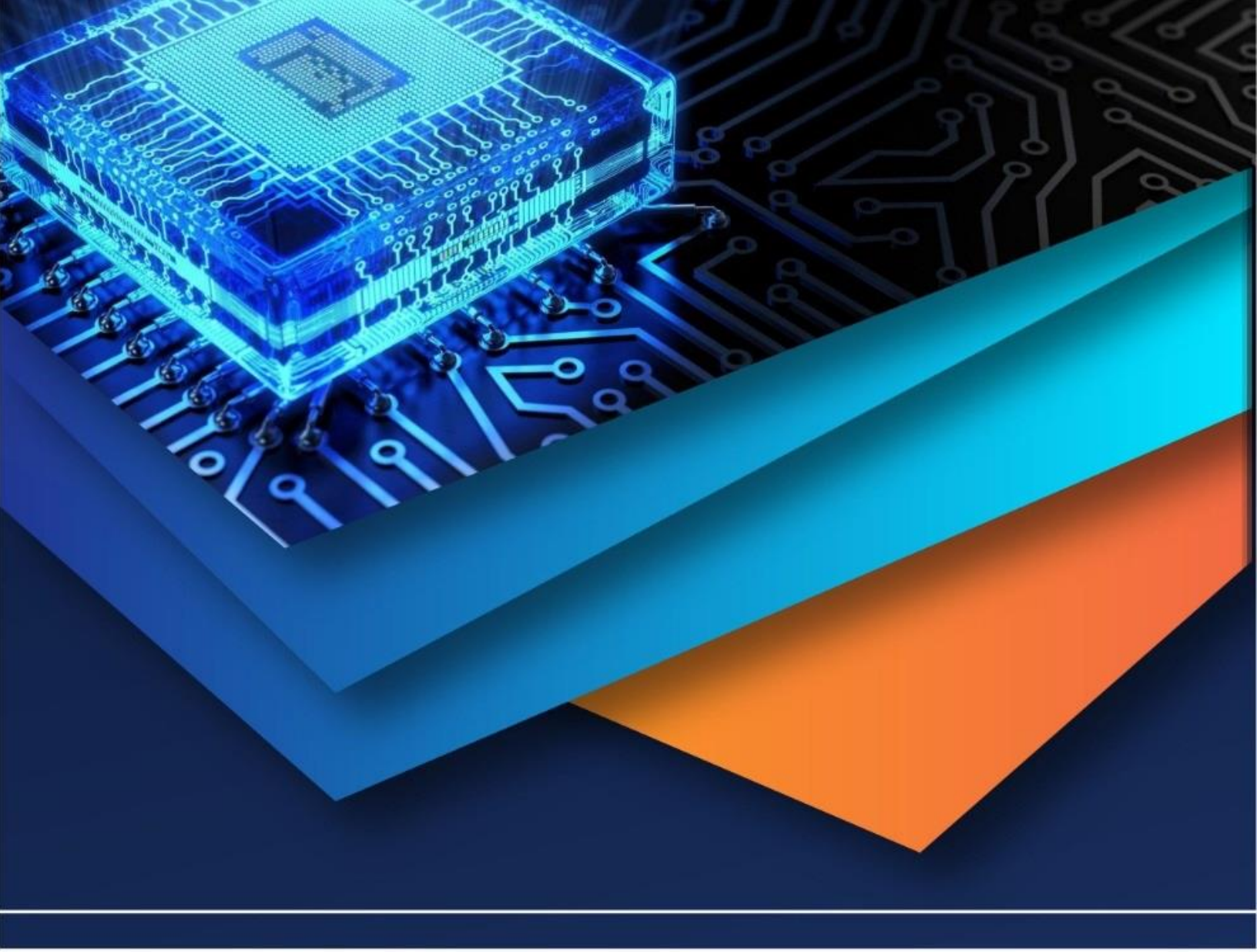
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