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Review Article

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REVIEW ON SUSTAINED RELEASE PELLETS: AN OVERVIEW OF FORMULATION TECHNOLOGIES, DEVELOPMENT AND EVALUATION

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ABSTRACT

The present work focuses on the formulation, development, and evaluation of sustained release pellets to achieve controlled drug delivery and prolonged therapeutic efficacy. Sustained release formulations are designed to maintain steady plasma drug concentrations, reduce dosing frequency, and enhance patient compliance. The prepared pellets were evaluated for particle size distribution, surface morphology, flow properties, drug dissolution,drug content uniformity, and in vitro drug release behavior.The study concludes that sustained release pellets can be successfully developed using polymer-based coating offering a potential pathway to improve therapeutic

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results and sustained release of drugs along with patient adherence.

KEYWORDS

Pellets, Pelletisation, sustained-release pellets, reduced dosing frequency, extrusion-spheronisation.,

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INTRODUCTION

Sustained release pellets refer to small, spherical drug delivery units that are formulated to release a drug gradually over an extended period of time. These gradual deliveries maintain a consistent concentration of the medication in the bloodstream for a prolonged duration,reducing the requirement of frequent dosing and immediate drug absorbance. The reason for timed or sustained released drugs is to half the life of the drug in the body.

The sustained release mechanism in these pellets is achieved through specialized formulations, such as coatings or the incorporation of rate-controlling materials, which slow down the release of the drug. This helps to avoid the peaks and troughs in drug concentration associated with immediate release dosage forms, thus minimizing side effects and ensuring a more stable therapeutic effect. Sustained release pellets are often used in oral drug delivery systems to treat conditions that require consistent drug levels, such as chronic pain, hypertension, or certain psychiatric disorders **[5].**

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MATERIALS AND METHODS

The objective of this review article, “Review on Sustained Release Pellets: An Overview of Formulation Technologies, Development and Evaluation,” is to briefly summarize the major formulation methods, development processes, and evaluation parameters used in preparing sustained-release pellets. Search Strategy and Keywords: A concise literature search was conducted using PubMed, ScienceDirect, Google Scholar, shodh ganga, Elicit,and ResearchGate. Relevant studies were identified using keywords such as “sustained-release pellets,” “pelletization techniques,” “multiparticulate systems,” and “pellet evaluation.” Selected sources were reviewed to gather essential information related to the topic.

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RESULTS

Types of pellets

1. Matrix-type Pellets :

Mechanism:

i. The drug is evenly distributed within a matrix material, which controls the release of the drug as it slowly diffuses through the matrix.

ii. The medium penetrates the matrix through a network of channels or pores.

iii. The drug particles closest to the surface dissolve.

iv. The dissolved drug then diffuses out of the matrix into the surrounding environment, driven by a concentration gradient.

Materials

Used: Polymers like hydroxypropyl methylcellulose (HPMC), ethylcellulose, or other hydrophilic or hydrophobic materials.Sodium alginate (SA) Hydroxypropyl cellulose (HPC) Carbopol (Carbomer) Polyvinylpyrrolidone (PVP) (sometimes used as a binder that dissolves to form pores)

Example: Extended-release formulations of drugs like theophylline or ibuprofen, Diclofenac sodium,Duloxetine HCl.,Esomeprazole,Fenofibrate and Gliclazide [6].

2. Osmotic-controlled Release Pellets (OROS) :

Mechanism:

i. These pellets use osmotic pressure to control the release of the drug.

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ii. The core contains a drug and an osmotic agent, and the outer membrane is semipermeable, allowing water to enter and release the drug over time.

iii. utilizing osmotic pressure to consistently push a dissolved or suspended drug out of a semi-permeable membrane at a controlled, predetermined rate.

Materials Used: Polyethyleneglycol, osmotic gents, cellulose acetate,ethyl cellulose, acrylate copolymers .

Example: Certain antihypertensive medications or pain management drugs.Concerta (methylphenidate HCl) Procardia XL / Adalat (nifedipine) Glucotrol XL (glipizide) Cardura XL (doxazosin mesylate) Invega (paliperidone) Ditropan XL / Lyrinel XL (oxybutynin chloride) Tegretol XR / XL (carbamazepine) [22].

3. Reservoir type pellets :

Reservoir-type pellets consist of a drug-containing core surrounded by a rate-controlling polymer coating.Drug release occurs mainly through diffusion across the polymer membrane. Mechanism:- the fluid dissolves the active pharmaceutical ingredients within the core, creating a high concentration gradient across the polymer membrane.

Material used :- Felodipine and microcrystalline cellulose were used as diluents , polyvinylpirrolidone – PVP was used as binder and triethyl citrate as plasticizer as polymer coating .

Example :- controlled release drug as metoprolol [20].

4. Ion exchange pellets :

Drug release occurs when ions in the gastrointestinal fluids exchange with the ions on the resin, gradually freeing the drug. These pellets help achieve sustained or controlled release without relying on polymer coatings.

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Mechanism :- the drug is allied with ion exchange edible resin which is triggered by coming in contact with gastric fluids.

Material used :-
polymethacrylate Ion-
exchange resins

Anionic resins (e.g., Amberlite IRP 88)

Example :- used to overcome poor solubility, deliquescence and poor dissolution of drugs .

5. multiparticulate system :

Mechanism:-

1.Diffusion-Controlled Release: Drug diffuses through a polymer coating or matrix surrounding the pellet. Release rate depends on coating thickness, polymer type, and porosity.

Dissolution-Controlled Release: The drug layer dissolves gradually in gastrointestinal fluids. Often used in reservoir-type or drug-layered pellets.mixture of various pellets with multidimensional drug delivery systems .

Material used:- coating polymers like hpmc , plasticizers and other excipients. Example:-used in formulations which require sustained release of drugs [19].

6. Drug-in-Polymer Pellets :

Mechanism:-The drug is uniformly dissolved or dispersed within a polymer matrix. (This is essentially the same as a matrix pellet).

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The mechanism is dependent on the polymer type and can involve diffusion,erosion, or a combination; often produced via hot-melt extrusion.

Materials Used: Polymers like polyvinyl alcohol, HPMC, or polyvinylpyrrolidone. Example: Extended-release formulations for pain management or antibiotics.

Advantages

1. Improve flow property and uniformity.

2. Better invitro-invivo release of drugs.

3. Homogeneous spreadability in GIT.

4. Useful in case of difficulty in swallowing and dysphagia like in the case of children and aged people.

5. More stable blood drug level [6].

Disadvantages

1. Complex Manufacturing:

Multi-Step Process: Extrusion, spheronization, drying,

coating Requires specialized equipment (high investment).

2. Limited Drug Suitability:

High-Dose Drugs: Bulk limits (e.g., >500 mg).

Unstable Drugs: Heat/moisture damage during processing [8].

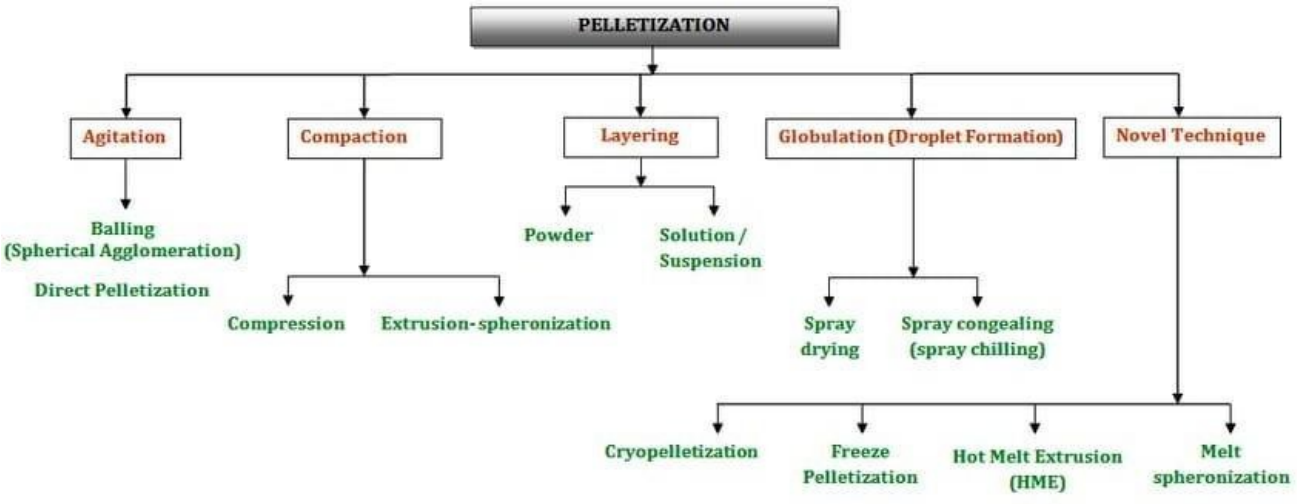
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Methods of Pelletisation

Pellitisation: Pelletization is the process of forming small, compressed, rounded masses or pellets from materials like powders or granules. It is widely used across industries like agriculture, pharmaceuticals, and mining to make materials easier to handle, transport, and process. By creating a more uniform and compact shape, it can improve flowability, reduce dust, and allow for controlled release formulations.

An ideal pellet should have the following properties:

- It should be spherical in shape.
- It should have a smooth surface texture.
- Its particle size should range between 500-1500µm.
- It should hold a maximum quantity of active ingredients to maintain its size [9].



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Figure 1: Methods for Pelletization

Drug layering

Drug layering is a pelletisation method in which the active pharmaceutical ingredient (API) is deposited onto preformed inert cores (seeds) in a layered fashion using a binding solution or suspension.

a) Solution/Suspension Layering

The drug is dissolved or suspended in a binder solution and sprayed onto inert cores.Fluid bed coater (Wurster process)

b) Powder layering

Dry drug powder is applied along with a binder spray to make it stick to the cores.Conventional coating pan or fluid bed processor [8].

2. Globulation

Globulation is a pelletisation process in which liquid droplets (globules) of the drug or excipient are formed and solidified to produce spherical pellets or beads.It involves droplet formation and solidification either by cooling, solvent removal, or chemical reaction.

Basic Principle:

1. Droplet Formation:

The liquid formulation (drug + excipients) is converted into small liquid droplets by spraying, dripping, or atomizing.

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2. Droplet Solidification:

These droplets are solidified by one of the following mechanisms:

● Cooling or congealing (for molten systems)

● Solvent evaporation or extraction

● Cross-linking or chemical reaction in an immiscible medium

a. Spray Drying Principle:A solution, suspension, or emulsion containing the drug and excipients is atomized into fine droplets. These droplets are dried instantly in a stream of hot air, forming solid spherical particles.

Equipment:Spray dryer **[15].**

b. Spray Congealing (Spray Cooling) Principle:

A molten mixture of drug and carrier (e.g., wax, lipid, or polymer) is atomized into a cooling chamber. As the droplets fall, they solidify by cooling, forming spherical pellets.

Equipment:Spray congealer or spray cooler **[16].**

1. Compaction

The compaction technique involves compressing or compacting fine powders or granules under pressure to form pellets, tablets, or briquettes of defined size and shape **[11].**

a) compression: Compression (Tabletting)Powders compressed into small cylindrical or spherical pellets using diesTablet press, pellet press.

b) Extrusion–spheronization: It is a multi-step pelletisation process used to convert powder mixtures or wet masses into spherical pellets of uniform

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size, typically ranging from 0.5–2.0 mm **[13,17].**

2. Agitation

The agitation technique of pelletisation involves formation and growth of pellets by continuous rolling or tumbling of moistened powder particles in the presence of a liquid binder.Under agitation, fine particles collide, adhere, and gradually build up into spherical agglomerates (pellets).It's especially suitable for multiparticulate drug delivery systems (e.g., sustained- release capsules).

a) Balling: Balling pelletisation (also known simply as balling) is the process of forming spherical pellets (balls) from fine powders or particles by agitation, tumbling, or rolling in the presence of a liquid binder.

It is a wet agglomeration process, meaning that surface moisture and capillary forces play key roles in binding particles together.

b) Direct pelletisation: It is the process of agglomerating fine powder particles into spherical pellets by the addition of a binding liquid under controlled conditions of agitation or mechanical force all done in a single step **[2]**.

4. Novel Techniques of Pelletisation

Novel pelletisation techniques are advanced methods used to produce spherical pellets, often with improved uniformity, drug release properties, and process efficiency compared to conventional methods. These techniques often avoid multiple steps like wet granulation or extrusion-spheronization.

a) Cryopelletization: Formation of pellets by dropping a drug solution or suspension into a cryogenic liquid (e.g., liquid nitrogen), instantly freezing the droplets.

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Process:

● Drug solution/suspension prepared.

● Droplets dropped into cryogenic liquid.

● Frozen pellets collected and lyophilized (freeze-dried) to remove solvent.

b) Freeze Pelletisation: Similar to cryopelletization, but emphasizes controlled freezing of droplets and subsequent drying. Often used for protein or vaccine formulations.

Process:

● Droplets of solution are dropped into cold media (e.g., chilled oil or liquid nitrogen).

● Frozen droplets are freeze-dried to yield pellets.

c) Hot-Melt Extrusion (HME): Pellets are prepared by melting a mixture of drug and thermoplastic polymer, extruding it through a die, and then cutting or spheronizing.

Process:

● Drug mixed with thermoplastic polymer.

● Mixture heated and melted.

● Extruded into rods or filaments.

● Cut into pellets; sometimes spheronized for uniformity.

d) Melt Spheronization: Similar to conventional spheronization, but uses thermoplastic binders that melt during processing to form spherical pellets.

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Process:

- Powder blend prepared with thermoplastic binder.
- Binder melted (thermally or mechanically) to agglomerate powder.
- Material is spheronized → spherical, dense pellets **[3,17].**

Evaluation Parameter For Pellets

1. Friability

Friability of pellets was determined by subjecting 10 g of pellets in (Roche friabilator) at 4 min at 25 rpm. The abraded samples were sieved and the pellets retained on the sieve were weighed and percent friability was calculated from the difference in the weight of the pellets before and after friability .

Various processes of pelletization may impact the properties of pellets. It may get chipped and result in formation of dust while coating and handling. Lower friability of pellets is required for subsequent coating. Turbula and awake are the types of apparatus used for the determination of pellet friability **[18].**

2. Flow Properties

The flow properties of polymer coated pellets were studied by determining its Carr compressibility index and Hausner ratio. The data of the tapped density and bulk densities were utilized for the determination of flow properties of the coated pellets.

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It includes the angle of repose, bulk and tapped densities, Hausner's ratio,and Carr's index, which are used to assess flowability and compressibility. These tests quantify how well pellets move and pack, which is crucial for consistent manufacturing and dosing.

Angle of Repose (0):

<25°: Excellent flow; >40°: Poor flow.
Carr's Compressibility Index:

<10%: Excellent flow; >21%: Poor flow [12

3. Surface area

The surface area of pellets is controlled by the particle size, shape, porosity and roughness of pellets. It is an important parameter that has an impact on the release rate of drugs from the pellets [14].

4. Drug content

It can help to determine the concentration of drugs in pellets. The concentration of a drug can be determined with the help of a suitable UV method or HPLC method or some other suitable analytical methods [1].

5. Pellets porosity

Porosity impacts the drug release from pellets as it affects drug dissolution characteristics. Mercury porosimetry can be used for quantitatively estimating pellets porosity [7,20] .

6. Disintegration time

Disintegration time is one of the important tests to measure the disintegration of pellets. This test is usually performed in 0.1 N HCl45 [10] .

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7. Hardness (Crushing Strength)

The ability of an individual pellet to resist crushing under an external, static force. It ensures the pellet can withstand handling and transport stresses [14] .

8. Drug release rate

Measures how quickly the drug is released from the pellet, which is a critical performance parameter for both immediate and sustained-release formulations [7] .

DISCUSSION

Sustained release pellets represent an advanced multiparticulate drug delivery system designed to provide controlled and consistent drug release over an extended period. Their small, uniform size ensures better flow, reduced dose dumping, and improved therapeutic outcomes compared to conventional dosage forms. Formulation approaches such as extrusion–spheronization, drug layering, and novel techniques like hot-melt extrusion help achieve desired release profiles. Polymers such as HPMC and ethyl cellulose play a key role in modulating drug diffusion and dissolution. Evaluation parameters like friability, porosity, drug content, and release rate ensure pellet quality. Overall, sustained release pellets enhance patient compliance and therapeutic efficiency.

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CONCLUSION

Pellets are the multi-unit dosage forms which offer improved safety and prolonged therapeutic efficacy of the active ingredients with excellent flow properties which are then fabricated in single dosage forms. The pelletisation technique produces more spherical pellets and offers more advantages than granulation process.This approach offers a promising strategy to optimise therapeutic outcomes for chronic disease management.

ABBREVIATIONS

(OROS) Osmotic-controlled Release Pellets

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CONFLICT OF INTERESTS

Author Declare No conflict of interest

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