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Review Article

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A Review on Fast Dissolving Tablet

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Abstract For the treatment or management of diseases, oral administration has received much more attention since the ancient decade. A new concept in oral administration are orodispersible tablets (MDT), which are now widely accepted. Orodispersible tablets are solid dosage forms that, when placed in the mouth, disintegrate and dissolved, release active agent within a few minutes without the need of water. It is more relevant for geriatric, pediatric, bedridden because they have swallowing problem and dysphasia patients. It is more useful for travelers and busy patients who do not have easy access to water. Tablets that dissolve in the mouth are prepared by various technologies with the help of superdisintegrants. Orodispersible tablets are more reliable than conventional dosage forms such as tablets, capsules because of better patient compliance. Advances in this field allow the development of an economical and better way to manage the disease, eliminating several problems associated with other delivery systems.

Keywords: Orodispersible tablet, conventional dosage form, patient compliance, Disintegration

Introduction

A fast dissolving drug delivery system (FDDDS) can be defined as a dosage form for oral administration, which when placed in mouth, rapidly disintegrates or dissolves and can be swallowed in the form of liquid. Conventional dosage form is very popular in pharmaceutical industries because of its easy transportation and low manufacturing cost. However for pediatrics and geriatrics fast dissolving tablet is preferred due to its swallowing conveniences.

Advantages of fast dissolving drug delivery system

- It offers ease of administration for pediatrics, geriatrics, mentally ill, and uncooperative.
- It require no water intake
- It shows quick disintegration and dissolution of the dosage form.
- It overcomes unacceptable taste of the drugs.
- It can be designed to leave minimal or no residue in the mouth after administration and also to provide a pleasant mouth feel.

Characteristics of fast dissolving drug delivery system

Taste of the medicament: As most drugs are unpalatable, mouth-dissolving delivery systems usually contain the medicament in a taste-masked form. Delivery systems dissolved or disintegrate in patient's mouth, thus releasing the active ingredient which come in contact with the taste buds and hence, taste masking of the drugs becomes critical to patient compliance.

Hygroscopicity: several fast dissolving dosage forms are hygroscopic and cannot maintain physical integrity under normal conditions of temperature and humidity. Hence they need protection from humidity, which calls for specialized packaging[1].

Friability: in order to allow fast dissolving tablets to dissolve in the mouth, they are made of either into tablets with very low compression force, which makes the tablets friable and/or brittle, which are difficult to handle, often requiring specialized peel-off blister packing. To overcome this problem, some companies introduced more robust forms of fast dissolving tablets, such as wowtab by yamanouchi-shaklee and durasolv by CIMA labs[2].

Introduction to solid dispersion system

Solid dispersion system[3]

It is defined as a dispersion of one or more active ingredients in an inert carrier or matrix at solid state prepared by the melting, solvent or melting solvent method. The solid dispersion may also be called solid-state dispersion. Dispersion obtained through the fusion process is often called melts and those obtained by the solvent method are frequently referred to as coprecipitates or coevaporates. The two basic procedures used to prepare solid dispersion the fusion and cosolvent techniques. Modification of these method and combination of them has also been used.

Method of solid dispersion preparation[4]

Solid dispersion can be prepared by different method based on the physical properties and thermal stability of the drug and the carriers.

- **Melting or fusion method**

A physical mixture of an active agent and a water-soluble carrier is heated until it is melted. The melt is rapidly solidified in ice bath under rigorous stirring. The fused mass is then pulverized and sieved. Rapid congealing is desirable because it results in super saturation of drug as a result of entrapment of solute molecules in the solvent matrix by instantaneously solidification. The solidification process can be achieved on stainless steel plates attached to a cooling system to favor rapid heat loss. Spray congealing from a modified spray drier onto a cold metal surface has also been used. Product from spray congealing can be obtained in pellet form without the necessity of a grinding step that may alter crystalline modification.

Advantages of melting or fusion method

This method is very simple and economical as no solvents are involved.

Super saturation of a solute or drug in a system can be obtained by quenching the melt rapidly from a high temperature.

Disadvantages of melting or fusion method

Many substances either drug or carriers may decompose or evaporate during the fusion process at high temperatures

The tacky and intractable nature of the resulting solidification melt and irregular crystallization owing to the presence of a miscibility gap on the phase diagram for a given drug carrier system[5].

- **Solvent method**

Physical mixture of two solid components is dissolved in a common solvent and then the solvent is usually removed by evaporation under reduced pressure at varying temperatures. The choice of solvent and its removal rate is critical to the quality of the dispersions. A mixture of solvent may also be used. Freeze-drying and spray drying can also achieve the solvent removal. This method is also called co-precipitation. Co precipitation is a recognized technique for increasing the dissolution of poorly water-soluble drugs such as Ketoprofen, spironolactone, nifedipine, so as to consequently improve their bioavailability.

Advantages of solvent method

The thermal decomposition of drug or carriers can be prevented because of the low temperature required for the evaporation of the organic solvent.

Disadvantages of solvent method

It possess higher cost of preparation

It possess difficulty in completely removing liquid solvent

The method has possibility of adverse effect of the negligible amount of the solvent on the chemical stability of the drug

A super saturation of the solute in the solid system cannot be attained except in a system showing highly viscous properties.

- **Melting-solvent method**

It has found that 5-10 % w/w of liquid compound could be incorporated in PEG 6000 without significant loss of its solid properties. Hence it is possible to prepare solid dispersion by first dissolving drug in a suitable solvent and then the solution is incorporated directly into the melt of PEG (70 0 C) without removing the liquid solvent.

Advantages of melting-solvent method

This method combines the advantages of both the melting and the solvent methods.

Disadvantages of melting-solvent method

It is limited to drug with low therapeutic dose i.e. 50 mg or less.

It is possible that the selected solvent or dissolved drug may not be with the melt of PEG.

The liquid solvent used may affect the polymorphic form of the drug precipitated in the solid dispersion.

- **Hot melt extrusion:**

This process is almost similar to that of the fusion method. In this an extruder was employed for the vigorous mixing of the ingredients. The obtained product stability and its dissolution are similar to that of the fusion method, but this method has the ability to shape the eutectic mixture into oral dosage forms, implants and ophthalmic inserts. As like in the fusion method, miscibility of the matrix and the drug can be an issue to be solved.

- **Super critical fluid method:**

In this method supercritical fluids like carbon dioxide are used. In brief, both the matrix and the drug are dissolved in the supercritical CO2 and nozzle sprayed into a vessel with low pressure where the particles are formed. The process of the rapid cooling is due to the adiabatic expansion. This method is also known as the Rapid Expansion of Supercritical Solution (RESS).[6-8]

Mechanisms of fast dissolution from solid dispersions

The enhancement in dissolution rates as a result of solid dispersion formation relative to pure drug varies from as high as 400 fold to less than two fold. The increase in dissolution rate for solid dispersion can be attributed to a number of factors. Corrigan reviewed the current understanding of the mechanisms of release from solid dispersion. It is very difficult to show experimentally that any one particular factor is more important than another.

Following are the possible mechanisms for faster drug dissolution from solid dispersions than a parent drug:

Reduction of particle size of the drug in the solid dispersion system

In the case of glass, solid solution and amorphous dispersions, particle size is reduced to a minimum level. This can result in an enhanced dissolution rate due to both an increase in the surface area and solubilization. Insight into the relative increase in activity (solubility) on size reduction of a crystal is calculated by the Kelvin equation. It is necessary for the particles to be in the submicron range in order to show a dramatic change in solubility.

The carrier material, as it dissolves may have a solubilization effect on the drug

The carrier material may also have an enhancing effect on the wettability and dispersibility of the drug in the dissolution media. This should retard any agglomeration or aggregation of the particles, which can slow the dissolution process.

Formation of metastable dispersions that have a greater solubility would result in faster dissolution rate.

Selection of carriers for solid dispersions

The properties of the carrier have a major influence on the dissolution characteristics of the dispersed drug. Different researchers for different drug have tried number of carrier. All the carriers should possess the following ideal requirement to be suitable for increasing dissolution rate of a drug:

They should be freely water soluble with intrinsic rapid dissolution properties.

They must be nontoxic and pharmacologically inert.

They must be thermo stable with a low melting point for the melt method.

They should be soluble in variety of solvent for the solvent methods.

They should be chemically compatible with the drug and not form a strongly bonded complex with the drug.
A list of materials used as carriers for solid dispersion formation is shown in following Table:

Table 1: Materials used as carriers for solid dispersion

Category	Examples
Sugars	Dextrose, Sucrose, Galactose, Sorbitol, Maltose, Xylitol, Mannitol, Lactose
Acids	Citric acid, Succinic acid
Polymeric materials	Polyvinyl pyrrolidone (PVP), Polyethylene glycol (PEG), Methyl cellulose, HPMC, HEC, HPC, Pectin, Galactomannan, Cyclodextrins
Insoluble or enteric polymers	HPMC phthalate, Eudragit L-100, Eudragit RS, Eudragit S-100, Eudragit RL
Surfactants	Poloxamer 188, Deoxycholic acid, Tweens, Spans, Polyoxyethylene stearate
Miscellaneous	Pentaerythritol, Urea, Urethane

The enteric polymers have been found useful in the formation of solid dispersion of acid labile drugs. In some cases a combination of carriers has been found to be more useful.

Advantages of solid dispersions

Rapid dissolution rates of the drug that may results in an increase in the rate and extent of absorption of the drug.
Reduction in presystemic metabolism of the drug may be due to saturation of the enzyme responsible for biotransformation of the drug
Solid dispersion transforms a liquid form of drug to a solid form.
It avoids polymorphic changes and bioavailability problems of the drug.
The carrier in the drug dispersion system protects certain drugs against decomposition by saliva to allow buckle absorption.[9-10]

Disadvantages of solid dispersions

The major disadvantages of solid dispersion are related to their instability. Several systems have shown changes in crystallinity and a decrease in dissolution rate with aging.
Moisture and temperature have more deteriorating effect on solid dispersion than physical mixtures. Some solid dispersion may not lend them to easy handling because of tackiness (e.g. Drug-PEG)

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