



ISSN : 2320 4850

BI
MONTHLY

Asian Journal of Pharmaceutical Research And Development

(An International Peer Reviewed
Journal of Pharmaceutical
Research and Development)



A
J
P
R
D

Volume - 03

Issue - 05

SEP-OCT 2015

website: www.ajprd.com
editor@ajprd.com



Review Article

A BRIEF REVIEW ON WATER DISPERSIBLE TABLET

Anil Kumar*, Dilip Agrawal, Shankar Lal Soni, Abhishek Namdev, Surya Pratap Singh

Department of pharmaceutics, Kota College of Pharmacy, Ranpur, Kota, Rajasthan, India

Received: August 2015

Revised and Accepted: September 2015

ABSTRACT

Aceclofenac has been shown to have potent analgesic and anti-inflammatory activities, similar to indomethacin and diclofenac and due to its preferential cox-2 blockade it has better safety than conventional NSAIDs with respect to adverse effects on gastrointestinal and cardiovascular system. Aceclofenac is superior form other NSAIDs as it has selectivity for cox-2, a beneficial cox inhibitor, well tolerated, better GI tolerability and improved cardiovascular safety when compared to other selective cox-2 inhibitors. Aceclofenac has a faster and more potent effect than the other NSAIDs. Aceclofenac has an outstanding anti-inflammatory profile, involving a classical inhibition of prostaglandins E₂, a decrease in the expression of several cytokines including interleukin and tumor necrosis factor. It also inhibits activated oxygen species production and influences cell adhesion. Thus it can be concluded that Aceclofenac may be a better option for the management of pain.

KEYWORDS : NSAIDs, Adverse effects, Anti-inflammatory, Management of pain.

INTRODUCTION

Developing a solid oral dosage form in today's market can be challenging. There are many pressures to discover new entities and maximize the lifecycle of products while maintaining safety, cost-effectiveness, and speed to market. Tablets are almost certainly the most cost-effective and efficient form of dispensing medicines. The tablet provides a versatile, compact, robust and accurate platform for drug delivery. While the functional versatility of the tablet as a dosage form has been appreciated for decades, the design versatility of the tablet has historically been underappreciated. A variety of shapes can provide distinction without compromising manufacturing requirements.

Recent advances in Novel Drug Delivery System (NDDS) aims to enhance safety and efficacy of drug molecule by formulating a convenient dosage form for administration and to achieve better patient compliance. Oral delivery is currently the gold standard in the pharmaceutical industry where it is regarded as the safest, most convenient and most economical method of drug delivery having the highest patient compliance. The tablet is the most widely utilized oral dose format. A novel tablet concept which offers ease of oral administration and benefits of increased patient compliance is the fast dissolving/disintegrating tablet (FDDT).

Fast dissolving drug delivery system

Approximately one-third of the population, primarily the geriatric and pediatric populations, has swallowing difficulties, resulting in poor compliance with oral tablet drug therapy which leads to reduced overall therapy effectiveness. A new tablet dosage

Corresponding author:

*Anil Kumar

M.pharm(Pharmaceutics)

Kota College of Pharmacy,

Kota, Pin-302005, Rajasthan, India

E mail: anilkumarbaswal@gmail.com

Mob. - 7737797616

format, the fast dissolving tablet has been developed which offers the combined advantages of ease of dosing and convenience of dosing. These tablets are designed to dissolve or disintegrate rapidly in the saliva or in a water which disintegrate with in few secs. Drug delivery systems (DDS) are a strategic tool for expanding markets/indications, extending product life cycles and generating opportunities. DDS make a significant contribution to global pharmaceutical sales through market segmentation, and are moving rapidly. Fast dissolving drug delivery (FDDTs,) can be achieved by various conventional methods like direct compression, wet granulation, moulding, spray drying, freeze drying, and sublimation.¹

Advantages of Fast Dissolving Drug Delivery System FDDTs^{2,3,4,5}

Fast dissolving technology offers:

- Improved compliance/added convenience
- No chewing needed
- Better taste
- Improved stability
- Suitable for controlled/sustained release actives
- Allows high drug loading.
- Ability to provide advantages of liquid medication in the form of solid preparation.
- Adaptable and amenable to existing processing and packaging machinery
- Cost effective.

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 ingredients 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 can not maintain physical integrity under normal

conditions of temperature and humidity. Hence they need protection from humidity, which calls for specialized packaging⁶.

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 wow tab by yamanouchi-shaklee and durasolv by CIMA labs⁷.

Various Approaches for Fast Dissolving Tablets

The fast-dissolving property of the tablet is attributable to a quick ingress of water into the tablet matrix resulting in its rapid disintegration. Hence, the basic approaches to developing fast dissolving tablets include maximizing the porous structure of the tablet matrix, incorporating the appropriate disintegrating agent, and using highly water-soluble excipients in the formulation.^{8, 9, 10}

Various technologies used in the manufacture of Fast dissolving tablets include

- Freeze –drying or lyophilization
- Tablet Molding
- Direct compression
- Spray drying
- Sublimation
- Taste masking
- Mass extrusion.

Fast dispersible tablet

Solid oral dosage forms are most convenient from patient as well as from manufacturing chemist's perspective. They ensure uniformity of dosage, are more robust, have less microbiological issues compared to liquid dosage forms. However immediate release tablets cannot act as a substitute for suspension. Thus, there is a need for a formulation, which overcomes the problems associated with the swallowing of solid dosage forms and act as a viable substitute for suspensions. One such dosage form is

dispersible tablet. Dispersible tablets as defined in Ph. Eur. are uncoated or film coated tablets intended to be dispersed in water before administration giving a homogeneous dispersion. Typically a dispersible tablet is dispersed in about 5-15 ml of water and the resulting dispersion is administered to the patient. Dispersible tablets are required to disintegrate within 3 minutes in water at 15-25.degree. C.

Also the dispersion produced from a dispersible tablet should pass through a sieve screen with a nominal mesh aperture of 710 microns. The dosage form provides advantages of both tablets and liquid formulations. These are convenient to carry, easy to manufacture and more stable.¹¹

The oral administration of solid dosage forms, for example tablets, capsules, often presents ingestion problems for the patient, especially in case of children or old people. In order to get around this problem other forms of pharmaceutical formulations are resorted to, for example chewable tablets, dispersible tablets and monodose sachets, the contents of which are to be dissolved or suspended in water and taken orally.¹²

The therapeutic action of a pharmaceutically active ingredient depends much on the formulation characteristics. One of the prerequisites of an acceptable formulation is the ease with which it can be administered e. g. to epilepsy patients. The act of swallowing solid dosage form by these patients may become difficult with the possibility of choking. To achieve optimum therapeutic benefit of the anti-epileptic drug, it is desirable to present the drug in a formulation, which can rapidly disperse in water, so that when needed the drug may be taken in the form of an aqueous dispersion. The route of administration described above can be advantageous, for children and elderly people, who often have troubles in swallowing medicines in any disease, in solid form, such as tablets or capsules.¹³

Of all the orally administered dosage forms, tablet is most preferred because of ease of administration, compactness and flexibility in manufacturing. Because of changes in various

physiological functions associated with aging including difficulty in swallowing, administration of intact tablet may lead to poor patient compliance and ineffective therapy. The pediatric and geriatrics patients are of particular concern. To overcome this, dispersible tablets¹⁴ and fast-disintegrating tablets¹⁵ have been developed. Most commonly used methods to prepare these tablets are; freeze-drying/Lyophilization¹⁶ tablet molding¹⁷ and direct-compression methods¹⁸. Lyophilized tablets show a very porous structure, which causes quick penetration of saliva into the pores when placed in oral cavity¹⁹. The main disadvantages of tablets produced are, in addition to the cost intensive production process, a lack of physical resistance in standard blister packs and their limited ability to incorporate higher concentrations of active drug. Moulded tablets dissolve completely and rapidly. However, lack of strength and taste masking are of great concern²⁰. Main advantages of direct compression are low manufacturing cost and high mechanical integrity of the tablets²¹. Therefore, direct-compression appears to be a better option for manufacturing of tablets. The fast disintegrating tablets prepared by direct compression method, in general, are based on the action established by superdisintegrants such as croscarmellose sodium, crospovidone and sodium starch glycolate. The effect of functionality differences of the superdisintegrants on tablet disintegration has been studied²².

Test for Dispersible Tablets:

Disintegration:

Dispersible tablets are disperse within 3 min when examined by the test for disintegration of tablets and capsules but using water R at 15-25 °C.

Fineness of Dispersion:

Take two tablets and dissolve in 100 ml water stir well until it dissolves completely and then dispersion is formed was passed through 22 # sieve. No any particle of formulation are remain on to the # 22 for passing this test.²³



Advantages of dispersible tablets

The major advantage of the dispersible tablet formulation is that it combines the advantage of both liquid and conventional tablet formulations, while also offering advantages over both traditional dosage forms. It provides convenience of a tablet formulation, while also allowing the ease of administration as it disintegrates within water before administration. It allows the convenience of much more accurate dosing than primary alternative, oral liquids like suspension.

A major advantage of some dispersible tablets is increased bioavailability compared to traditional tablets. Because of dispersion before administration, during administration it could be absorbed through saliva, there can be pre-gastric absorption from some formulations in these cases where the drug dissolves quickly. Buccal, pharyngeal and gastric regions are all areas of absorption of the many formulations. However, other formulations show nearly identical plasma concentration profiles. Any pre-gastric absorption avoids first-pass metabolism.

SUPERDISINTEGRANT

Disintegrants are substances or mixture of substances added to the drug formulation that facilitate the breakup or disintegration of tablet or capsule content into smaller particles that dissolve more rapidly than in the absence of disintegrants^(24,25). Superdisintegrants are generally used at a low level in the solid dosage form, typically 1 – 10 % by weight relative to the total weight of the dosage unit. Tablet disintegration has received considerable attention as an essential step in obtaining fast

drug release. The emphasis on the availability of drug highlights the importance of the relatively rapid disintegration of a tablet as a criterion for ensuring uninhibited drug dissolution behavior. Number of factors affects the disintegration behavior of tablets. The development of fast dissolving or disintegrating tablets provides an opportunity to take an account of tablet disintegrants. Recently new materials termed as superdisintegrant have been developed to improve the disintegration processes. Selecting appropriate formulation excipients and manufacturing technology can obtain the design feature of fast disintegrating tablet. The disintegrants have the major function to oppose the efficiency of the tablet binder and the physical forces that act under compression to form the tablet.

The stronger the binder, the more effective must be the disintegrating agents in order for the tablet to release its medication. Ideally, it should cause the tablet to disrupt, not only into the granules from which it was compressed, but also into powder particles from which the granulation was prepared.

Mechanism of tablet disintegrants^{26,27,28}

The tablet breaks to primary particles by one or more of the mechanisms listed below:-

- By capillary action
- By swelling
- Because of heat of wetting
- Due to disintegrating particle/particle repulsive forces
- Due to deformation
- Due to release of gases