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A Review on Formulation Development and Evaluation of ODT of Anticoagulant Drug

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ABSTRACT: The oral route of administration is as the most widely accepted route because of its convenience of self administration, compactness and easy manufacturing. They administered in the mouth, these dosage forms disintegrate instantly to release the drug, which dissolves or disperses in the saliva. Bioavailability is significantly greater than that observed from conventional tablet dosage form. In Fast dissolving tablets are gaining prominence as new drug delivery systems. oral dosage forms dissolve or disintegrate in the oral cavity within a matter of seconds without the need of water or chewing. ODT are useful for pediatric, geriatric and dysphagia patients, leading to improved patient compliance. oral dosing remains the preferred mode of administration for many types of medication due to its simplicity, versatility, convenience, and patient acceptability.

KEYWORDS: Orodispersible tablet, rapid dissolution, high solubility, disintegration.

I. INTRODUCTION

ORALLY DISINTEGRATING TABLETS (ODT)

Orodispersible tablets are also known as mouth-dissolving tablets, rapid dissolving tablets, fast-disintegrating tablets, fast-dissolving tablets. European Pharmacopoeia has used the term orodispersible tablets. This may be defined as uncoated tablets intended to be placed in the mouth where they disperse readily within 3 min before swallowing.[1] oral route is the perfect route for the administration of therapeutic agents because of low cost of therapy, ease of administration, accurate dosage, self-medication, pain avoidance, versatility, leading to high levels of patient compliance. Tablets and capsules are the most popular dosage forms. But one drawback of such dosage forms is 'Dysphasia' or difficulty in swallowing. This is seen to afflict nearly 35% of the general population. This disorder is also associated with a number of conditions like:

1. Parkinsonism
2. Motion sickness
3. Unconsciousness
4. Elderly patients
5. Children
6. Mentally disabled persons
7. Unavailability of water [2]

oral route is the major route of administration of drug because the low cost of therapy, manufacturing and ease of administration lead to high levels of patient compliance. Many patients have difficulty swallowing tablets and hard gelatin capsules do not take medications as prescribed. The acceptance for solid dosage forms can be dissolved and suspended in water, chewed, or rapidly dissolved in the mouth is particularly strong in the pediatric and geriatric markets, with further application to other patients who prefer the convenience of a readily administered dosage form[3]

The oral route of administration is as the most widely accepted route because of its convenience of self administration, compactness and easy manufacturing[4]. They administered in the mouth, these dosage forms disintegrate instantly to release the drug, which dissolves or disperses in the saliva. the drug may get absorbed from the pharynx and oesophagus or from other sections of g.i.t as the saliva travels down. In such cases, bioavailability is significantly greater than that observed from conventional tablet dosage form[2].

II. IDEAL PROPERTIES OF ODT

- ODTs are as advanced dosage form in most instances over conventional immediate release dosage form for various categories of drugs.
- It is expected to bear certain remarkable features that make the ideal. orally disintegrate tablets disintegrate or dissolves in mouth within a very short time.
- orally disintegrate tablet do not required water on administration, because of present acceptable taste masking properties, high drug loading capacity, pleasing mouth feel, stable in environmental condition .[9].
- Due to their rapid dissolution of drug at the buccal cavity ODTs would be always dosage form of choice in case of drugs that are unsuitable to be delivered through GI for many reasons.
- advantages offered by ODTs over immediate release formulations may include ease of formulation designing and manufacturing, unit packaging, easy to handle by patients, no need of water to administration, on rapid disintegration of tablet results in quick dissolution and rapid absorption which provide rapid onset of action that may lead to enhanced therapeutic efficiency due to increased bioavailability.[3]

III. ADVANTAGES OF FAST DISSOLVING DRUG DELIVERY SYSTEM [11,12,13,14]

- Improved compliance/added convenience
 - Ease administration for patients .
 - No water needed
- Can be designed to leave minimal or no residue in mouth after administration and also to provide pleasant mouth feel.
 - No chewing needed ,
 - Better taste obtained by taste masking
 - Improved stability, low sensitivity to environmental condition
 - Suitable for controlled/sustained release actives
 - Allows high drug loading.
 - cost effective, low production.
 - Adaptable and amenable existing processing and packaging high speed machinery.
 - The technology is versatile and suitable for the development of enhanced products for veterinary medicines, OTC, Rx medicines & line extension
 - For superior therapeutic benefit.

IV. DISADVANTAGES OF ODT:[15]

- orally disintegrating tablets are hygroscopic in nature so it should be kept at controlled environment i.e. humidity and temperature.
- For proper stabilization and safety of stable product, ODT requires special packaging.
- Usually have insufficient mechanical strength. Hence, careful handling is required.
- Leave unpleasant taste and/or grittiness in mouth if not formulated properly [16].

V. EVALUTION TEST OF ODT TABLET-[16-17]

1. Wetting time-

Wetting time of tablet dosage form is related to the contact angle. It needs to be assessed to give an insight into the disintegration properties of the tablets; the lower wetting time implies a quicker disintegration of the tablet. For this purpose, a tablet is placed on a piece of tissue paper folded twice and kept in a small Petridish (ID = 6.5 cm) containing 6 ml of water, and the time for complete wetting is measure.

2. Disintegration test-

Disintegration of ODTs is generally less than one minute and normal disintegration time that patient can experience ranges from 5-30 seconds. The standard procedure of disintegration test for tablet dosage forms having several limitations and they are not suitable for the measurement of very short disintegration times. The method needs modifies for ODTs as disintegration is required without water; so the test should minimise disintegration in salivary contents. A modified dissolution apparatus is applied to an ODT with a disintegration time that is too fast to disintegrate differences between tablets when the compendial method is used. A basket sinker containing the tablets is placed just below the water surface in a container with 900 mL of water at 37 °C, and a paddle rotating at 100 rpm is used.

3. Dissolution test –

The development of dissolution methods for orally disintegrating tablet is comparable to the approach taken for Conventional tablets, and is practically identical. Dissolution for drugs listed in a pharmacopoeia monograph, is a good place to start with scouting runs for a bioequivalent ODT. Other media such as 0.1M HCl and buffer (pH 4.5 and 6.8) it should be evaluated for ODT much in the same way as their ordinary tablet counterparts. It has suggested that USP 2 paddle apparatus is the most suitable and common choice for orally disintegrating tablets, with a paddle speed of 50 rpm commonly used.

4. Moisture uptake studies-

Moisture uptake studies for orally disintegrating tablet should be conducted to have an insight into the stability of the formulation, as several excipients used are hygroscopic. Ten tablets from each formulation are kept in a desiccator over calcium chloride at 37 °C for 24 h. The tablets weighed and exposed to 75% RH at room temperature for two weeks. The required humidity (75% RH) is achieved by keeping saturated sodium chloride solution at the bottom of the desiccator for three days. One tablet as control (without superdisintegrant) is kept to assess the moisture uptake due to their excipients. Tablets are weighed and the percentage increase in weight is recorded.

5. Fitness of Dispersion-

Is the qualitative test specified by EP for orally disintegrating tablet. It is an assessment of the grittiness which arises due to disintegration of the tablet into coarse particles. The test is performed by placing two tablets in 100 mL water and stirring it gently, the tablets get completely disintegrated. The formulation is considered to form a smooth dispersion if the complete dispersion passes through a sieve screen with a nominal mesh aperture of 710 microns without leaving any residue on the mesh.

6. Tablet thickness- Thickness of tablet is an important characteristic in reproducing the appearance. Various filling equipment utilizes the uniform thickness of the tablets as a counting mechanism. Thickness was measured by vernier calliper.

7. Weight variation-

20 tablets were selected randomly from the lot and weighed individually to check for weight variation. Weight Variation Specification as per IP was given by Average Weight of Tablet % Deviation 80 mg or less ± 10 More than 80 mg but less than 250 mg ± 7.5 250 mg or more ± 5

8. Friability-

Friability is decreasing the disintegration time increase the friability of orally disintegrating tablet than the conventional tablets. Friability is a measure of mechanical strength of the tablet. If a tablet has more friability it remains intact during packaging, transport or handling. Roche friabilator is used to determine the friability. Friability can be calculated by following procedure Pre weighed tablets are placed in the friabilator. Friabilator consisting of a plastic chamber that revolves at 25 rpm, dropping those tablets at a distance of 6 inches with each revolution. The tablets were rotated in the friabilator for at least 4 minutes. At the end of test tablets are dusted and reweighed; the loss in the weight of tablet is the measure of friability and is expressed in percentage as:

$$\% \text{ Friability} = \left(\frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \right) \times 100$$

Limit- less than 1%

9. Hardness (Crushing strength)-

Hardness of tablet is measured with hardness testers like Monsanto. Hardness is calculated a tablet is placed in the hardness tester and load required to crush the tablet is measured. The hardness of orally disintegrating tablet is



generally lower than conventional tablets, when increase hardness decrease the disintegration of the tablet. It is measured in kg and the hardness of about 3-5 kg/cm² is considered to be satisfactory for uncoated tablets.

V. CONCLUSION

The Drug-excipients compatibility studies showed that the excipients used in the final formulation have no interaction with the drug. The excipients were compatible with API.

All the formulation parameters of the tablets were found to be satisfactory and the drug release profile of the formulated tablets was compared to the reference product and the drug release was found to be as per the specifications. Evaluation of physicochemical parameters like hardness, friability, dissolution and assay indicated that the tablets were mechanically stable and complied with necessary Pharmacopoeial specifications and comparable to innovator product.

REFERENCES

- [1] Fu Y, Yang S, Jeong SH, Kimura S, Park K (2004). Orally fast disintegrating tablets: Developments, technologies, taste masking and clinical studies. *Crit Rev Ther Drug Carrier Syst* 21: 433–76.
- [2] Tejvir Kaur et al. a Review article on Month dissolving tablets published in international journal of current pharmaceutical research in vol-3; issue-1-2011.
- [3] Mrs. Rajeshree Panigrahi et al. a review article on fast dissolving tablets published in www.medcentral.com; article ID-Wmc00809; 29-sep- 2010.
- [4] Sastry SV, Nyshdham JR, Fix JA. Recent technological advances in oral drug delivery: A review. *Pharmaceutical Science and Technology Today*. 2000; 3:138-45.
- [5] Biradar SS, Bhagavati ST. Fast dissolving Drug Delivery System: A brief overview. *The Internet Journal of pharmacology* 2006; 4(2):1531-2972.
- [6] Slowson M, Slowson S. What to do when patients cannot swallow their medications". *Pharm. Times* 1985; 51: 90-6.
- [7] Seager H. Drug delivery Products and the Zydis Fast dissolving Dosage Form. *J. Pharm. and Pharmacol* 1998; 50: 375-82.
- [8] Reddy LH, Ghose, B., Rajneesh. *Indian J. Pharm. Sci* 2002; 64(4): 331- 36.
- [9] Kumari S, Visht S, Sharma PK, Yadav RK. Fast Dissolving Drug Delivery System: Review Article. *Journal of Pharmacy Research*. 2010; 3(6): 1444- 1449.
- [10] Bhowmik D, Chranjib B, Pankaj K, Chandira RM. Fast Dissolving Tablet: An Overview. *Journal of Chemical and Pharmaceutical Research*. 2009; 1(1):163-177.
- [11] Lachman L, Liberman H, Kanig J, "The theory and practice of industrial pharmacy", Varghese Publishing House, Mumbai, 3rd Edn, 1987: 297.



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