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Review on mouth dissolving tablet of atorvastatin calcium using natural superdisintegrants

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ABSTRACT

Oral route is the most preferred for administration of various drugs because it regards as safety, convenient and economic route. Fast dissolving tablets (FDT) are most accepted and exploited for the drug delivery for the patients who are having difficulty with swallowing i.e. mainly paediatrics and geriatric. Atorvastatin calcium is an anti-hyperlipidemic drug that reduces the level of bad cholesterol. Atorvastatin is used to treat high cholesterol and to lower the risk of stroke, heart attack and other heart complication in people with type 2 diabetes, coronary heart disease. In this formulation super disintegrates such as sodium starch glycolate, crosspovidone, Palnatago ovata and guar gum at various concentration used for the preparation of tablets.

Keywords: Mouth dissolving tablet, Atorvastatin calcium, Superdisintegrant.

INTRODUCTION

Hypolipidemic agent Atorvastatin Calcium is a selective and competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl-coenzyme A to mevalonate, a precursor of sterols, including cholesterol. Studies done clinical and pathologic reflected that raised-up plasma levels of total cholesterol (total-C), LDL-cholesterol (LDL-C), and Apolipoprotein B (apo B) promote human atherosclerosis and are the risk factors for developing cardiovascular disease, while increased levels of HDL-C are associated with a decreased cardiovascular risk. As it has long half-life (14hrs), it is not suitable drug for controlled release formulation. Tablet dosage form is preferable because other dosage form don't have good shelf life in case of atorvastatin due to its degradation and impurity issue. Different processing parameters on final formulation & first case study were carried out for optimization of the best condition of the formulation. [1]

Atorvastatin calcium is highly receptive to heat, moisture, a low pH environment and light. Again, the amorphous form is many times unstable than its counterpart crystalline form. In acidic environment it degrades into corresponding lactone. The in-vitro evaluation of an immediate release dosage form by using Atorvastatin calcium in amorphous form was used in tablets prepared by Dry granulation/Roller compaction techniques. The percent drug releases at 0, 5, 10, 15 and 30 mins were selected as responses. The release of Atorvastatin Calcium was immediate within 2-3 mins, indicating the usefulness of the formulations for once daily dosage forms. [2]

Oral dosages form is the most desirable and preferred dosages form. Oral medication is generally considered as the first avenue investigated in the discovery and development of new drug entities and pharmaceutical formulations, mainly because of convenience in administration of drug and cost-effective manufacturing process. [1]

It is estimated that 90% of drug formulations are administered by oral route. When a new drug molecule is discovered, every pharmaceutical company makes full efforts that it can be intended effectively by oral route and if it cannot be intended by oral route then it is relegated to administration in a hospital setting or physician's office. If self-administration of drug is not possible, then sale of pharmaceutical company is decrease. [2]

Oral dosages form includes solid dosages form (tablets, capsules) and liquid dosages form (syrups, suspension) etc. Liquid dosages form generally contains one dose of medication in 5-30 ml so there are chances of drug inaccuracy when medication is self- administered by the patient but tablets and capsules have advantage of unit dosages form and accurate amount of drug is placed in it. Tablets and capsules account for near half of the total number and cost of all prescription written by physician.

MOUTH DISSOLVING TABLETS

Mouth dissolving tablet is defined as "a solid dosage form containing medicinal substance or active ingredient which disintegrate rapidly usually within a matter of seconds when placed upon the tongue." Mouth dissolving tablets are also known as melt-in mouth tablets, oral dispersible tablets, porous tablets, quick dissolving tablet. Mouth dissolving tablets dissolve or disintegrate in the oral cavity without the need of water. Most Mouth dissolving tablets must include substances to mask the bitter taste of the active ingredient. This masked active ingredient is then swallowed by the patient's saliva along with the soluble and insoluble excipients. [3, 4]

In recent years, a variety of improved methods for delivering drugs have been developed with the aim of improving bioavailability convenience and patient compliance. Some tablets are designed to dissolve in saliva within a few seconds, and so-called true Mouth-dissolving tablets. [5]

Mouth dissolving technology offers following advantages:

- Improved compliance/added convenience
- No water needed
- No chewing needed
- Better taste
- Improved stability
- Suitable for controlled as well as fast release actives
- Ability to provide advantages of liquid
- Medication in the form of solid preparation.
- Adaptable and amenable to existing processing and packaging machinery
- Cost-effective.
- Mouth dissolving tablets are solid dosage form that disintegrates and dissolve without water within 60 seconds or less and are also called as Fast dissolving tablets, melt-in mouth tablets, oral-dispersible tablets, rapid melt, porous tablets, quick dissolving tablets, freeze dried wafers etc. The faster the drug goes into solution, the quicker the absorption and onset of clinical effect. Mouth dissolving tablets are preferring over the condition of dysphagia or difficulty in swallowing (35% peoples facing this), many elderly persons with have difficulties in taking conventional dosage forms because of their hand tremors and dysphagia, young individuals because of their under developed muscular and nervous system and also other groups, who may experience problems in swallowing solid dosage forms, are the mentally ill; they are mentally disabled, uncooperative patient and reduced liquid intake plans or nausea. [6]

Desired characteristics for mouth dissolving tablets [7]

- No need of water for administration of tablet.
- Fast disintegration of tablet within few seconds.
- Taste of tablet should be pleasant.
- Tablet should be hard or less friable.
- Tablet should depart no residue in mouth.
- Tablet should maintain its physical integrity.
- Dose of drug should be less.
- It should be economical.

Desired characteristics of drugs for fast dissolving tablets [8]

- Dose of drug should be low.
- Drug should have no bitter taste.
- Drug should have good stability in saliva.
- Drug should have low molecular weight.

- Drug should have good permeability through oral mucosa.

Undesired characteristics of drugs for mouth dissolving tablets [8]

- Drugs with short half-life and frequent dosing.
- Drugs having extensively bitter taste.
- Drugs which requires sustained or controlled release.

Advantages of mouth dissolving tablets

Clinical advantages

- It improves oral absorption.
- It fastens the onset of action.
- It minimizes the first-pass effect.
- It improves bioavailability.

Medical advantages

- No tablet or capsule to swallow or chew.
- No need of water.
- It has better taste.
- It improves safety and efficacy.
- It improves patient compliance.

Technical advantages

- It provides accurate dose.
- It improves better stability due to better packaging.
- It uses common process and conventional equipment's.

Business advantages

- It provides product differentiation.
- It provides exclusive market.
- It extends product patent.

Challenges in mouth dissolving tablets

- It requires rapid disintegration.
- It requires pleasant mouth feel.
- It should not depart any residue in mouth.
- It should have sufficient mechanical command.
- It should have small size.

Reasons for developing mouth dissolving tablets

Necessitate of patient

Patient's geriatrics, pediatrics and those who have problem of dysphasia are not able to continue their conventional drug therapy which cause in-effective drug therapy. So to provide patient compliance, mouth dissolving tablets were developed.

Necessitate of Industry

The increasing needs of industries like enhanced solubility, stability, bioavailability along with safety and compliance require Mouth dissolving tablets.

Necessitate of Market

19 drugs in 2012, 7 drugs in 2013 and 14 drugs in 2014 have lost their patent. So it is necessary for a company to formulate drug compound into new formulation to extend patent, which gave development of Mouth dissolving tablets.

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