FORMULATION AND EVALUATION OF FAST DISSOLVING TABLETS OF LAMIVUDINE

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Abstract
The aim of present work was to formulate and evaluate fast dissolving tablets of lamivudine to prevent mother to child transmission (MTCT) of HIV virus in perinatal infants. The tablets were prepared by direct compression method, using various superdisintegrants like sodium starch glycolate, croscarmallose sodium, and crospovidone at various concentrations(2%-10%). A total of fifteen formulations were made using one type of superdisintegrants for each of five formulations. Fourier Transmission InfraRed (FT-IR) and Differential Scanning Calorimetry studies (DSC) were performed to ensure the compatibility of drug with the super disintegrants. It was found to be satisfactory. The results of precompression studies reveals that the powder blends of all formulations acquire good flow properties. From the results of post compression studies for tablets of all formulations, it was concluded that the formulation containing 10% crospovidone as superdisintegrants emerged as overall best formulation with lowest disintegration time and highest drug release rate.

Keywords: Fast Dissolving Tablets, Lamivudine, Human Immunodeficiency Virus, Direct compression method, Superdisintegrants, Mother To Child Transmission (MTCT)

INTRODUCTION
Fast dissolving tablets (FDTs) are solid single-unit dosage forms that are placed in mouth, allowed to disperse/dissolve in the saliva without the need of water and provides a quick onset of action. Some drugs are absorbed from mouth, pharynx and oesophagus as the saliva passes down into the stomach. In such cases, bioavailability of drug is significantly greater than those observed from conventional tablet dosage form. FDTs are appreciated by a significant segment of population, particularly children and elderly, which have difficulty in swallowing conventional tablets or capsules. FDTs are prepared by various techniques mainly direct compression, lyophilization and moulding. The simplicity and cost effectiveness of the direct compression process have positioned this technique as an attractive alternate to traditional granulation technologies. Usually superdisintegrants are added to a drug formulation to facilitate the break-up or disintegration of tablet into smaller particles that can dissolve more rapidly than in absence of disintegrants. Lamivudine is a reverse transcriptase inhibitor and zalcitabine analog in which a sulphur atom replaces the 3’ carbon of the pentose ring. It is used to treat Human Immuno deficiency Virus Type 1 (HIV-1) and hepatitis-B (HBV). It is chemically 4-amino-1-[2R,5S]-2-(hydroxymethyl)-1,3-oxathiolan-5yl]-1,2- dihydropyrimidin-2-one. Hence, in present study an attempt was made to formulate fast dissolving tablets of lamivudine using three different superdisintegrants at various concentration levels, to prevent MTCT of HIV Virus in perinatal infants.

Materials and methods
Materials
Lamivudine was obtained as a gift sample from Strides Acrolabs, Bangalore. Croscarmallose sodium, Sodium starch glycolate and crospovidone were obtained as a gift sample from Octis research laboratories, Uttarkhand. Microcrystalline cellulose was purchased from HPLC Pvt Ltd, Mumbai.

Preformulation Evaluations
Differential Scanning Calorimetry (DSC) Studies
DSC analysis (DSC200 TA instruments, USA) of samples are carried out by heating the samples under nitrogen atmosphere on an aluminium pan at a heating rate of 10 °C / min, over the temperature range 5 - 200 °C and a nitrogen gas flow of 20 lb / cm².

Fourier Transmission Infra-Red (FT-IR) Studies
The studies are performed to check the compatibility of drug and excipients used in the formulation in order to prevent degradation by interaction. FT-IR spectra (Spectrum RX -1 Perkin-Elmer, German) for the drug and various physical mixtures are obtained in a FT-IR spectroscopy in the transmission mode with a wave number region 4000 – 400 cm⁻¹. KBr pellets are prepared gently by mixing 1mg sample powder with 100mg.
Formulation of Fast Dissolving Tablets of Lamivudine
The Fast dissolving tablets of lamivudine were prepared by direct compression method. Three different superdisintegrants are used namely Croscarmallose sodium, Sodium starch glycolate and Crospovidone. Fifteen formulations were prepared using different superdisintegrants for each of five formulations, in a concentration ranging from 2% to 10% (2, 4, 6, 8 &10). An accurately weighed quantity of drug, superdisintegrants & microcrystalline cellulose are taken in a glass mortar and ground well, the other excipients like mannitol, sodium saccharin, magnesium stearate and talc are added in an order and mixed well to ensure thorough mixing of all ingredients. Then the powder is analysed for flow properties like Angle of repose, Bulk density, Tapped density, Compressibility Index and Hausner’s ratio. The total powder blend is weighed individually for fifty tablets for each formulation, as per the calculations derived from the drug content of the powder blend. Then the individually weighed powders are compressed in the tablet compressing machine.

Precompression evaluations for the powder blend
The prepared blend was evaluated by following tests.

Angle of repose
Angle of repose is determined by using funnel method. The accurately weighed blend is taken in a funnel. The height of the funnel is adjusted in such a way that the tip of the funnel just touches the apex of the heap of blend. The drug - excipient blend is allowed to flow through the funnel freely on the surface of a paper. The diameter of the powder cone is measured and angle of repose is calculated using the following equation:

\[ \tan \theta = \frac{h}{r} \]

Where
\[ h = \text{height of the cone} \]
\[ r = \text{radius of the cone} \]

Bulk density
Apparent bulk density is determined by pouring a weighed quantity of blend in to a graduated cylinder and measuring the volume and weight. The weight of the powder

\[ \text{Bulk Density} = \frac{\text{Weight of the powder}}{\text{Volume of packing}} \]

Tapped density
The tapped density is determined by placing a graduated cylinder, containing a known mass of drug - excipients blend. The cylinder is tapped on a flat surface from a height of 10cm at 2 seconds intervals. The tapping is continued until no further change in volume is noted.

\[ \text{Tapped density} = \frac{\text{Weight of the powder}}{\text{Tapped volume}} \]

Compressibility Index
The compressibility index of the blend is determined by Carr’s compressibility index.

\[ \text{Carr’s compressibility index} = \frac{\text{Tapped density}-\text{bulk density}}{\text{Tapped density}} \times 100 \]

Hausner’s ratio
Hausner’s ratio is determined by the following formula.

\[ \text{Hausner’s ratio} = \frac{\text{Tapped density}}{\text{Bulk density}} \]

Post compression evaluations
Hardness
The hardness of the tablets is an indication of its strength measuring the force required to break the tablet across tests it. The force is measured in kg and hardness of about 3-5kg/cm² is considered to be satisfactory for
uncoated tablets. Hardness of ten tablets from each formulation was determined by using mansanto hardness tester

**Thickness**

Thickness of the tablets is determined by using vernier calliper.

**Diameter**

The diameter of the tablets is determined by using vernier calliper.

**Drug content**

Five tablets from each batch are weighed and powdered, 10mg equivalent of the powder is taken and diluted with 10ml of distilled water and the volume is made up to 100 ml. From this 10ml of the solution is taken and the volume is made up to 100ml with distilled water. The absorbance of the solution is measured using UV-Spectrophotometer at 271 nm.

**Weight variation test**

Twenty tablets are taken and their weight is determined individually and collectively on a digital weighing balance the average weight of one tablet is determined from the collective weight.

USP specification for the uniformity of weight

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<tr>
<th>S.NO.</th>
<th>AVERAGE WEIGHT (mg)</th>
<th>MAXIMUM % DIFFERENCE ALLOWED</th>
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<td>1</td>
<td>130 or less</td>
<td>10%</td>
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<tr>
<td>2</td>
<td>130-324 mg</td>
<td>7.5%</td>
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<tr>
<td>3</td>
<td>More than 324 mg</td>
<td>5%</td>
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</table>

**Friability**

Friability is the loss of weight of tablet in the container due to removal of particles from surface. Friability test is carried out to access the ability of the tablet to withstand abrasion in packaging, handling and transport. Roche friabilator is employed for finding the friability of tablets. 20 tablets from each formulation are employed for finding the friability of tablets. The tablets are weighed and placed in roche friabilator. That is rotated at 25 rpm for 4 min. The tablets are dusted and weighed again. The percentage of weight loss is calculated again using the formula.

\[
\text{Percentage friability} = \frac{\text{Initial weight} - \text{final weight}}{\text{Initial weight}} \times 100
\]

**Wetting time and Water absorption ratio**

For determination wetting time and water absorption ratio, a piece of tissue paper is folded twice and placed in a small petridish (having internal diameter of 5 cm) containing 6 ml of water. A small quantity of amaranth red dye is added to the water. A tablet is placed on the paper and the time required for the complete wetting is measured. The wetted tablet is then weighed. The water absorption ratio ‘R’ is determined using the equation

\[
R = \frac{W_a - W_b}{W_b} \times 100
\]

Where,

- \(W_a\) = Weight of the tablet after water absorption.
- \(W_b\) = Weight of the tablet before water absorption.
**Disintegration Test**
The disintegration test is performed using an USP disintegration apparatus with distilled water at 27±0.5°C. The time reported to obtain complete disintegration of 6 tablets are recorded and average is reported\(^{15}\).

**Dissolution Studies**
The release rate of the formulated Lamivudine tablets are characterized using USP type 2 (Paddle) at 50rpm, 900ml of distilled water is used as dissolution medium\(^{16}\). 10ml of samples are withdrawn from the dissolution medium and replace with 10ml of blank media. The samples are withdrawn at 5, 10, 15, 30 and 45 mins, and analysed using UV-Spectrophotometer.

**RESULTS AND DISCUSSION**

**Preformulation Evaluations**

**Differential Scanning Calorimetry (DSC) Studies**
DSC experiments are carried out in order to characterise the physical state of drugs in formulation. The thermograms of pure drug exhibit the single isothermic peak at 177.4°C. In thermogram of physical mixture of drug with excipients, the drug peaks were shifted to lower temperature with reduced intensity which may due to baseline shift. Baseline shift are caused by changes in sample weight or specific heat of sample. (Figure 1 to 6)
Fig – 3 DSC Thermogram of sodium starch glycolate

Fig – 4 DSC thermogram of lamivudine + Sodium starch glycolate
Fourier Transmission Infra–Red (FT-IR) Studies

Before formulation, preformulation study was carried out by comparing FT-IR spectra of pure Lamivudine and its physical mixture with superdisintegrants using Fourier Transmission Infrared spectrophotometer. There was no difference in their spectra. It was observed that the drug remained intact in the presence of superdisintegrants. (Figure 7 to 11)
Fig- 9 FT-IR spectrum of croscarmellose sodium

Fig- 10 FT-IR spectrum of lamivudine + SSG
Formulation of fast dissolving tablets of lamivudine

The individually weighed powder blends of each formulation were compressed into tablets in a single punch tablet compressing machine. Fifty tablets for each formulation were obtained. The tablets were white in colour and round in shape. The contents for tablets of each formulation were shown in Table 1.

Precompression evaluations for the powder blend

Precompression evaluations were done to ensure the flow properties of the powder blend. Good flow properties of the powder blend will yield the tablets of desired quality and ease the tableting process. So it was mandatory to assess the flowability of the blend before compression. The various precompression evaluations were as follows: Angle of repose, Bulk density, Tapped density, Compressibility Index and Hausner’s ratio.

Angle of repose

The angle of repose was used for the measurement of frictional force in a loose powder which in turn will influence the flow properties of the powder blend. The angle repose of all the formulations ranges from 30.06° to 30.72°. It was evident from the results, that the powder blends of all formulations possess good flow properties. The results of angle of repose for all the formulations were summarised in Table 2.

Bulk density

The bulk density was determined to assess the free flowing property of the powder blend. The bulk density of all formulations ranges from 0.3368 g/cm³ to 0.3916 g/cm³. The results indicate that the powder blends of all fifteen formulations were having good flow properties. The results were summarised in Table 2.

Tapped density

The tapped densities of all fifteen formulations were determined to analyse the powder blends for their free flowing property. The tapped density of all the formulations ranges from 0.4436 g/cm³ to 0.4663 g/cm³. From the results, it was inferred that the powder blend of all formulations possess good flow properties. The results of all the formulations were summarised in Table 2.

Compressibility Index

The compressibility index was the simplest method to measure the free flowing of powder blends of all formulations. The ease with which a material was induced to flow was given by compressibility index. The compressibility index of all the formulations ranges from 15.9 to 24.14. The results indicate that the powder blend of all formulations possess good flow properties. The results of all the formulations were summarised in Table 2.

Hausner’s ratio

The Hausner’s ratio was an indirect index of ease of powder to flow. The Hausner’s ratio for powder blends of all fifteen formulations ranges from 1.18 to 1.31. It was observed from the results that the powder blends of all formulations have good flow properties except for formulations (F1, F4, F5). The results were summarised in Table 2.

Hausner’s ratio

- <1.25 – Good flow property
- >1.25 – Poor flow property
It was evident from the results of the precompression studies, that the powder blends of all fifteen formulations possess good flow properties, which were within the standard limits and were qualified for compression into tablets.

**Post compression evaluations**

The tablets obtained after compression were evaluated on various parameters to determine their quality and to ensure that the resultant product meets all necessary criteria’s required for the fast dissolving tablets.

**Hardness**

The hardness for tablets determines the resistance of the tablets to abrasion or breakage under conditions of storage, transformation and handling before usage. The hardness for tablets of all the fifteen formulations was found to be 3kg/cm². The results indicate that the tablets of all formulations have uniform hardness, which in turn protect them from mechanical damage. The results were summarised in Table 3.

**Thickness**

The thickness of tablets gives appearance, prevents damage from external forces and ensures uniform die filling of the powder blends. The thickness for tablets of all fifteen formulations was found to be 3mm. The results indicate that the tablets of all formulations were of uniform size. The results were summarised in Table 3.

**Diameter**

The diameter was measured to ensure the uniformity in size and shape of the tablets. The diameter of all fifteen formulations was found to be 8mm. The results indicate that the tablets of all batches were of uniform size and shape. The results were summarised in Table 3.

**Drug content**

The drug content of the tablets was estimated to ensure that all the tablets of a formulation contains the therapeutic dosage of the active ingredient meant for the particular dosage form. The drug contents for tablets of all the formulations ranges from 95.74% to 97.16%. The results indicate that the contents for tablets of all formulations were uniform and contains therapeutic dose of the active ingredient. The results were summarised in Table 3.

**Weight variation test**

The weight variation test was carried out to ensure that the tablets of each formulation were of uniform weight, which in turn will indicate the uniform distribution of contents of the powder blends of each formulations. The weight variation for tablets of all formulations was found to be within the range of ±7.5%. The results indicate that all tablets of each formulation were of uniform weight. The results were shown in Table 3.

**Friability test**

The friability test was carried out to ensure the mechanical strength of tablets to avoid the loss of the external surface of the tablets during the process of packing, handling, transit, and storage. Friability below 1% was an indication of good mechanical resistance. The results indicate that the friability for tablets of all formulations were below 1% and hence passes the test. The results were summarised in Table 3.

**Wetting time and Water absorption ratio**

The wetting time and water absorption ratio indicates the capacity of the superdisintegrants to absorb water and completely wet the tablet at the earliest time possible, which were the significant characteristics of fast dissolving tablets. The minimum wetting time and maximum water absorption ratio will enable faster disintegration of the tablets, which were the prime important criteria for fast dissolving tablets. The wetting time for formulations (F1, F2, F3, F4, F5) containing CCS as superdisintegrant was found to be 15, 90, 103, 36, 151. The wetting time of formulations (F6, F7, F8, F9, F10) containing SSG was found to be 70, 74, 88, 57, 100. The wetting time of formulations (F11, F12, F13, F14, F15) containing Crospovidone was found to be 74, 30, 25, 24, 19. 15 seconds respectively. The wetting time of various superdisintegrants used was in the order of Crospovidone > Croskarmallose sodium > Sodium starch glycolate. The water absorption ratio of formulations (F1, F2, F3, F4, F5) containing CCS as superdisintegrant was found to be in the range of 144% to 59.6%, formulation F4 was found to have maximum water absorption ratio. The water absorption ratio of formulations (F6, F7, F8, F9, F10) containing SSG was found to be in the range of 119.8% to 105.9%, formulation F8 was found to have maximum water absorption ratio. The water absorption ratio of formulations (F11, F12, F13, F14, F15) containing Crospovidone was found to be in the range of 129.6% to 107.5%, formulation F11 and F15 was found to have maximum water absorption ratio. The water absorption ratio of various superdisintegrants was found to be in the order of Croscarmallose sodium > Sodium starch glycolate > Crospovidone. The results indicates that the wetting time and water absorption ratio of all tablets were within the limits. The results were summarised in Table 3.

**Disintegration time**

The disintegration time was the time taken by the tablet to break down in to small particles, in the presence of aqueous medium. It varies with type and concentration of the superdisintegrants incorporated in the formulation. As the name implies disintegration time were the prime most criteria for fast dissolving tablets, which should be less than 30 secs to 3 minutes as per the standards. The disintegration time for formulations...
(F1, F2, F3, F4, F5) containing CCS as super disintegrant was found to be 623, 173, 179, 42.6, 311 seconds. The disintegration time for formulations (F6, F7, F8, F9, F10) containing SSG as superdisintegrant was found to be 217, 91, 171, 120, 150 seconds. The disintegration time for formulations (F11, F12, F13, F14, F15) containing Crospovidone as superdisintegrant was found to be 72, 87, 29, 21, 4 seconds respectively. F4 was found to have the least disintegration time among the formulations containing CCS as superdisintegrant. F7 was found to have the least disintegration time among the formulations containing SSG as superdisintegrant. F15 was found to have the least disintegration time among the formulations containing Crospovidone as superdisintegrant. The results indicate that the disintegration time for tablets of all formulations are within the limits except for formulations (F1, F5, F6), which indicate that the tablets of all formulations disintegrate quickly. The order of disintegration time of various superdisintegrants was found to be Crospovidone > Croscarmallose sodium > Sodium starch Glycolate. The results were summarised in Table 3.

**Dissolution studies**

The dissolution studies were performed to evaluate the release profile of the drug, which relates the percentage of drug release from its dosage form with the function of time. The superdisintegrants were added to the solid dosage formulations to enhance the disintegration time and thereby enhancing the faster release of active drug from its dosage form, which ultimately results in enhanced rates of absorption and bioavailability of the drug.

The desired quality of fast dissolving tablets was to have a maximum release of therapeutic dose at a very minimal time period. The maximum drug release at a time period of five minutes is noted for all the formulations. The drug release for tablets of all formulations ranges from 19.27% to 97.19%. The results indicate that the drug release of all the formulations were found to be above 80% in five minutes except for formulations (F1 19.27% and F2 77.60%). The release rate of the three superdisintegrants were in the order of Crospovidone > Sodium Starch Glycolate > Croscarmallose sodium. The graphical representation for the release rates of formulations containing three superdisintegrants are as shown in Figure-12,13&14. From the results obtained from the post compression studies of tablets of all fifteen formulations, the formulation fifteen with concentration of 10% Crospovidone was found to be the best formulation with a disintegration time of 4secs, wetting time of 19secs and drug release of 97.19±0.28 which was the highest of all formulations. The results were summarised in Table 3.
CONCLUSION

It was concluded, that lamivudine can be successfully formulated as fast dissolving tablets using various superdisintegrants in different concentrations by direct compression method. The formulation containing 10% of crospovidone as superdisintegrant was found to be outstanding than other formulations in terms of disintegration time and rate of dissolution, which in turn will enable the tablets to disintegrate quickly in the buccal environment and ensures fast appearance of the drug in systemic circulation and there by enhanced bioavailability in comparison with conventional formulations.

REFERENCES

Table 1: Formulation Of Fast Dissolving Tablets

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<td>Compressibility index(%)</td>
<td>Hausner’s ratio</td>
<td>Drug content (%)</td>
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Table 3: Post Compression Evaluation Of Fast Dissolving Tablets Of Lamivudine

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<th>Weight variation (mg)</th>
<th>Friability (%)</th>
<th>Wetting time (sec)</th>
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