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# Formulation and evaluation of Fast Dissolving Tablets of Lamivudine to prevent Mother to Child Transmission

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## Abstract

A fast dissolving tablet can be defined as a solid dosage form that can disintegrates into smaller granules which slowly dissolve in the mouth. The disintegration time for fast dissolving tablet varies from a few seconds to more than a minute depending on the formulation and the size of the tablet. A fast disintegrating or dissolving system or tablet can be defined as a solid dosage form that can disintegrate or dissolve within 30 seconds, in the oral cavity resulting in a solution or suspension without administration of water. The fast disintegrating tablets are synonymous with fast dissolving tablets; melt in mouth tablets, rapimelts, Porous tablets, Orodispersible, quick dissolving or rapidly disintegrating tablets. Patient may suffer from tremors therefore they have difficulty to take powder and liquids. In dysphasia physical obstacles and adherence to an esophagus may cause gastrointestinal ulceration. Swallowing of solid dosage forms like tablet and capsules and produce difficulty for young adult of incomplete development of muscular and nervous system and elderly patients suffer from dysphasia. Liquid medicaments (suspension and emulsion) are packed in multidose container; therefore achievement of uniformity in the content of each dose may be difficult. Buccal and sublingual formation may cause irritation to oral mucosa, so patients refused to use such medications cost of products is main factor as parenteral formulations are most costly and discomfort.

**Key-words**: Fast Dissolving Tablets, Lamivudine, Formulation

## Introduction

Mouth Dissolving Tablet should-Not require water to swallow, but it should dissolve or disintegrate in the mouth within matter of seconds. Be compatible with taste masking Be portable without fragility concern. Have a pleasing mouth feel. Leave minimal or no residue in the mouth after oral administration. Exhibit low sensivity to environmental condition as humidity and temperature. Be manufactured using conventional processing and packaging equipment at low cost. Ease of administration to patients who refuse to swallow a tablet, such as pediatric and geriatric patients and psychiatric patients. Convenience of administration and accurate dosing as compared to liquids. No need of water to swallow the dosage from, which is highly convenient feature for patients who are traveling and do not have immediate access to water.

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Good mouth feel property of MDDS helps to change the basic view of medication as "bitter pill", particularly for pediatric patients. Rapid dissolution and absorption of drug, which may produce rapid onset of action. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach, and in such cases bioavailability of drugs in increased. Ability to provide advantages of liquid medication in the form of solid preparation.

Pregastric absorption can result in improved bioavailability and as a result of reduced dosage, improved clinical performance through a reduction of unwanted effects. Mouth-feel perception, resulting in a product that is perceived as being less gritty, even if the only change is the flavor. Effervescence can be added to aid disintegration and improve mouth-feel by reducing the "dryness" of a product. 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 product packaging.

Friability - In order to allow fast dissolving tablets to dissolve in the mouth, they are made of either very porous or soft molded matrices or compressed 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-Shadlee and Dura Solve by CIMA labs. Excipients balance the properties of the actives in fast-melting tablets. This demands a thorough understanding of the chemistry of these excipients to prevent interaction with the actives. Determining the cost of these ingredients is another issue that needs to be addressed by formulators. The role of excipients is important in the formulation of fast-melting tablets. These inactive food-grade ingredients, when incorporated in the formulation, impart the desired organoleptic properties and product efficacy. Excipients are general and can be used for a broad range of actives, except some actives that require masking agents.

**BULKING MATERIALS:**

Bulking materials are significant in the formulation of fast-melting tablets. The material contributes functions of a diluent, filler and cost reducer. Bulking agents improve the textural characteristics that in turn enhance the disintegration in the mouth, besides; adding bulk also Reduces the concentration of the active in the composition. The recommended bulking agents for this delivery system should be more sugar-based such as mannitol, polydextrose, lactitol, DCL (direct compressible lactose) and starch hydrolystate for higher aqueous solubility and good sensory perception. Mannitol in particular has high aqueous solubility and good sensory perception. Bulking agents are added in the range of 10 percent to about 90 percent by weight of the final composition.

**EMULSIFYING AGENTS:**

Emulsifying agents are important excipients for formulating fast-melting tablets they aid in rapid disintegration and drug release without chewing, swallowing or drinking water. In addition, incorporating emulsifying agents is useful in stabilizing the immiscible blends and enhancing bioavailability. A wide range of emulsifiers is recommended for fast- tablet formulation, including alkyl sulfates, propylene glycol esters, lecithin, sucrose esters and others. These agents can be incorporated in the range of 0.05 percent to about 15 percent by weight of the final composition.

**LUBRICANTS:**

Lubricants, though not essential excipirnts, can further assist in making these tablets more palatable after they disintegrate in the mouth. Lubricants remove grittiness and assist in the drug transport mechanism from the mouth down into the stomach.

**FLAVOURS AND SWEETENERS:**

Flavours and taste-masking agents make the products more palatable and pleasing for patients. The addition of these ingredients assists in overcoming bitterness and undesirable tastes of some active ingredients. Both natural and synthetic flavours can be used to improve the organoleptic characteristic of fast-melting tablets. Formulators can choose from a wide range of sweeteners including sugar, dextrose and fructose, as well as non-nutritive sweeteners such as aspartame, sodium saccharin, sugar alcohols and sucralose. The addition of sweeteners contributes a pleasant taste as well as bulk to the composition.

**Conventional Technique Used In The Preparation Of MFDTS.**

- Freeze drying technique
- Tablet molding technique
- Spray drying technique
- Direct compression technique
- Sublimation technique
- Mass extrusion technique

**Freeze Drying Technology** (Zydis Technology)

Lyophilization can be used to prepare tablets that have very porous open matrix network into which saliva rapidly moves to disintegrate lyophilized mass after it is placed in mouth.

The drug is entrapped in a water soluble matrix whichis freeze dried to produce a unit which rapidly disperses when placed in mouth. Apart from the matrix and active constituents, the final formulation may contain other excipients, which improve the process characteristics or enhance the quality of final product. These include suspending agents, wetting agents, preservatives, antioxidants, colors and flavors. The preferred drug characteristics for freeze drying formulations are water insoluble, low dose, chemically stable, small particle size and tasteless. Lyophilization is relatively expensive and time consuming manufacturing process. Other drawback includes fragility, which make the use of conventional packing difficult and poor stability during storage under stressful condition.

**Tablet Molding**

In this technology, water-soluble ingredients are used so that tablet disintegrate and dissolve rapidly. The powder blend is moistened with a hydro alcoholic solvent and is molded in to tablet using compression pressure lower than used in conventional tablets

compression. The solvent is then removed by air-drying. Molded tablets have a porous structure that enhances dissolution. Two problems commonly encountered are mechanical strength and poor taste masking characteristics. Using binding agents such as sucrose, acacia or poly vinyl pyrrolidone can increase the mechanical strength of the tablet. To overcome poor taste masking characteristic Van Scoik incorporated drug containing discrete particles, which were formed by spray congealing a molten mixture of hydrogenated cottonseed oil, sodium bicarbonate, lecithin, polyethylene glycol and active ingredient into a lactose based tablet triturate form.

**Spray Drying**

Spray dryers are widely used in pharmaceuticals and biochemical processes. Due to processing solvent is evaporated rapidly; spray drying can produce highly porous, fine powder. Spray drying can be used to prepare rapidly disintegrating tablets. This technique is based on a particulate support matrix, which isprepared by spray drying an aqueous composition containing support matrix and other components to form a highly porous and fine powder. This is then mixed with active ingredients and compressed into tablets.

**Direct Compression Method**

In this method, tablets are compressed directly from the mixture of the drug and excipients Without any preliminary treatment. The mixture to be compressed must have adequate flow properties and cohere under pressure thus making pretreatment as wet granulation unnecessary. Few drugs can be directly compressed into tablets of acceptable quality. A type of disintegrant and its proportion are of prime importance. The other factors to be considered are particle size distribution, contact angle, pore size distribution, tablet hardness and water absorption capacity. All these factors determine the disintegration. The disintegrant addition technology is cost effective and easy to implement at industrial level.

**Mass-Extrusion (Mass-Extrusion)**

This technology involves softening the active blend using the solvent mixture of water-soluble polyethylene glycol and methanol and subsequent expulsion of softened mass through the extruder or syringe to get a cylinder of the product into even segments using heated blade to form tablets. The dried cylinder can also be used to coat granules for bitter drugs and thereby achieve taste masking

**PATENTED TECHNOLOGIES OF FDT**

Currently, four fast-dissolving/disintegrating technologies have reached the U.S. market:

- Zydis
- WOWTAB
- OraSolv
- DuraSolv
- Three others are available outside the U.S. :
- FlashDose.

**Zydis Technology**

Zydis formulation is a unique freeze dried tablet in which drug is physically entrapped or dissolved within the matrix of fast-dissolving carrier material. When zydis units are put into the mouth, the freeze-dried structure disintegrates instantaneously and does not require water to aid swallowing.

The zydis matrix is composed of many materials designed to achieve a number of objectives. To impart strength and resilience during handling, polymers such as gelatin, dextran or alginates are incorporated. These forms a glossy amorphous structure, which imparts strength. To obtain crystallinity, elegance and hardness, saccharides such as mannitol or sorbitol are incorporated. Water is used in the manufacturing process to ensure production of porous units to achieve rapid disintegration. Various gums are used to prevent sedimentation of dispersed drug particles in the manufacturing process. Collapse protectants such as glycine prevent the shrinkage of zydis units during freeze drying process or long term storage. Zydis products are packed in blister packs to protect the formulation from moisture in the environment.

**Durasolv Technology**

Durasolv is the patented technology of CIMA labs. The tablets made by this technology consist of a drug, fillers and a lubricant. Tablets are prepared by using conventional tableting equipment and have good rigidity. These can be packaged into conventional packaging system like blisters. Durasolv is an appropriate technology for products requiring low amounts of active ingredients. Durasolv has much higher mechanical strength than its predecessor due to the use of higher compaction pressures during tabletting.

The Durasolv product is thus produced in a faster and in more effective manner.

**Orasolv Technology**

Orasolv Technology has been developed by CIMA labs. In this system active medicament is taste masked. It also contains effervescent disintegrating agent. Tablets are made by direct compression technique at low compression force in order to minimize oral dissolution time. Conventional blenders and tablet machine is used to produce the tablets. The tablets produced are soft and friable and

packaged in specially designed pick and place system.

**Wowtab Technology**

Wowtab Technology is patented by Yamanouchi Pharmaceutical Co. WOW means "Without Water ". In this process, combination of low mouldability saccharides and high mouldability saccharides is used to obtain a rapidly melting strong tablet. The active ingredient is mixed with a low mouldability saccharide and granulated with a high mouldability saccharide and compressed into tablet.

**Flash Dose Technology**

Flash dose technology has been patented by Fuisz. Nurofen meltlet, a new form of ibuprofen as melt-in-mouth tablets, prepared using flash dose technology is the first commercial product launched by Biovail Corporation. Flash dose tablets consists of self-binding shearform matrix termed as "floss". Shearform matrices are prepared by flash heat processing.

**Flashtab Technology**

Prographarm laboratories have patented the Flashtab technology. Tablets prepared by this system consist of an active ingredient in the form of microcrystals. Drug microgranules may be prepared by using the conventional techniques like coacervation, microencapsulation, and extrusion- spheronisation. All the processing utilized conventional tabletting technology.

**Oraquick Technology**

The Oraquick fast dissolving/disintegrating tablet formulation utilizes a patented taste masking technology. KV Pharmaceutical claims its micro sphere technology, known as Micro Mask, has superior mouth feel over taste-masking alternatives. The taste masking process does not utilize solvents of any kind, and therefore leads to faster and more efficient production. Also, lower heat of production than alternative fast- dissolving/disintegrating technologies makes Oraquick appropriate for heat-sensitive drugs. KV Pharmaceutical also claims that the matrix that surrounds and protects the drug powder in microencapsulated particles is more pliable, meaning tablets can be compressed to achieve significant mechanical strength without disrupting taste-masking Oraquick claims quick dissolution in a matter of seconds, with good taste-masking. There are no products using the Oraquick technology currently on the market, but KV pharmaceutical has products in development such as analgesics, scheduled drugs, cough and cold, psychotropics, and anti-infectives.

**Each technology has a different mechanism, and each fast-dissolving/disintegrating dosage form varies regarding the following:**

Mechanical strength of final product;
Drug and dosage form stability;
Mouth feel;
Taste;
Rate of dissolution of drug formulation in saliva;
Swallow ability;
Rate of absorption from the saliva solution; and
Overall bioavailability.

## Material and Methods

**Calibration of lamivudine**

An accurately weighed quantity of 100mg lamivudine pure drug is taken in a 100ml standard flask. It is mixed with sufficient quantity of distilled water and shaken well until the drug is completely dissolved. From this, 10ml of the solution is pipetted out and made up to 100ml with distilled water. From this 5,10,15,20 and 25ml of solutions are pipetted out in separate standard flasks and the volume is made up to 100ml with distilled water. The absorbance is measured at 271nm in UV- Spectrophotometer.

**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 / $cm^2$.

***Fourier Transmission Infra-Red (FT-IR) Studies***

The studies are performed to check the compatability 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 KBr.

**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
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
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.

**Post compression evaluation**

***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/cm$^2$ 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. (Althaf *et al.*,2011)

***Diameter***

The diameter of the tablets is determined by using vernier calliper.(Ravikumar *et al.*, 2009)

***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. (C.P Jain *et al.*, 2009)

***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. (P.S Kwtikwar *et al.*, 2009)

USP specification for the uniformity of weight

***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 (Harish chander *et al.*, 2011).

***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.

***Disintegration test***

The disintegration test is performed using an USP disintegration apparatus with distilled water at 27± 0.5℃ .the time reported to obtain complete disintegration of 6 tablets are recorded and average is reported (Viral shah *et al.*, 2011).

***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.10mlof 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 of the dissolution rate are recorded.

## Results and Discussion

**Calibration of lamivudine**

The $\lambda_{max}$ of Lamivudine was determined by scanning the 10µg / ml solution of drug using UV-Spectrophotometer and was found to be 271nm.The absorbance of the solution 5 to 25 µg/ml was measured in UV-Spectrophotometer at 271nm.(Table-1). The linear correlation was found to be 0.9995(Distilled water)

**Formulation of fast dissolving tablets of lamivudine**

The individually weighed powder blends of each formulation were compressed in to 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 tablets of all formulations were found to have minimum wetting time and maximum water absorption ratio which is the desired characteristic of fast dissolving tablets, which enables faster disintegration of tablets. The disintegration time of all tablets were found to be less than three minutes, which ensures faster disintegration except for

formulations (F1, F5 and F6).The tablets of all the formulations were found to release more than 80% in 5 minutes, which is the desired quality of fast dissolving tablets that helps in faster absorption of the drug and quick onset of therapeutic effect except for formulations (F1 & F2). The dissolution pattern of various disintegrants used in the formulation was found to be in the order of Crospovidone > Sodium starch glycolate > Croscarmallose sodium.

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.

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**Table 1: Calibration of lamivudine**

| S.No | Concentration(µg/ml) | Absorbance at 271nm (Avg ± S.D) |
|---|---|---|
| 1 | 5 | 0.197 ± 0.0045 |
| 2 | 10 | 0.423 ± 0.004 |
| 3 | 15 | 0.611 ± 0.0024 |
| 4 | 20 | 0.804 ± 0.005 |
| 5 | 25 | 1.005 ± 0.0076 |
| | | $r^2$=0.9995 |

**Table 2: Formulation of fast dissolving tablets of lamivudine**

| Formulation code | Angle of repose(°) | lk density (g/cm$^3$) | ped density (g/cm$^3$) | npressibility index (%) | Hausner's ratio | Drug content (%) |
|---|---|---|---|---|---|---|
| F1 | 30.50 | 0.3368 | 0.4440 | 24.14 | 1.31 | 96.92 |
| F2 | 31.40 | 0.3614 | 0.4436 | 18.53 | 1.22 | 96.69 |
| F3 | 30.69 | 0.3760 | 0.4655 | 19.22 | 1.23 | 96.92 |
| F4 | 30.54 | 0.3624 | 0.4660 | 22.23 | 1.28 | 96.45 |
| F5 | 30.25 | 0.3621 | 0.4656 | 22.22 | 1.28 | 96.69 |
| F6 | 30.66 | 0.3906 | 0.4650 | 16 | 1.19 | 96.21 |
| F7 | 30.56 | 0.3760 | 0.4444 | 15.39 | 1.18 | 96.69 |

| | | | | | | |
|---|---|---|---|---|---|---|
| F8 | 30.54 | 0.3913 | 0.4658 | 15.99 | 1.19 | 95.98 |
| F9 | 30.46 | 0.3916 | 0.4663 | 16 | 1.19 | 96.92 |
| F10 | 30.72 | 0.3915 | 0.4661 | 16 | 1.19 | 96.21 |
| F11 | 30.72 | 0.3914 | 0.4659 | 15.9 | 1.19 | 96.45 |
| F12 | 30.43 | 0.3914 | 0.4660 | 16 | 1.19 | 96.92 |
| F13 | 30.59 | 0.3915 | 0.4661 | 16 | 1.19 | 96.21 |
| F14 | 30.52 | 0.3913 | 0.4659 | 16 | 1.19 | 96.21 |
| F15 | 30.06 | 0.3914 | 0.4660 | 16 | 1.19 | 96.69 |

**Table 03: Precompression evaluations**

| **Formulation code** | **Hardness (kg/cm$^{3)}$** | **hickness (mm)** | **iameter ( mm)** | **Dru g ontent ( %)** | **Weight variation(mg)** | **ria lity (%)** | **Wetting time ( sec)** | **Water absorption ratio in (%)** | **Disintegration time ( sec)** | drug release in 5 minutes |
|---|---|---|---|---|---|---|---|---|---|---|
| F1 | 3 | 3 | 8 | 95.74 | 184.1 -214.04 | 0.51 | 15 | 75.22 | 623 | 19.27±0.56 |
| F2 | 3 | 3 | 8 | 96.21 | 184.47-214.27 | 0.72 | 90 | 113 | 173 | 77.60±0.76 |
| F3 | 3 | 3 | 8 | 96.69 | 185.04-214.84 | 0.55 | 103 | 131 | 179 | 88.55±0.50 |
| F4 | 3 | 3 | 8 | 96.21 | 184.5 - 214.5 | 0.56 | 36 | 144 | 42.6 | 95.34±0.64 |
| F5 | 3 | 3 | 8 | 97.16 | 184.26-214.12 | 0.53 | 151 | 59.6 | 311 | 83.06±0.42 |
| F6 | 3 | 3 | 8 | 95.98 | 185.06-215.06 | 0.71 | 70 | 86.3 | 217 | 95.98±0.67 |
| F7 | 3 | 3 | 8 | 96.21 | 184.82-214.78 | 0.54 | 74 | 110.8 | 91 | 90.71±0.66 |
| F8 | 3 | 3 | 8 | 96.45 | 184.7 -214.64 | 0.52 | 88 | 119.8 | 171 | 93.24±0.28 |
| F9 | 3 | 3 | 8 | 96.21 | 184.63-204.49 | 0.52 | 57 | 105.9 | 120 | 92.26±0.43 |
| F10 | 3 | 3 | 8 | 96.69 | 185 -214.98 | 0.66 | 100 | 110.3 | 150 | 93.06±0.29 |
| F11 | 3 | 3 | 8 | 95.74 | 184.76-214.72 | 0.65 | 74 | 129.6 | 72 | 90.21±0.24 |
| F12 | 3 | 3 | 8 | 96.45 | 184.92-214.9 | 0.66 | 30 | 108.7 | 87 | 92.41±0.15 |
| F13 | 3 | 3 | 8 | 95.74 | 184.88-214.86 | 0.48 | 25 | 107.5 | 29 | 93.37±0.18 |
| F14 | 3 | 3 | 8 | 96.21 | 184.85-214.81 | 0.50 | 24 | 126 | 21 | 96.24±0.15 |
| F15 | 3 | 3 | 8 | 96.69 | 184.88-214.86 | 0.70 | 19 | 129.6 | 4 | 97.19±0.28 |

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