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FORMULATION AND EVALUATION OF FAST DISSOLVING TABLETS OF LAMIVUDINE

Avesh Khan
Sanskar College of Pharmacy & Research, Ghaziabad, 201302, Uttar Pradesh, India

Ajeet
Sanskar College of Pharmacy & Research, Ghaziabad, 201302, Uttar Pradesh, India

Babita Kumar
Sanskar College of Pharmacy & Research, Ghaziabad, 201302, Uttar Pradesh, India

Corresponding author:
Avesh Khan
Email:
aveshkhan1344@gmail.com

ABSTRACT

The oral cavity serves as an attractive pharmaceutical delivery target, with the buccal mucosa circumventing gastric acid degradation and first-pass hepatic metabolism to enhance drug bioavailability. Salivary flow modulates the pharmacokinetic profile of buccal films, while the inherent mucin layer enables mucoadhesive formulations to establish prolonged residence time through polymer-mucosal interactions. This intimate contact between the pharmaceutical agent and epithelium promotes enhanced permeation and therapeutic efficacy. Strategic formulation engineering neutralizes pH-related challenges and modulates transmucosal permeability through excipient selection to optimize drug transport. Buccal patch formulations employ a bilayered architecture with a drug-loaded polymeric matrix cast onto a backing substrate, complemented by an occlusive backing layer that prevents reverse diffusion and maintains formulation integrity.

Keywords- BCCDS, Buccal drug delivery system, pH, mouth, oral cavity.

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INTRODUCTION

Contemporary pharmaceutical development increasingly leverages innovative formulation strategies as a cornerstone approach for market expansion, therapeutic indication diversification, and lifecycle extension of existing therapeutics. Among the diverse routes of pharmaceutical administration, the oral pathway has established itself as the predominant choice for achieving systemic pharmacological action, primarily attributed to its convenient administration profile, elimination of pain-associated barriers, broad applicability across therapeutic domains, and most critically, its demonstrated capacity to enhance therapeutic adherence and patient satisfaction. The manufacturing paradigm for solid pharmaceutical dosage forms confers substantial economic advantages, as these preparations circumvent the stringent aseptic processing requirements mandated for parenteral formulations, consequently enabling cost-effective large-scale production.[1,2,3] The tablet format—recognized as the cornerstone of solid oral delivery—commands this position due to its superior integration of patient acceptability, precise dose quantification, and optimization of manufacturing economies. The pharmaceutical landscape faces transformative pressures as advances in genomic medicine and personalized therapeutics reshape drug discovery trajectories. These evolutionary shifts in therapeutic modalities will necessarily compel reassessment of excipient portfolios and manufacturing infrastructure, potentially necessitating paradigm shifts in technological approaches to solid dosage form fabrication.[4,5] As the pharmaceutical pipeline increasingly incorporates macromolecular candidates—particularly proteins and peptide-based therapeutics—the conventional tablet architecture may progressively diminish in clinical utility, attributable to the inherent pharmaceutical challenges associated with dosing complex biological macromolecules.[6,7] Parenteral administration routes, while therapeutically efficacious, encounter considerable resistance to patient acceptance when administered through conventional injection methodologies; however, the advent of user-centric delivery technologies, such as pre-filled auto-injector systems, has substantially mitigated this resistance by enhancing ease of self-administration and reducing patient anxiety associated with needle-based delivery.

Rapid disintegration solid dosage forms represent pharmaceutical preparations engineered to fragment into minute particulates that progressively dissolve within the oral cavity. The temporal requirement for complete disintegration ranges from fractional seconds to approximately sixty seconds, contingent upon formulation composition and tablet dimensions.[8,9,10]

CHALLENGES INHERENT TO CONVENTIONAL ORAL THERAPEUTICS

Patient populations experiencing neuromuscular tremors encounter substantial impediments when attempting oral administration of powdered or liquid pharmaceutical preparations. Dysphagia—characterized by impaired swallowing mechanics—combined with anatomical obstacles and esophageal transit complications

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may precipitate gastrointestinal mucosal injury. Pediatric populations with underdeveloped neuromuscular systems and geriatric patients with age-related dysphagia encounter difficulties with solid dosage formats including tablets and capsules. Multi-dose liquid formulations (suspensions and emulsions) present challenges in maintaining dosimetric uniformity across sequential administrations.[11,12]

DESIRED CRITERIA

Intraoral dissolution formulations should facilitate disintegration or dissolution within the oral cavity in seconds without requiring aqueous media. These systems must integrate taste-masking compatibility, exhibit robust structural integrity during transport, deliver sensory palatability, minimize postadministration oral residue, maintain stability against hygrothermal degradation, and incorporate pharmaceutical excipients that enhance dissolution kinetics and bioavailability while reducing oral grittiness.[13]

PHARMACEUTICAL EXCIPIENTS FOR RAPID DISINTEGRATION TABLETS

Bulking Agents: These substances function as volumetric fillers and cost-containment agents, providing structural framework without compromising disintegration characteristics.[14]

Surfactant Compounds: These excipients facilitate rapid disintegration and pharmaceutical release without mastication or fluid ingestion. Surfactants stabilize incompatible ingredient blends and augment systemic absorption.

Flow Enhancement Agents: Though supplementary, these substances ameliorate organoleptic properties post-disintegration by eliminating textural roughness and facilitating gastrointestinal transit.[15]

Flavoring and Sweetening Substances: These palatability agents counteract bitter or unpalatable active ingredient profiles. Both botanical and synthetic derivatives enhance sensory characteristics.[16]

Rapid Disintegration Polymers: These excipients facilitate matrix fragmentation upon hydration. Disintegration mechanisms include: Sodium Carboxymethyl Starch (2-8% optimal concentration at 4%) via rapid hydrophilic expansion with minimal viscosity development; Microcrystalline Cellulose (2-15% w/w) utilizing capillary absorption and moisture transport; Cross-linked Vinyl Polymer (2-5% w/w) demonstrating insolubility with rapid expansion, wicking action, and minimal gel formation; Low-substitution Hydroxyl Propyl Cellulose (1-5% concentration) exhibiting rapid hydration with pronounced swelling capacity.

Gas-Liberating Disintegrants: These agents generate gaseous byproducts facilitating ultra-rapid disintegration in formulations requiring expedited dissolution or when conventional disintegration proves inadequate.[17,18]

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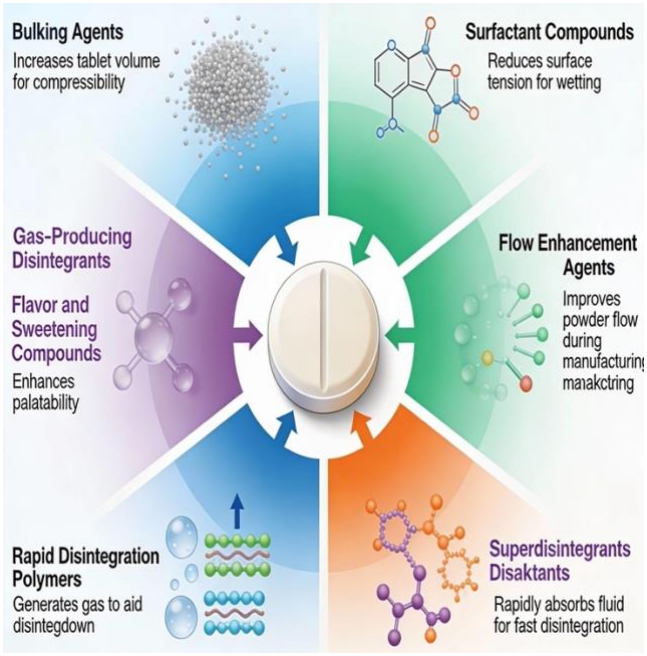

Fig 1: FDT formulation

MANUFACTURING METHODOLOGIES

Thermal Processing (Freeze-Drying): Generates highly porous matrix through rapid solvent removal, enabling instantaneous salivary penetration and disintegration.[19]

Compression Molding: Utilizes hydro-alcoholic moistening with reduced compaction force, creating porous architecture upon solvent evaporation.[20]

Aerosolization: Produces finely-dispersed, high-porosity powder suitable for rapid disintegration tablet fabrication.

Direct Compression: Combines drug and excipients without preprocessing, requiring superior flow characteristics and pressure-induced cohesion.

Volatilization: Incorporates ephemeral inert substances (camphor, ammonium salts, naphthalene derivatives) subsequently removed via thermal vaporization, generating porosity.

PROPRIETARY FORMULATION SYSTEMS

Zydis Platform: Freeze-dried formulation with pharmaceutical agent entrapped within carrier matrix. Upon oral placement, instantaneous disintegration occurs without aqueous supplementation. Enables pregastric absorption, circumventing hepatic first-pass transformation. Disadvantages include elevated manufacturing expenditure, fragility limitations, thermal-hygroscopic sensitivity, and time-intensive production.[21]

Durasolv Technology: Conventional compression utilizing robust mechanical characteristics and conventional packaging compatibility. Superior mechanical integrity via elevated compaction pressures; however, incompatible with higher pharmaceutical loads.

Wowtab System: Employs combined saccharide matrices (variable moldability ratios) generating rapid-melt formulations with superior mechanical robustness and pleasing oral sensations.[22,23]

Flash Dose Platform: Licensed by Fuisz Corporation; commercially exemplified by ibuprofen-based melt tablets.

Flash Tab Framework: Microcrystalline pharmaceutical architecture by Prographarm Technologies. **The aim of the study was** Development and assessment of Lamivudine fast-dissolving tablets with enhanced disintegration and dissolution characteristics, designed for pediatric use

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Materials and methods

MATERIALS

All the materials used in the study was of laboratory grade fit for the development of tablets.

METHODOLOGY

CALIBRATION OF LAMIVUDINE

A precisely measured 100mg of lamivudine pharmaceutical standard is introduced into a 100ml volumetric flask. The substance is dissolved in purified aqueous solvent through vigorous agitation until complete solubilization. A 10ml aliquot is pipetted and diluted to 100ml with purified solvent. This procedure generates a concentration range for establishing pharmaceutical quantification through spectrophotometric absorbance measurement.

PREFORMULATION EVALUATIONS

a) DSC

Thermal investigations are conducted utilizing DSC 200 instrumentation (TA Instruments, USA). Pharmaceutical samples are heated under inert nitrogen atmosphere within aluminum crucibles at a heating rate.[24]

b) FTIR

Infrared spectroscopic analysis is conducted using Spectrum RX-1 Perkin-Elmer spectrophotometer to evaluate physicochemical compatibility between pharmaceutical agent and formulation excipients, identifying potential chemical interactions or degradation mechanisms. Spectroscopic examination is performed in transmission mode across the infrared wavelength region of 4000-400 cm^{-1}. Specimen preparation involves gentle mechanical mixing of 1mg pharmaceutical powder with 100mg potassium bromide, followed by compression into optically transparent pellet structure. The resulting spectroscopic profiles establish baseline pharmaceutical structural fingerprints and identify incompatibility indicators through alteration of characteristic infrared absorption band[25,26]

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FORMULATION

Fast dissolving tablets of lamivudine were formulated using the direct compression technique. In these formulations, three distinct superdisintegrants were incorporated

Table 1: Formulation of fast dissolving tablets of Lamivudine

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13	F14	F15
Lamivudine	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
Croscarmallose sodium	4	8	12	16	20	-	-	-	-	-	-	-	-	-	-
Sodium Starch Glycolate	-	-	-	-	-	4	8	12	16	20	-	-	-	-	-
Crospovidone	-	-	-	-	-	-	-	-	-	-	4	8	12	16	20
Mannitol(27.5%)	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55
Magnesiumstearate(2%)	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
Sodium Sacharrin (5%)	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Talc (0.5%)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Micro CrystallineCellulose	96	92	88	84	80	96	92	88	84	80	96	92	88	84	80
Total weight of tablet	200	200	200	200	200	200	200	200	200	200	200	200	200	200	200

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Precompression evaluation of powder blend

The prepared lamivudine powder blends were subjected to the following precompression tests to assess flow and packing properties.

- **Angle of repose**

  A known quantity of powder was allowed to flow through a funnel onto a flat surface to form a conical heap. θ was calculated using the equation:

  $\tan\theta = h/r$

  Where, h height and *r* radius of the powder cone.

- **Bulk density**

  Apparent bulk density was determined by gently transferring an accurately weighed amount of the blend into a graduated cylinder and recording the unsettled volume. Bulk density was calculated as:

  Bulk density=Weight of powder / Bulk volume

- **Tapped density**

  For tapped density, a measured quantity of the blend was placed in a graduated cylinder and subjected to a fixed number of taps by dropping the cylinder from a height of about 10 cm at regular intervals.[27,28]

  Tapped density=Weight of powder/Tapped volume

- **Carr's compressibility index**

  The compressibility of the blend was expressed as Carr's index, calculated using bulk and tapped densities as:

  Carr's index=Tapped density−Bulk densityTapped density×100

- **Hausner's ratio**

  Flowability was further assessed by Hausner's ratio, determined from the relationship:

  Hausner's ratio=Tapped density/Bulk density

Postcompression evaluation of tablets

- **Hardness**

  Tablet mechanical strength was assessed using a Monsanto hardness tester. A hardness value in the range of about 3–5 kg/cm² was considered acceptable for uncoated tablets.[29]

- **Thickness**

  Tablet thickness and diameter were measured individually using a Vernier caliper, and mean values were reported to ensure dimensional uniformity.

- **Drugcontent**

  For drug content determination, five tablets were weighed, powdered, and an amount equivalent to 10 mg lamivudine was transferred to a volumetric flask and initially dispersed in distilled water. The volume was adjusted to 100 ml and suitably diluted to obtain the required concentration. [30]

- **Weight**

  Twenty tablets from each batch were individually weighed, and the average tablet weight was calculated. [31]

- **Friability**

  Resistance to abrasion was evaluated using a Roche friabilator. After dusting, tablets were

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reweighed, and percentage friability was calculated as:

% Friability=Initial weight−Final weight/ Initial weight×100

Values below 1% were considered satisfactory.

- **Wetting time**

  A tablet was gently placed on the tissue, and the time required for the upper surface to become completely colored (indicating full wetting) was recorded as wetting time.[32]

- **Disintegration**

  Disintegration time was determined using a USP disintegration apparatus with distilled water maintained at 27±0.5∘C

  In-vitro drug releaase

  The drug release profile of the lamivudine tablets was obtained using a USP type II (paddle) dissolution apparatus. The samples were suitably filtered and analyzed spectrophotometrically at 271 nm, and the cumulative percentage of drug released was calculated and documented.[33,34,35]

Result and discussion

CALIBRATION OF LAMIVUDINE

A calibration curve plotted for these concentrations exhibited a linear relationship with a correlation coefficient of 0.9996, confirming excellent linearity of the method.

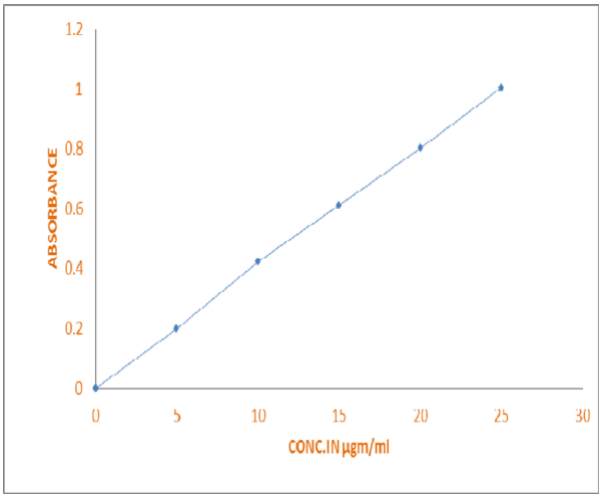

Fig 1: Calibration curve of Lamivudine

PREFOFORMULATION EVALUATIONS

a) DSC

The thermogram of the pure drug displayed a single sharp endothermic peak at 177.4ºC.

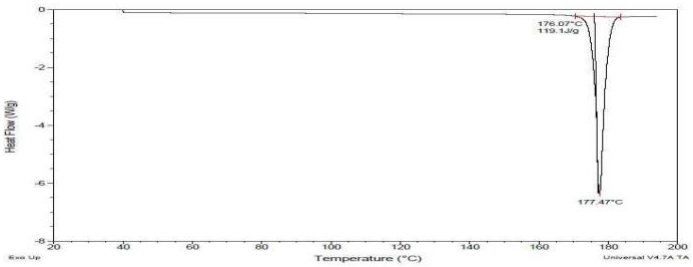

Fig 2: Thermogram of Lamivididudine

FTIR

The spectra showed no noticeable variation, indicating that the drug retained its chemical integrity in the presence of the superdisintegrants.

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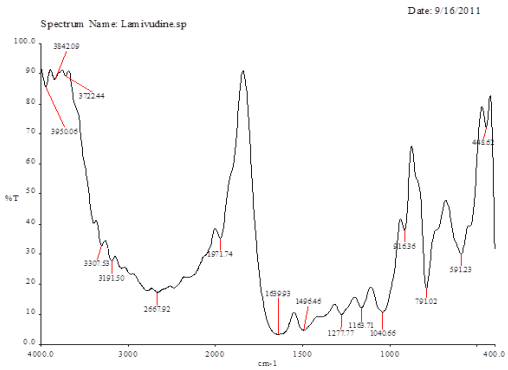
Fig 3: Lamivudine



Precompression Evaluations for the Powder Blend

a. Angle of repose

The observed angle of repose for all formulations ranged between 30°06′ and 30°72′, indicating satisfactory flow characteristics of the powder mixtures.

b. Bulk density

These data demonstrated that all formulations exhibited favourable flow performance.

c. Tapped density

The obtained values confirming that each formulation exhibited satisfactory flow nature.

d. Compressibility index

It provides an estimate of how readily a material consolidates under pressure.

e. Hausner's ratio

The ratios for all fifteen formulations ranged between 1.18 and 1.31.

2. Post-compression Evaluations

The compressed tablets were subjected to post-compression testing to assess their overall quality and confirm compliance with the requirements for fast-dissolving formulations.

a. Hardness

All fifteen formulations showed a uniform hardness of approximately 3 kg/cm², reflecting consistent strength and satisfactory resistance to breakage.

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Table 3: Postcompression evaluation parameters

rmulationcode	Hardness(kg/cm$^{3)}$	hickness(mm)	iameter(mm)	iability(%)
F1	3	3	8	0.51
F2	3	3	8	0.72
F3	3	3	8	0.55
F4	3	3	8	0.56
F5	3	3	8	0.53
F6	3	3	8	0.71
F7	3	3	8	0.54
F8	3	3	8	0.52
F9	3	3	8	0.52
F10	3	3	8	0.66
F11	3	3	8	0.65
F12	3	3	8	0.66
F13	3	3	8	0.48
F14	3	3	8	0.50
F15	3	3	8	0.70

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b. Thickness

All formulations produced tablets with a consistent thickness of approximately 3 mm. The respective data are presented in Table 4.

c. Diameter

All fifteen formulations exhibited a consistent diameter of 8 mm, signifying excellent uniformity in size and shape.

d. Drug content

The drug content values ranged between 95.74% and 97.16%, confirming uniform drug distribution among all formulations. Detailed results are listed in Table 4.

e. Weight variation

The percentage deviation of ±7.5%, confirming satisfactory uniformity in tablet weight.

f. Friability

Tablets showing friability values below 1% are generally considered mechanically robust. All formulations demonstrated friability values below this limit, indicating sufficient strength to withstand mechanical stress.

g. Wetting time and water absorption ratio

Formulations that show shorter wetting times and higher water absorption ratios tend to disintegrate more quickly. The wetting times for formulations F1–F15 ranged between 15 and 151 seconds.

h. Disintegration time

For fast-dissolving tablets, an ideal disintegration time lies within 30 seconds to 3 minutes. The disintegration times recorded for formulations F1–F15 ranged from 4 to 623 seconds.

i. Dissolution studies

Maximum drug release for all formulations was achieved within 5 minutes, with release percentages ranging from 19.27% to 97.19%.

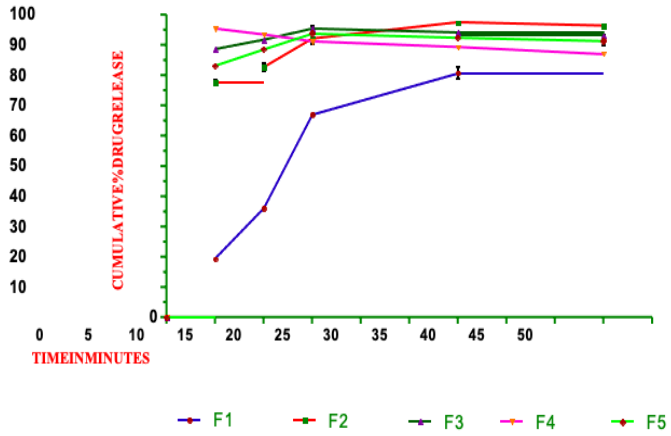

Fig 4: release profile of various concentrations of croscarmellose sodium

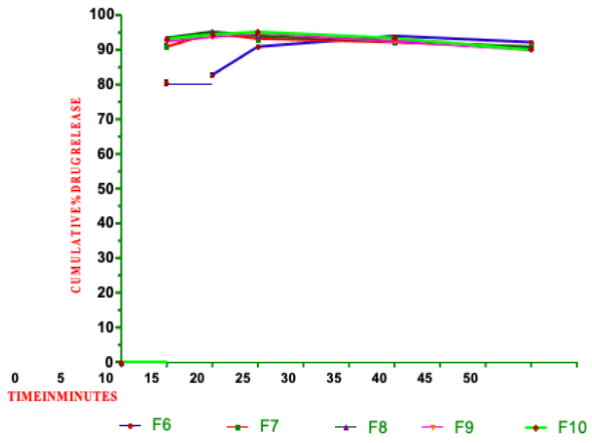

Fig 5: release profile of various concentrations of sodium starch glycolate

Discussion

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The findings from FTIR Spectroscopy confirmed the absence of any chemical interaction between Lamivudine.

All compressed tablets were subjected to various physicochemical tests. The evaluation results showed that the tablets possessed uniform hardness, thickness, and diameter, ensuring consistent size and mechanical strength. The drug content across all formulations was within pharmacopeial limits, confirming excellent content uniformity.

Additionally, all batches met the criteria for weight variation, indicating even distribution of the powder blend during compression. The tablets also displayed short wetting times and high water absorption ratios, suggesting the effectiveness of the superdisintegrants in promoting faster disintegration.

The disintegration times for all formulations were under three minutes—well within the acceptable limits for fast-dissolving tablets. Although formulations F1, F5, and F6 showed slightly higher values, their performance remained satisfactory.

Conclusion

The study established that Lamivudine can be successfully formulated into fast-dissolving tablets by employing various superdisintegrants at different concentrations. Among all tested formulations, the batch containing 10% Crospovidone exhibited the most favourable results, achieving the shortest rate, thus proving to be the optimized formulation.

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