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FORMULATION AND EVALUATION OF FAST DISSOLVING TABLETS OF LAMIVUDINE

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ABSTRACT

Fast dissolving tablets (FDTs) disperse within the oral cavity in a matter of seconds and dissolve in the saliva, removing the need to swallow an intact solid dose. Such dosage forms are particularly useful for pediatric and geriatric patients, who frequently struggle with conventional tablets and capsules. The present work was undertaken to develop and evaluate FDTs of lamivudine intended for pediatric administration. Fifteen batches (F1–F15) were prepared by direct compression using three superdisintegrants, namely croscarmellose sodium, sodium starch glycolate and crospovidone, each incorporated at five concentration levels (4, 8, 12, 16 and 20 mg per tablet). The blends were assessed for flow properties, and the resulting tablets were examined for hardness, thickness, diameter, weight variation, friability, drug content, wetting time, disintegration time and in-vitro dissolution. Across the batches, hardness was uniform at about 3 kg/cm², friability remained below 1%, drug content fell between 95.74% and 97.16%, disintegration times spanned 4 to 623 s, and cumulative dissolution at 5 min ranged from 19.27% to 97.19%. The batch containing crospovidone at the 10% level (F13) emerged as the optimised formulation, offering the fastest disintegration together with the highest drug release.

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

INTRODUCTION

Of the various routes available, oral administration continues to dominate clinical use because it is painless, broadly applicable across therapeutic classes, and supportive of patient adherence. From a manufacturing standpoint, solid oral preparations are also attractive: they do not demand the aseptic processing that injectables require, and so can be produced economically at scale. New formulation approaches are therefore pursued as a means of expanding markets, broadening therapeutic indications and prolonging the commercial life of established medicines.[1,2,3] Within solid oral delivery, the tablet remains the dominant format, valued for its patient acceptability, accurate dose definition and favourable production economics. Ongoing advances in genomic medicine and personalised therapy, however, are reshaping the drug discovery pipeline and will, in time, require excipient libraries and manufacturing platforms to be revisited and, where necessary, redesigned.[4,5] With the pipeline now skewed toward macromolecular candidates such as proteins and peptides, the classical compressed tablet may gradually lose ground, since dosing complex biological macromolecules in this format is inherently problematic.[6,7] Although parenteral therapy is clinically effective, patient acceptance of conventional injections is poor; user-friendly devices such as pre-filled auto-injectors have lowered this barrier by simplifying self-administration and easing needle-related apprehension.

Rapidly disintegrating solid dosage forms are designed to break apart into fine particles inside the mouth, where they then dissolve in the saliva. Complete disintegration is achieved within a few seconds to about a minute, depending on the composition and the size of the tablet.[8,9,10]

CHALLENGES INHERENT TO CONVENTIONAL ORAL THERAPEUTICS

Swallowing difficulty, or dysphagia, is widely reported in paediatric patients whose neuromuscular coordination is still developing and in geriatric patients in whom it is age-related, leaving both groups unable to take standard tablets and capsules with ease. Poorly swallowed solids can lodge against the oesophageal wall and trigger mucosal injury, an outcome that becomes more likely when anatomical anomalies or motility problems coexist. Liquid alternatives, such as suspensions and emulsions intended for multiple dosing, partially overcome the swallowing barrier but raise their own concern, namely the difficulty of delivering a uniform dose with each administration.[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

A typical fast-dissolving tablet formula draws on several functional categories of excipients. Bulking agents act mainly as fillers, helping to keep the cost of the formulation low while providing the structural framework of the tablet without slowing its disintegration.[14]

Surfactants are included to promote rapid wetting and drug release in the mouth without chewing or sipping water; they also help to keep otherwise incompatible components together and can improve systemic absorption.

Flow-enhancing additives play a secondary role; once the tablet has disintegrated they help to smooth the mouth-feel by reducing residual grittiness and easing onward passage through the gastrointestinal tract.[15]

Flavours and sweeteners, drawn from either natural or synthetic sources, are added largely to mask the bitter or otherwise unpleasant taste of the active drug and to improve overall sensory acceptance.[16]

A central role is played by the rapid-disintegration polymers, which cause the compressed matrix to break apart as soon as it takes up water; commonly used examples include Sodium Carboxymethyl Starch, typically used at 2-8% (optimum near 4%) and acting through rapid hydrophilic expansion with little viscosity build-up, Microcrystalline Cellulose at 2-15% w/w, which works largely by capillary uptake and moisture transport, Cross-linked Vinyl Polymer at 2-5% w/w, which is insoluble yet expands and wicks rapidly with negligible gel formation, and Low-substitution Hydroxyl Propyl Cellulose at 1-5%, which hydrates quickly and shows pronounced swelling.

Where even shorter disintegration times are required, or where conventional disintegrants are not effective enough, gas-liberating disintegrants are used; these release a gas in contact with water and so accelerate matrix breakdown still further.[17,18]

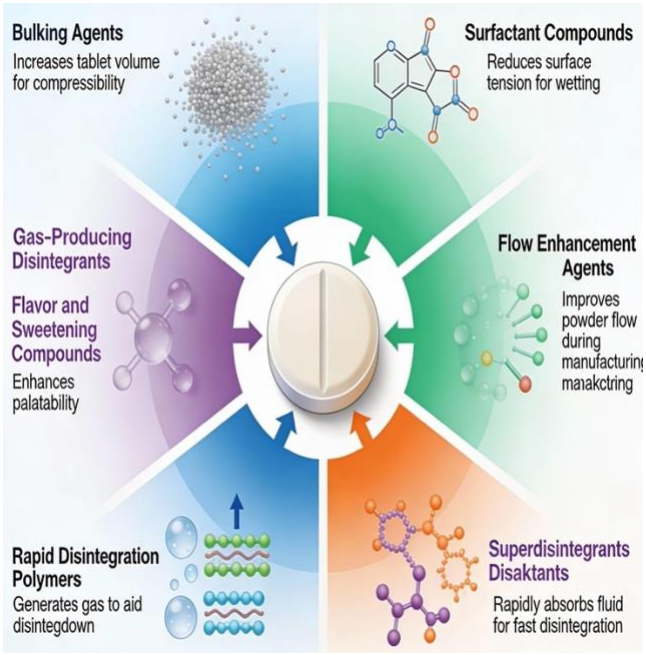


Fig 1: FDT formulation

MANUFACTURING METHODOLOGIES

Several manufacturing strategies have been described for fast-dissolving tablets. In thermal processing by freeze-drying, the solvent is removed rapidly to leave behind a highly porous matrix into which saliva can penetrate at once, allowing almost instant disintegration.[19]

Compression moulding takes a different route: the powder mass is wetted with a hydroalcoholic solvent and lightly compressed, and as the

solvent evaporates the resulting tablet retains a porous internal architecture.[20]

Aerosolisation, by spray-processing, yields a finely dispersed and highly porous powder that is well suited to subsequent compression into rapid-disintegration tablets.

Direct compression is the simplest of these approaches: drug and excipients are blended and compressed directly, with no granulation step, which places strong demands on powder flow and on the cohesion that can be developed under pressure.

PROPRIETARY FORMULATION SYSTEMS

A number of proprietary fast-dissolving tablet platforms have been commercialised. The Zydis platform produces a freeze-dried matrix that disintegrates instantly on contact with saliva and so permits pregastric absorption, bypassing hepatic first-pass metabolism, though it carries higher manufacturing cost, fragile mechanical strength, thermal and hygroscopic sensitivity, and a long production cycle.[21]

In the Wowtab system, combinations of saccharides with differing mouldability are used to give a rapid-melt tablet that is both mechanically robust and pleasant in the mouth.[22,23]

The Flash Dose platform, licensed by Fuisz Corporation, is exemplified commercially by ibuprofen-based melt tablets.

.Against this background, the present work set out to develop and evaluate lamivudine fast-dissolving tablets with improved disintegration and dissolution behaviour, intended for paediatric administration.

Materials and methods

MATERIALS

Every excipient and reagent employed in this work was of laboratory grade and suitable for tablet development.

METHODOLOGY

CALIBRATION OF LAMIVUDINE

A stock solution was prepared by dissolving 100 mg of lamivudine reference standard in 100 ml of purified water with continuous stirring until complete dissolution. Serial dilution of a 10 ml aliquot to 100 ml in the same solvent provided the working concentrations used to construct the spectrophotometric calibration curve.

DRUG-EXCIPIENT COMPATIBILITY STUDIES

a) DSC

Thermal behaviour was characterised on a DSC 200 instrument (TA Instruments, USA), with the samples sealed in aluminum crucibles and heated under a nitrogen purge at a defined heating rate.[24]

b) FTIR

Compatibility between lamivudine and the selected excipients was assessed by FTIR using a Spectrum RX-1 Perkin-Elmer spectrophotometer; samples were prepared by blending 1 mg of drug with 100 mg of potassium bromide and the spectra were recorded in transmission mode over 4000-400 cm^{-1}. Any chemical interaction or degradation would be expected to shift or attenuate the characteristic absorption bands of the drug[25,26]

FORMULATION

Fifteen lamivudine formulations (F1-F15) were produced by direct compression, with croscarmellose sodium, sodium starch glycolate, or crospovidone introduced as the superdisintegrant across the batches at five concentration levels each (4, 8, 12, 16 and 20 mg).

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

Precompression evaluation of powder blend

The lamivudine blends were screened for flow and packing behaviour through a panel of five standard descriptors. Flow tendency was inferred from the angle of repose, obtained by allowing the powder to fall through a funnel onto a flat surface and applying the equation below, where h and r denote the height and basal radius of the resulting cone. The unsettled (bulk) and tapped volumes of a weighed amount of blend were recorded in a graduated cylinder, with the tapped reading taken after dropping the cylinder a fixed number of times from approximately 10 cm; from these two values the apparent bulk density and tapped density were derived. Consolidation behaviour was then quantified as Carr's index, while Hausner's ratio served as a complementary index of flowability.[27,28]

$\tan f_0 \theta = h/r$

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

Bulk density=Weight of powder / Bulk volume

Tapped density=Weight of powder/Tapped volume

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

Hausner's ratio=Tapped density/Bulk density

Postcompression evaluation of tablets

- Mechanical and physical attributes were judged across the following parameters. Crushing strength was checked individually on a Monsanto hardness tester, with values of approximately 3-5 kg/cm² regarded as acceptable for uncoated tablets,[29] while tablet thickness and diameter were measured one tablet at a time with a Vernier caliper and reported as means to confirm dimensional uniformity. Weight variation was assessed by individually weighing twenty tablets from each batch and computing the average weight,[31] and abrasion resistance was evaluated on a Roche friabilator, with the percentage friability calculated from the equation below; values below 1% were taken as satisfactory. For drug content, five tablets were weighed and powdered, an amount equivalent to 10 mg of lamivudine was transferred to a volumetric flask and initially dispersed in distilled water, then made up to 100 ml and further diluted to the required concentration for spectrophotometric assay.[30]

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

Release-relevant attributes were captured in three additional tests. For wetting time, a single tablet was placed gently on the tissue surface and the interval needed for the upper face to become fully

coloured, indicating complete wetting, was recorded.[32]

Disintegration time was measured with a USP disintegration apparatus using distilled water held at 27±0.5∘C.

For in-vitro drug release, the dissolution profile of the lamivudine tablets was generated on a USP type II (paddle) apparatus; aliquots were filtered, read against a blank by UV spectrophotometry at 271 nm, and expressed as the cumulative percentage of drug released.[33,34,35]

Result and discussion

CALIBRATION OF LAMIVUDINE

When plotted against absorbance, the working concentrations gave a straight-line response with a correlation coefficient of 0.9996, indicating that the spectrophotometric method was linear over the range examined.

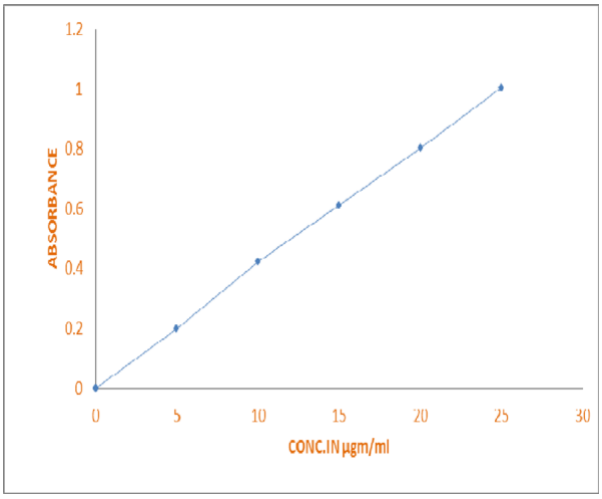
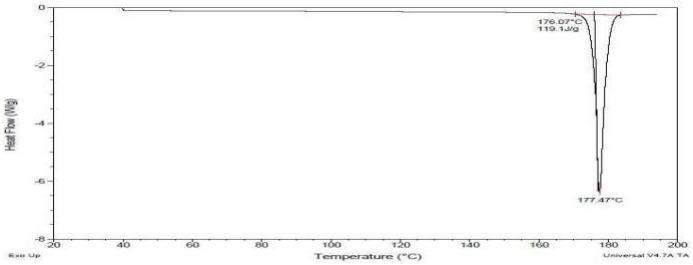


Fig 1: Calibration curve of Lamivudine

PREFOFORMULATION EVALUATIONS

a) DSC

A single sharp endothermic event was observed in the thermogram of pure lamivudine, occurring



at 177.4ºC.

Fig 2: Thermogram of Lamividudine

FTIR

No appreciable change was seen in the spectra of the drug-superdisintegrant blends relative to the pure drug, which suggests that lamivudine

remained chemically intact in the presence of the chosen excipients.

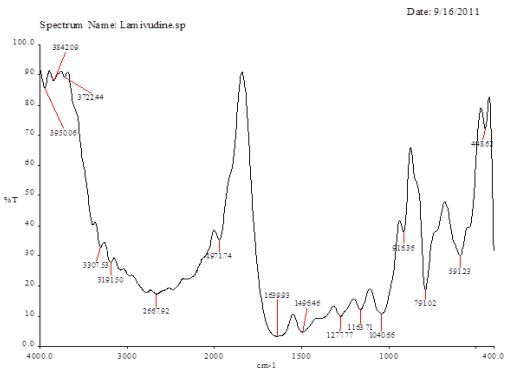


Fig 3: Lamivudine

Precompression Evaluations for the Powder Blend

Across all fifteen batches, the powder blends performed acceptably on the panel of flow descriptors. The angle of repose was confined to a narrow window of 30°06′ to 30°72′, and the Hausner's ratio remained between 1.18 and 1.31, with the corresponding bulk density, tapped density and Carr's compressibility index sitting in ranges normally regarded as indicative of satisfactory powder flow and packing.

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.

On post-compression evaluation, all fifteen formulations conformed to the quality expectations for fast-dissolving tablets. Crushing strength was uniform at about 3 kg/cm² with thickness held close to 3 mm and a constant diameter of 8 mm, percentage weight variation stayed within ±7.5%, friability was consistently below 1%, and the assayed drug content lay between 95.74% and 97.16%, all of which point to acceptable mechanical robustness, dimensional uniformity and content uniformity across the batches.

Table 3: Postcompression evaluation parameters

Formulation code	Hardness(kg/cm$^{3)}$	hickness(mm)	Diameter(mm)	Friability(%)
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

Turning to the release-related parameters, the wetting times for F1-F15 lay between 15 and 151 s, the corresponding disintegration times ran from 4 to 623 s, and cumulative dissolution at 5 min spanned 19.27% to 97.19%, the upper end of the range being reached by the crospovidone-containing batches.

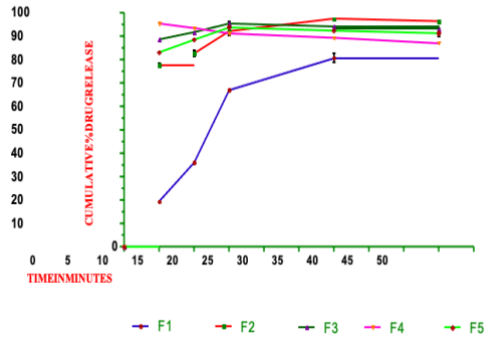


Fig 4: release profile of various concentrations of croscarmellose sodium

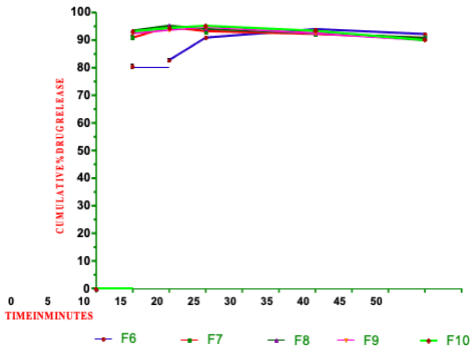


Fig 5: release profile of various concentrations of sodium starch glycolate

Discussion

FTIR spectra recorded for the binary mixtures showed no shift or attenuation of the characteristic bands of the drug, indicating that lamivudine retained its chemical integrity in the presence of the selected superdisintegrants and confirming the absence of any incompatibility.

Mechanical properties were uniform across the fifteen batches: hardness, thickness and diameter values fell within narrow ranges, indicating consistent compaction and good dimensional control. Both the weight variation and the drug content of the tablets met the official pharmacopoeial requirements, which together imply that powder distribution during compression and content uniformity of the active in the matrix were adequate.

The short wetting times and high water absorption ratios recorded across the batches reflect effective action by the superdisintegrants, which was also evident in the observed disintegration behaviour.

In every batch the disintegration time stayed under three minutes, comfortably within the limit normally accepted for fast-dissolving formulations; formulations F1, F5 and F6 sat at the higher end of the range but were still acceptable. Crospovidone-containing batches gave the fastest dissolution profile.

Conclusion

Lamivudine fast-dissolving tablets were obtained successfully by direct compression using three superdisintegrants, each examined at five concentration levels. All fifteen batches satisfied the official quality requirements for hardness, friability, weight variation, drug content and disintegration. Of these, formulation F13, which used crospovidone at 10%, gave both the fastest disintegration

and the highest cumulative drug release at 5 min. On this basis, F13 is proposed as the optimised paediatric fast-dissolving tablet of lamivudine.

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