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Formulation and Evaluation of Fast Dissolving Tablet of Lasmiditan

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ABSTRACT:
The objective of the present research was the formulation and evaluation of fast dissolving tablets (FDTs) of Lasmiditan, a 5-HT (1F) receptor agonist, for the acute treatment of migraine, with the aim of achieving a rapid onset of therapeutic action and improved patient compliance. Lasmiditan has poor aqueous solubility; therefore, fast dissolution is essential to ensure quick absorption and relief. Eight formulations (F1–F8) were developed using wet granulation. The concentration of crospovidone and croscarmellose sodium was varied to assess their influence on tablet performance. Other excipients, such as microcrystalline cellulose (MCC), mannitol, polyvinylpyrrolidone (PVP K30, binder), and flavoring agents, were kept constant. All formulations were evaluated for pre- and post-compression parameters, including organoleptic properties, hardness, friability, weight variation, drug content, disintegration time, wetting time, water absorption ratio, and in vitro drug release. The results revealed that all formulations complied with pharmacopeial limits. However, formulation F5, which exhibited the shortest disintegration time and 90% drug release within 15 minutes. This made it the most optimized batch. Drug-excipient compatibility was confirmed by FTIR analysis, which showed no significant interaction. Stability studies conducted on the optimized formulation under ICH guidelines revealed no significant changes in tablet characteristics over time. The optimized lasmiditan FDT (F5) offers rapid disintegration and drug release, making it a promising dosage form for effectively and immediately managing migraines and potentially improving patient adherence and therapeutic efficacy.

Keyword: Lasmiditan, fast dissolving tablet, Superdisintgrants, migraine, in vitro

I. INTRODUCTION

Despite a drug can be administered via different routes, oral route has been considered as most obvious route of administration in primary health care system. It is believed as most economical and simplest route of drug administration that does not require use of any device and therefore allows self-medication. Due to several benefits like non-invasive, low cost and high patient compliance of oral route, most of drugs are designed and formulated principally, for oral administration. Most conventional oral drug products, such as tablets and capsules, are formulated to release the active drug immediately. In the formulation of conventional drug products, no efforts have been made to modify drug release rate and hence they cause difficulty to achieve steady state condition and exhibits unavoidable fluctuation in the plasma concentration that results in under medication or over medication. Modified-release (MR) drug product alters the timing and/or the rate of release of the drug substance. The pattern of drug release from MR dosage forms is different from conventional dosage form. Two types of modified-release dosage forms are extended release and delayed release.

Extended release dosage form

It allows two fold reductions in dosage frequency as compared to conventional dosage form. Extended release drug products include controlled-release, sustained-release and long-acting drug products.

Delayed-release dosage form

It releases portions of drug at a time other than promptly after administration. An initial portion may be released promptly after administration. Delayed-release drug products include enteric-coated product. One of the major drawbacks of MR dosage form is poor in-vitro-in-vivo correlation with compromised dosage adjustment and retrieval of drug difficulty in case of toxicity, poisoning or hypersensitivity reactions. Intraoral dosage forms have evolved as an alternative to conventional tablets, capsules and liquid preparations. Intraoral dosage forms, quick dissolving dosage forms have gained much attention due to improved patient compliance and ease of administration.

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Tablet

Tablets may be defined as solid pharmaceutical dosage forms containing medicament or medicaments with or without suitable excipients & prepared either by compression or molding.

Advantages of Tablet

Some of the potential advantages of tablets are as follows.

- ✓ They are the unit dosage form having greatest capabilities amongst all the oral dosage form for the dose precision and least content variability.
- ✓ Their cost is lowest amongst all the oral dosage forms.
- ✓ They are the lightest and the most compact amongst all the oral dosage form.
- ✓ They are easiest and cheapest for packaging and transportation.
- ✓ They lend themselves to certain special release profile products such as enteric or delayed release products.
- ✓ Tablets are better suited to large-scale production than other unit oral dosage forms
- ✓ They have the best-combined properties of chemical, mechanical, microbiological stability amongst all the oral dosage forms

Classification of Tablets

1 Based on the route of administration or the function, the tablets are classified as follows.

1) **Tablets ingested orally.**
a) Compressed tablet
b) Multiple compressed tablet o Layered Tablet
o Compression coated Tablet
c) Repeat action Tablet
d) Delayed action and enteric coated Tablet
e) Sugar and chocolate coated tablet
f) Film coated tablet
g) Chewable Tablets.

2) **Tablets used in the oral cavity.**
a) Buccal Tablet
b) Sublingual Tablet
c) Fast Dissolving Tablet (FDT)
d) Troches and Lozenges
e) Dental cones

3) **Tablets administered by other routes.**
a) Implantation Tablet
b) Vaginal Tablets

4) Tablets used to prepare solution.
a) Effervescent Tablet
b) Dispensing Tablet
c) Hypodermic Tablet
d) Tablets Triturates

Fast Dissolving Tablet (FDT)

It is clear that most drugs are administered in solid dosage forms orally, such as powders, capsules, pills, cachets, and tablets. The oral route is clearly the preferred choice. It allows for self-administration, is the least expensive option, and is easily accepted by the human body because of its similarity to food. The dosage form is a process that transforms the drug into a more palatable, elegant, and easily acceptable form for the patient. The dosage form's primary purpose is clear: to deliver the drug to the site of action, ensuring maximum therapeutic effect and minimum adverse effects.

Advantages of Fast Dissolving Tablets [17-20]

- ✓ This is the best option for patients who cannot swallow, including pediatric, geriatric, bedridden, stroke victims, and institutionalized patients (especially for mentally retarded and psychiatric patients)
- ✓ Pregastric absorption increases bioavailability by ensuring rapid absorption of drugs from the mouth, pharynx, and esophagus as saliva passes down to the stomach. This also avoids hepatic metabolism.
- ✓ It is convenient for administration to traveling patients and busy people who do not have access to water.
- ✓ The excellent mouthfeel is produced by the use of flavors and sweeteners.

Drug and Excipients Profile

5.1 Drug Profile: Lasmiditan
Chemical Name: Lasmiditan
Chemical Structure:

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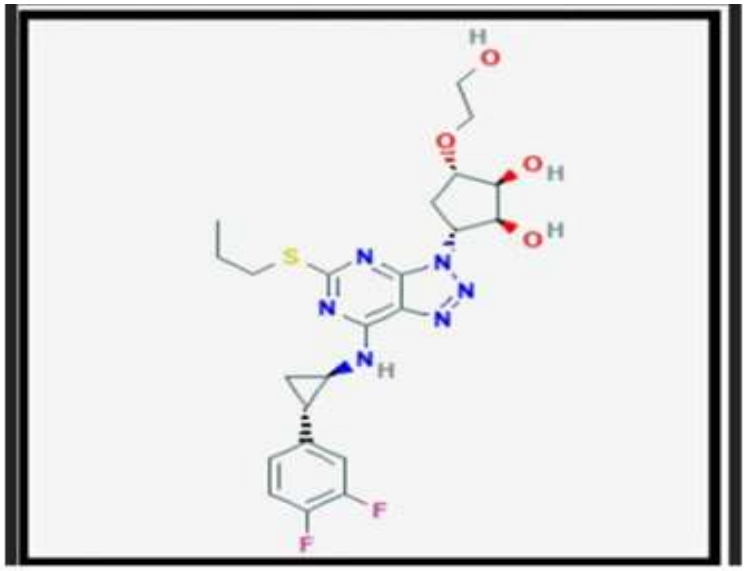

Figure 10: Structure of Lasmiditan

Molecular Formula: C19H18F3N3O2
Molecular Weight: 377.367 g/mol
Solubility: sparingly soluble in water, slightly soluble in ethanol, and soluble in methanol
Melting Point: Approximately 196-198°C. °C
Appearance: white, crystalline powder
Storage: stored at 20–25°C.
Half-Life: 5.7 hours
Route of Administration: By mouth, intravenous
Absorption:rapidly absorbed orally with a median Tmax of 1.8 hours and a bioavailability of 40%. It has linear pharmacokinetics, meaning the relationship between dose and concentration in the body is consistent. The drug's absorption and pharmacokinetic properties are similar whether taken during a migraine attack or during the interictal period

Distribution: The apparent volume of distribution of the central compartment is estimated to be 558 L, indicating that the drug is widely distributed throughout the body.

Uses and Applications:
To treat the symptoms of migraine headaches (severe throbbing headaches that sometimes are accompanied by nausea and sensitivity to sound and light).

Excipients Profile
1) Microcrystalline cellulose (MCC)
Synonyms: Avicel, Cellulose gel, Crtstalline cellulose, E460, Emcocel, Fibrocel Tabulose.
Empirical formula: (C6H10O5) n where n ≈ 220

Structural formula:

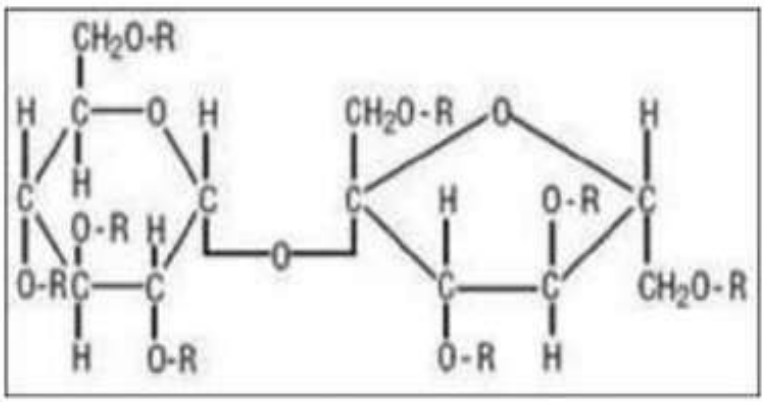

Figure : Structure of MCC

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Molecular weight: 370.35 g/mol
Description: Microcrystalline cellulose is purified, partially depolymerized cellulose thatoccur as a white, odorless, tasteless, crystalline powder composed of porous particles Functional category: Adsorbent; suspending agents; tablet and capsule diluent, tablet disintegrate.

Application in pharmaceutical

Formulation: Microcrystalline cellulose is widely used in pharmaceuticals, primarily as a binder/ diluent in oral tablet and capsule formulations where it is used in both wet-granulation and direct compression process.Stability and Storage conditions: Microcrystalline cellulose is a stable though hygroscopic material. The bulk material should be stored in a well-closed container in a cool place.

II. MATERIALS & METHODS

List of Equipment's
Following equipment's was used during present work.

Sr. No.	System	Model	Manufacturer
1	Fourier Transform Infrared (FT-IR) Spectrometer	Alpha	Bruker
2	UV-Visible spectrophotometer	Microprocessor double beam spectrophotometer LI-2702	Lasany
3	Single rotatory tablet compression machine	-	Bhagwati lab testing equipments
4	Tray dryer	-	Bhagwati lab testing equipments
5	Shifter	-	Bhagwati lab testing equipments
6	Digital Vernier Calliper	TH-M61	Themisto
7	Hardness Tester	Monsanto type	Bexco
8	Granulator	-	Agro
9	Tablet friability test apparatus	-	Sky technologies
10	Tablet disintegration test apparatus	-	Swastika scientific instruments
11	Uitrasonic cleaning bath	UCB-40	Spectrabab
12	pH meter	LI-120	Elico
13	Water purification system	MilliQ	Millipore
14	Magnetic stirrer with hot plate	-	SkyBound
15	Weighing balance	ViBRA HT	Essae

Fig. List Equipment

List of Glasswares.

Sr. No.	Glassware	Type
1	Conical Flask	Borosilicate glass
2	Beaker	Borosilicate glass
3	Petri plate	Borosilicate glass

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List of Drug and Chemicals

Chemicals used to prepare various solutions and to Carry out different test in present work are enlisted in the table .

Table 4: List of Chemicals

Sr. no.	Materials	Manufacturer
1	Lasmiditan (LDT)	Tokyo Chemical Industry (India) Pvt. Ltd. Hyderabad
2	Microcrystalline cellulose	Dipa Chemical Industries, Chh. Sambhajinagar
3	Mannitol	Dipa Chemical Industries, Chh. Sambhajinagar
4	Croscarmellose sodium	Dipa Chemical Industries, Chh. Sambhajinagar
5	Crospovidone	Dipa Chemical Industries, Chh. Sambhajinagar
6	PVP K30	Dipa Chemical Industries, Chh. Sambhajinagar

III. RESULTS & DISCUSSION

Organoleptic Properties Solubility and melting point determination of Lasmiditan (LDT):

The solubility study of Lasmiditan (LDT) revealed two key findings. First, it is sparingly soluble in water and freely soluble in organic solvents like methanol and ethanol. This indicates its moderate aqueous solubility and the potential need for solubility enhancement techniques in oral formulation. Organoleptic Properties of Lasmiditan

Tests	Specifications	Observation
Colour	white to off-white crystalline powder	white to off-white crystalline powder
Odour	No Characteristic odor	No Characteristic odor
Taste	Slightly Bitter	Slightly Bitter
Physical Appearance	fine, smooth texture	fine, smooth texture

- **Physical Parameter**
- **7.2.1Melting Point Determination of Lasmiditan**
- **Reported M.P.: 196-198°C**
- **Observed M.P.: 196.02 oC**

- **The** melting point of Lasmiditan is 196–198°C, matching established values and confirming the drug's purity. A sharp and consistent melting point range indicates the absence of polymorphic impurities and the thermal stability of the compound under normal processing conditions

Preparation of Standard curve for Lasmiditan

A calibration curve was constructed for Lasmiditan to establish a linear relationship between concentration and absorbance, which is essential for

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accurate quantitative analysis. A stock solution of Lasmiditan was prepared by dissolving an accurately weighed amount of the drug in 0.1 N HCl to obtain a concentration of 100 µg/mL. From this stock solution, a series of standard dilutions were prepared to yield concentrations typically ranging from 2 to 10 µg/mL. The absorbance of each solution was measured using a UV-visible spectrophotometer at the maximum absorption wavelength λ max, typically around 228 nm. Then, a graph of absorbance versus concentration was plotted, and the linear regression equation (y = mx + c) and correlation coefficient (R^2) were determined. The resulting calibration curve exhibited linearity within the selected range, indicating that it could reliably estimate Lasmiditan content in tablet formulations during drug content and dissolution studies.

TABLE.UV Calibration points of lasmiditan

Concentration (µg/ml)	Absorbance
2	0.215
4	0.416
6	0.628
8	0.824
10	1.032

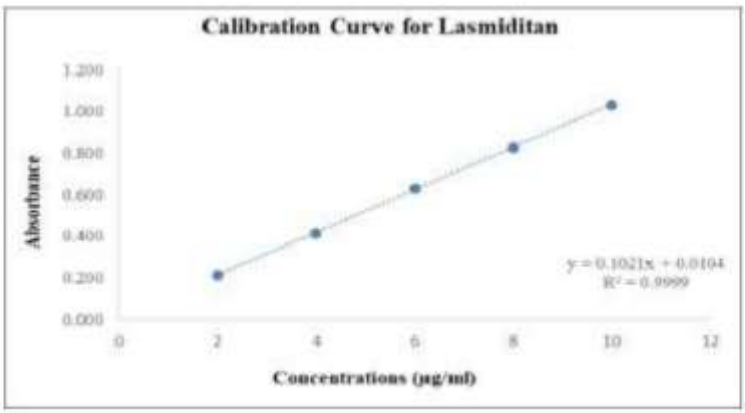

Table. U V Linear regression data for calibration curve lasmiditan

Sr. No.	Parameter	Lasmiditan
1	Slope	0.1021
2	Intercept	0.0104
3	Regression Coefficient	0.9999
4	Linearity Range	2-10 µg/ml

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Differential Scanning Colorimetric study of pure drug:

The DSC Thermogram revealed a sharp endothermic peak at approximately 196.02°C, which corresponds to the melting point of Lasmiditan. This finding indicates the drug's crystalline nature and thermal stability. The absence of additional peaks confirmed the drug's purity, with no signs of degradation. Thus, DSC is a crucial tool in pre-formulation studies to ensure Lasmiditan'scompatibility with excipients and suitability for controlled-release formulations**.**

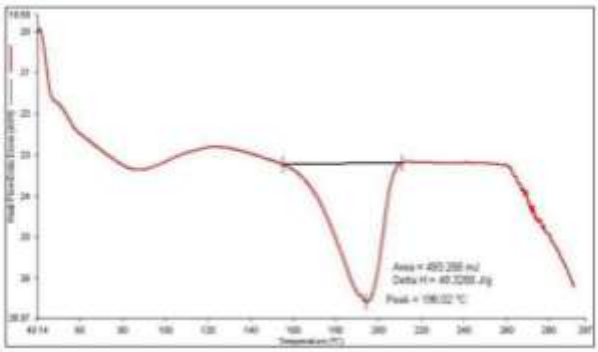

Fig. DSC Thermogram of lamiditan

Table . Evaluation of drug content Uniformity of LDL Tablet

Batch Code	Drug Content* (%)	Results
F1	96.42 ± 0.821	Pass
F2	95.18 ± 0.745	Pass
F3	97.31 ± 0.658	Pass
F4	96.95 ± 0.560	Pass
F5	99.87 ± 0.491	Pass
F6	95.44 ± 0.886	Pass
F7	94.83 ± 0.934	Pass
F8	93.91 ± 0.956	Pass

* Average of three determinations ± SD

In vitro Drug Release Study

An in vitro drug release study of Lasmiditan fast dissolving tablets (F1–F8) revealed distinct patterns influenced by polymer concentration. Dissolution studies were conducted for all the formulation via USP dissolution apparatus II paddle type, using phosphate buffer (pH 6.8) maintained at 37°C ± 0.5°C with a paddle rotation speed of 50 rpm. From the dissolution studies it had been observed from the drug release profile more than 90 % drug was released within 15 min. Formulation F5 that was formulated and showed 90 ± 0.205 % drug release within 15 min.

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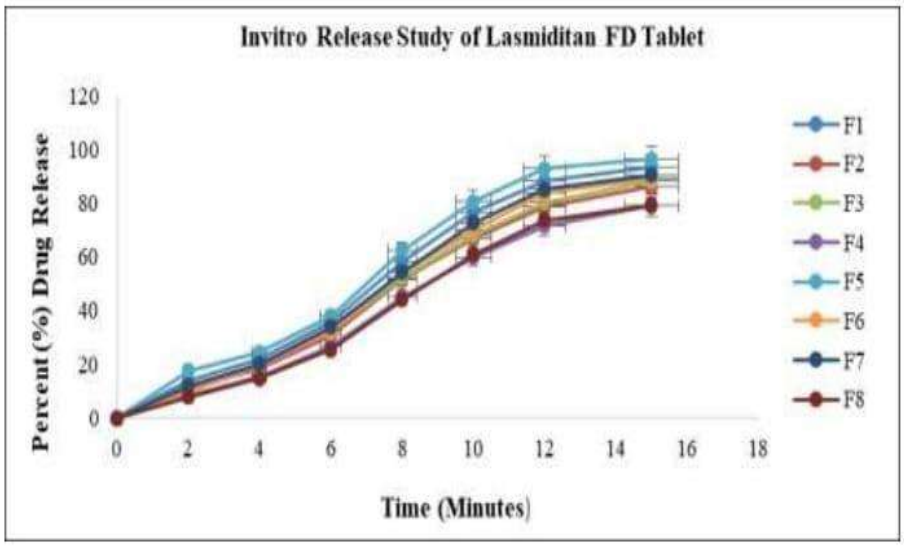
Tables. Percent drug release of batch of f1-f8

Time (Min)	% Release of Lasmiditan			
	F1	F2	F3	F4
0	0.000±0.0	0.000±0.0	0.000±0.0	0.000±0.0
2	13.654 ±0.36	10.684 ±0.57	11.932 ±0.20	8.164 ±0.42
4	22.158±0.27	18.624 ±0.46	19.745 ±0.45	15.514 ±0.20
6	35.647±0.33	30.516 ±0.34	32.164 ±0.38	26.787 ±0.37
8	58.210 ±0.21	51.546 ±0.28	52.146 ±0.37	45.121 ±0.39
10	76.802 ±0.46	66.962 ±0.12	68.107 ±0.26	59.976 ±0.46
12	88.214±0.38	78.541 ±0.46	80.367 ±0.18	71.631 ±0.18
15	93.624±0.26	86.368 ±0.25	88.226 ±0.15	79.128 ±0.25
	B5	B6	B7	B8
0	0.000±0.0	0.000±0.0	0.000±0.0	0.000±0.0
2	17.621 ±0.36	9.716 ±0.37	11.964 ±0.20	7.684 ±0.31



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In vitro release study of lasmiditan fast dissolving tablet

Stability Study of Optimized batch (F5)

To ensure the long-term safety, efficacy, and performance of the optimized formulation (F5), a stability study is carried out according to ICH guidelines (Q1A(R2)) under both accelerated condition. The optimized batch (F5) remained physically and chemically stable for six months during the accelerated stability study. There were no significant changes in Appearance, Hardness, Friability, drug content and disintegrating properties, which confirms the stability,

Stability study of optimized batch F5

Optimized Batch	parameters	40 ± 2 °C (75 ± 5% RH)
30 Days (1 Month)	Appearance	Uniform, Pink in color
	Hardness	6.51 ± 0.236
	Friability	0.69%
	Drug Content	99.81 ± 0.321
	Disintegration time	12.45± 0.04
	Wetting Time	09.13± 0.31
60 Days (2 Month)	Appearance	Uniform, white to light yellowish
	Hardness	6.50 ± 0.368
	Friability	0.68%
	Drug Content	99.52 ± 0.256
	Disintegration time	12.55± 0.02
	Wetting Time	10.12± 0.26
90 Days (3 Month)	Appearance	Uniform, white to light yellowish
	Hardness	6.48 ± 0.210
	Friability	0.68%
	Drug Content	98.96 ± 0.385
	Disintegration time	13.28± 0.03
	Wetting Time	10.56± 0.42

Summary

- ✓ The present study focused on the formulation and evaluation of fast dissolving tablets (FDTs) of Lasmiditan to enhance patient compliance and provide rapid relief in migraine treatment.
- ✓ Eight formulations (F1–F8) were prepared using the wet granulation method by varying concentrations of two superdisintegrants Croscarmellose sodium and Crospovidone while keeping other excipients constant.
- ✓ All batches were standardized to a total tablet weight of 300 mg (15 g per 50 tablets) and evaluated for key parameters including organoleptic properties, solubility, melting point, IR compatibility, disintegration time, wetting time, water absorption ratio, and in vitro drug release.
- ✓ Among the tested batches, F5 demonstrated the fastest disintegration and highest drug release (96.384% within 15 minutes), indicating optimal superdisintegrant combination.
- ✓ The IR spectral studies confirmed no major interaction between Lasmiditan and excipients. Thus, the study successfully developed an optimized FDT formulation of Lasmiditan with rapid disintegration and drug release properties, offering a promising approach for effective and patient-friendly migraine therapy.

IV. CONCLUSION

The present study successfully developed and evaluated fast dissolving tablets (FDTs) of Lasmiditan using wet granulation method to enhance onset of action in migraine therapy. Among the eight formulated batches (F1–F8), formulation F5 exhibited superior performance in terms of disintegration time and in vitro drug release, achieving complete drug release within 15 minutes. The results confirmed that the combination of Crospovidone and Croscarmellose Sodium in higher concentrations significantly improved tablet disintegration and dissolution. Thus, FDTs of

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Lasmiditan offer a promising and patient-compliant dosage form for rapid migraine relief.

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