Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/jptcp.v31i7.7305

FORMULATION AND EVALUATION OF CARBAMAZEPINE ORO DISPERSIBLE TABLET USING LOCUST BEAN GUM

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Abstract
This study has advanced the development of orally disintegrating tablets (ODTs) for epilepsy treatment by leveraging locust bean gum (LBG) as a natural disintegrant. The research employed a factorial design framework to assess nine distinct formulations, including various disintegrants like croscarmellose sodium and Crospovidone, to evaluate their efficacy against LBG. Formulation F3 was identified as the optimal formulation, achieving the most favorable balance across all evaluation parameters.
Formulation F3 demonstrated superior performance with rapid disintegration and improved drug release rates, outperforming other formulations that used synthetic disintegrants. Additionally, F3 exhibited significantly lower residual moisture content, enhancing tablet stability. These findings highlight the potential of LBG as an effective natural alternative in ODT formulations, offering a promising and patient-friendly solution for epilepsy management.
The study also emphasizes the successful application of factorial design in optimizing pharmaceutical formulations, showcasing the importance of rigorous methodologies in drug development. The promising results of using LBG in ODTs for epilepsy treatment may inspire further research and development, leading to more natural and sustainable alternatives in pharmaceutical formulations.

Keywords: Orally disintegrating tablets (ODTs), epilepsy treatment, locust bean gum (LBG), natural disintegrant, factorial design, croscarmellose sodium, Crospovidone, drug release rates.

1. INTRODUCTION

The term "dose form" describes the physical form that a medication is produced, kept, and given to patients. The drug's chemical characteristics, the mode of administration, the patient's preferences, and the therapeutic objectives all play a role in the dosage form selection process [1].

A. **Oral Forms of Dosage:**

- **Capsules and Tablets:** These are hard forms of dosage comprising the drug along with binders, fillers, and sometimes coatings. They are swallowed whole and dissolve in the gastrointestinal tract to release the drug.
- **Suspensions and Solutions:** These are liquid dosage forms where the drug is dissolved or suspended in a liquid vehicle. Suspensions need to be shaken before use, while solutions are homogeneous and ready to use.

- **Syrups and Elixirs:** These are liquid forms of dosage comprising a high absorption of sugars or alcohol to improve taste and stability.
- For elderly or pediatric patients who have trouble swallowing pills or capsules, they are frequently utilized.
- **Powders:** Powders are dry forms of dosage that can be reconstituted with water or another liquid before administration.
- They are often used for drugs that are unstable in solution or for customized dosing.

1.1 INTRODUCTION TO DISEASE:

Frequent, unprovoked seizures are a hallmark of epilepsy, a chronic neurological disorder. These seizures are abrupt brain electrical activity bursts that disrupt consciousness, behavior, and movement. Worldwide, epilepsy impacts almost 50 million people, ranking it among the most prevalent neurological illnesses [26].

a) **Definition:** The International League Against Epilepsy (ILAE) agrees that epilepsy is a neurological disorder that has social, psychological, cognitive, and neurobiological ramifications in addition to a permanent propensity to produce epileptic seizures. The diagnosis is usually made after two unprovoked seizures more than 24 hours apart. [22].

b) **Classification:** Epilepsy can be classified based on the type of seizures experienced and their origin within the brain [23].

a. **Focal Seizures:** Simple ones don't cause loss of consciousness, while sophisticated ones do involve altered consciousness. Both begin in one hemisphere of the brain.

b. **Generalized Seizures:** These encompass a variety of forms involving the brain's two hemispheres, including absence (petit mal), myoclonic, atonic, and tonic colonic seizures (formerly called grand mal).

c. **Focal to Bilateral Seizures:** Seizures that start in one hemisphere and spread to both.

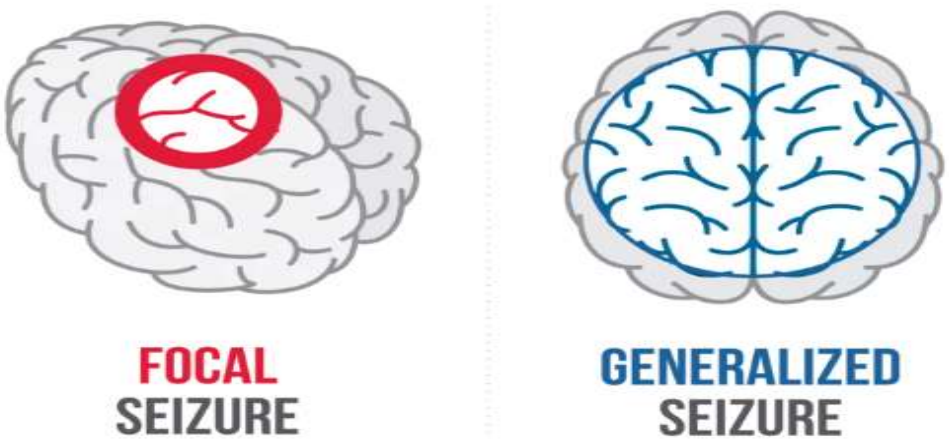


Figure 1: Types of seizures

c) Pathophysiology of Epilepsy

Abnormal, excessive, and synchronized neuronal activity in the brain is part of the pathophysiology of epilepsy. This can result from various mechanisms, including

- **Genetic Factors:** Certain genetic mutations can predispose individuals to epilepsy by affecting ion channels, neurotransmitter receptors, or other cellular components critical for normal neuronal function.
- **Structural Abnormalities:** Brain injuries, tumors, or developmental anomalies can disrupt normal neuronal circuits and lead to epilepsy.
- **Metabolic Disorders:** Conditions such as hypoglycemia, electrolyte imbalances, and mitochondrial dysfunctions can also precipitate seizures [21].

d) Treatment and Management: Management of epilepsy aims to control seizures minimize side effects, and improve quality of life:

- **Medications:** Antiepileptic drugs (AEDs) are the first line of treatment. The choice of AED depends on the type of seizures and individual patient characteristics.
- **Lifestyle Modifications**: Avoiding seizure triggers, maintaining regular sleep patterns, and managing stress.
- **Surgical Interventions:** For drug resistant epilepsy, surgical options such as respective surgery, laser ablation, or implantation of devices like the vagus nerve stimulator (VNS) may be considered.
- **Nutritional Therapies**: For certain people, a high-fat, low-carb ketogenic diet may be beneficial.
- **Supportive Therapies:** Psychological support, education, and social services to help patients and families cope with the disorder [28].

1.2 ORO DISPERSIBLE TABLET[5]

When placed on the tongue, solid medication forms containing pharmaceutical ingredients, known as Oro Dispersible Tablets (ODTs), dissolve within seconds. Upon ingesting, ODTs disperse quickly in the mouth, according to the European Pharmacopoeia.

These are perfect for anyone who have trouble taking regular pills, such as children, the elderly, and those who are bedridden. The oral, pharyngeal, or oesophageal stages of dysphagia (difficulty swallowing) might be caused by neurological problems, muscle disorders, structural abnormalities, or adverse effects of medicines. Suboptimal treatment results and noncompliance might result from dysphagia's effects on swallowing, drinking, and medicine intake [21].

ODTs distribute medication to the mouth, where it can be absorbed by the oral and mucosal tissues as well as the segments of the gastrointestinal system that are located before, during, and after the stomach. In contrast, the stomach and gastrointestinal tract need water to dissolve and absorb traditional pill forms.

These tablets are designed to provide a convenient and patient friendly alternative to traditional tablets or capsules, especially for individuals who have difficulty swallowing solid dosage forms or for situations where water may not be readily available.

1.3 CHALLENGES WITH CURRENT ORAL DOSAGE FORM [6]

a) Swallowing Difficulties
b) Compliance Issues
c) Taste and Palatability
d) Gastric Irritation
e) Delays in the Commencement of Therapeutic Effects
f) Water Dependency
g) Need for Special Handling
h) Multiple Dosage Forms

1.4 ADVANTAGES OF ORO DISPERSIBLE DOSAGE FORM [8]

a) Ease of Administration
b) Improved Patient Compliance
c) Enhanced Bioavailability
d) Taste Masking Capabilities
e) Versatility in Formulation
f) Convenience and Portability
g) Reduced Risk of Choking or Aspiration
h) Improved Stability and Shelf Life

1.5 DRAWBACKS OF ODT:

- A controlled environment, like temperature and humidity is necessary for the storage of fast-breaking tablets because of their hygroscopic nature.
- Special packaging is necessary for ODT to ensure the correct adjustment and safety of the stable product.
- Typically, do not possess sufficient mechanical strength. Careful attention is thus necessary.
- Unless it turns out exactly as planned, it will leave a bitter aftertaste and a film of grime on your mouth.

1.6 REQUIREMENT FOR ODT:

- If a patient has difficulty swallowing regular tablets, even when mixed with water, an orally dissolving dose structure may be the best option.
- People in their pediatric and elderly years
- Patients who do not want to take powerful preparations due to gag reflex fears
- A patient who is frequently sick, may be on the go, or has very limited access to water and is experiencing persistent nausea.

1.7 PROPERTIES OF ORO DISPERSIBLE TABLETS (ODTs) [8]

a) Ease of Administration
b) Taste of the Medicament
c) Hygroscopicity
d) Friability
e) Grittiness in the Mouth
f) No Need for Water
g) High Drug Load
h) Minimal Residues
i) Conventional Manufacturing

1.8 ORO Disposable Tablets' salient characteristics (ODTs)[2, 8]

- Convenient and easy to administer, especially for patients with swallowing difficulties.
- Rapid onset of action due to quick dissolution in the mouth.
- No need for water, making it suitable for use in various settings.
- Improved patient compliance and adherence to medication regimens.
- Ideal for pediatric and geriatric patients who may struggle with traditional tablets.
- Masking of unpleasant taste, enhancing medication palatability.
- Reduced risk of choking compared to traditional tablets.
- Faster absorption and bioavailability for certain medications.
- Enhanced stability and shelf life.
- Compatibility with different packaging materials.

1.9 ODT Drug Candidate Selection [11]:

When choosing potential medication dose forms for ODTs, several considerations must be taken into account. Assuming absorption happens in the post gastric GIT segments, an oral dosage form (ODT) is often developed as a comparable extension line of a preexisting oral form of dosage. The pharmacokinetic characteristics of certain medications' ODT formulations differ greatly from those of their traditional dose forms, hence this might not always hold true.

If a drug can penetrate the oral mucosal tissue and diffuse into the upper gastrointestinal tract (log P > 1, or better still > 2), then it is appropriate for oral drug delivery systems (ODTS).

This method is not appropriate for drugs that have short half-lives, have unpleasant flavors, or need controlled or continuous release.

1.10 SUPER DISINTEGRANTS [71]

Medication disintegrants are compounds or substances mixtures that aid in the breakdown or separation of tablet contents into smaller particles. There are two groups of Superdisintergrants that might be defined according to their availability:

A. Organic Superdisintegrants: Natural super dissolving agents are better than synthetic ones in many ways: they're more affordable, readily available, won't irritate skin, and won't do any harm.Natural materials such as mucilage and the gums have found widespread application in the drug delivery field. These materials possess a number of desirable qualities, including being easily accessible, affordable, environmentally friendly, emollient, non-irritant, non-toxic, amenable to a wide range of chemical enhancements, potentially biodegradable, and compatible.

B. Synthetic Superdisintegrants: The majority of these problems are resolved by synthetic superdisintegrants such as sodium starch glycolate, AcDiSol, and Crospovidone (Polyplasdone XL). Super disintegrants can be used in rapid dispersible tablets due to their optimal physical features.

S. no.	Natural polymer	Marketed drug	Disintegration time	Concentration used
1	Chitin and chitosan	Cinnarizine	60 sec	3% w/w
2	Guar gum	Glipizide	30 sec	1% w/w
3	Gum karaya	Amlodipine, granisetron hydrochloride	17.10 sec	4% w/w
4	Agar and treated agar	Theophylline	20 sec	1-2% w/w
5	Fenugreek seed mucilage	Metformin hydrochloride	15.6 sec	4% w/w
6	Soy polysaccharide	Lornoxicam	12 sec	8% w/w
7	Gellan gum	Metronidazole	155 sec	4% w/w
8	Mango peel pectin	Aceclofenac	11.59 sec	0.1–4% w/w
9	*Lepidium sativum* mucilage	Nimesulide	17 sec	5–15% w/w
10	*Plantago ovata* seed mucilage	Granisetron HCl	17.10 sec	5% w/w
11	Aegle marmelos gum	Aceclofenac	8–18 min	6% w/w
12	Locust bean gum	Nimesulide	13 sec	10% w/w
13	*Lepidium sativum*	Nimesulide	17 sec	10% w/w

Figure 2: List of all natural disintegrants used in ODT

Table no: 2. Synthetic disintegrant

S.NO.	Synthetic super disintegrant	Properties	Effective concentration for Disintegrants
1	Crospovidone	• It is insoluble in water. Rapidly disperses and swells in water. Greatest rate of swelling. compared to other disintegrants • 2. Available in grades if needed for improving state of dispersion in the powder blend 3. Swelling index 58±1.5% v/v	It is used in the range of 13% w/w
2	Croscarmellose sodium	1.It is insoluble in water, although it rapidly swells to 48 times its original volume on contact with water 2. Specific surface area 0.81 0.83m/g 3. Swelling index 65±1.7% v/v	It may be used as a tablet disintegrant at concentration up to5% w/w, although normally 2% w/w is used in tablets prepared by direct compression and 3% w/win tablets prepared by wet granulation process
3	Sodium starch glycol ate	1. Absorbs water rapidly, resulting in swelling up to 6%. High concentration causes gelling and loss of disintegration 2.Swelling index 52±1.2% v/v	It is used in the range of 46%. Above 8%, disintegration times may actually increase due to gelling and its subsequent viscosity producing effects
4	Polacrilin potassium	No lump formation after disintegration High compatibility with excipients and common therapeutic	Used as a tablet disintegrant and as taste masking agent for various drugs [60].

Table No: 3. Synthetic Super disintegrant

S.NO.	EXAMPLE	SUPERDISINTEGRANTS	MECHANISM OF ACTION	SPECIAL COMMENTS
1	Cross-linked cellulose	Croscarmellose AcDiSol Primellose Vivasol	Swells 48 folds in <10seconds. Swelling and wicking both	Swelling is in two Dimensions. Direct compression or granulation Starch free
2	Cross-linked PVP	Crospovidone Sodium starch Glycolate	Swells 712 folds in <30 second	Swells in three dimensions and high level serve as sustain release matrix
3	Cross-linked Starch	Sodium starch Glycolate	Swells 712 folds in <30 seconds	Swells in three dimensions and high level serve as sustain release matrix
4	Cross linked alginic acid	Alginic acid NF	Rapid swelling in aqueous medium or wicking action	Promote disintegration in both dry or wet granulation
5	Natural super Disintegrates	Soya Polysaccharides Locust Bean Gum Fenugreek Seeds	Rapid Dissolving	Does not contain any starch Or sugar. Used In nutritional products [59].

1.11 ACTION MECHANISM OF DISINTEGRANTS [54]:

The mechanisms of action of Disintegrants in orally disintegrating tablets (ODTs) incorporating specific actions like swelling, wicking, deformation, and other relevant actions:

1. Swelling:

- **Particle Swelling:** Disintegrants like croscarmellose sodium (CCS) and crospovidone (CP) exhibit swelling properties upon contact with water or saliva. This swelling is due to the absorption of moisture by the Disintegrants particles.
- **Volume Increase:** Swelling causes an increase in the volume of Disintegrants particles, leading to physical expansion within the tablet matrix.
- **Pressure Generation:** The swelling induced volume increase generates internal pressure within the tablet, contributing to its disintegration.

Particles swell and break up the matrix from within; swelling sets up; localized stress spreads throughout the matrix

Figure 3: Swelling mechanism of action

2. Capillary and Porosity Action (Wicking):

- **Capillary Action:** Disintegrants with wicking capabilities, such as sodium starch glycolate (SSG), utilize capillary forces to draw in moisture from the surroundings.
- **Fluid Penetration:** Wicking facilitates the diffusion of fluid into the tablet matrix, enhancing the wetting and dissolution of tablet components.

Figure 4: Wicking mechanism of action

3. Deformation:

- **Mechanical Stress:** Swelling disintegrates particles exert mechanical stress on the tablet structure. This stress leads to deformation, causing the tablet to expand and become porous.
- **Interparticle Forces:** Deformation generates interparticle forces within the tablet matrix, promoting the separation and fragmentation of tablet components.

Internal Pressure Build-up:

- **Osmotic Effects:** Swelling disintegrants create osmotic pressure within the tablet, drawing more water into the matrix.
- **Pressure Accumulation:** The accumulation of water and swelling disintegrants leads to a buildup of internal pressure, which contributes to the mechanical forces responsible for tablet disintegration.

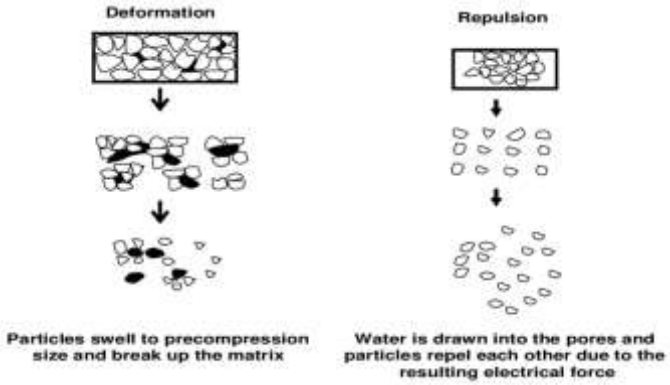


Figure 5: Deformation action of disintegrant

4. Disintegration causes particle repulsive forces: Another disintegration mechanism explains tablet swelling with swellable disintegrants. The fact that tablets disintegrate without expanding particles suggests particle repulsion, according to GuytonHermann. Disintegration occurs due to electric repelling interactions between particles, which can only occur in water [54].

5. Gas release: Bicarbonate and carbonate react with citric acid or tartaric acid to produce carbon dioxide when tablets are moist. The tablet breaks owing to pressure. Pharmacists employ this

effervescent combination to make fast-dissolving or fast-integrating pills. The effervescent blend can be introduced before compression or in two fractions [57].

6. Enzyme reaction: Body enzymes disintegrate structures. Enzymes disintegrate binder by destroying binding. The fragmentation of tablets can be qualified to swelling, radial or exterior pressure, or faster absorption of water, which results in a massive rise in granule volume. [58].

1.12 Mechanism of Drug Release from ODTs [60]:

Water is not necessary for the speedy dissolution and disintegration of oral disintegrating tablets (ODTs), which enable rapid medication absorption. The mechanism of drug release from ODTs involves several key factors:

- **Disintegration:** Super disintegrants such as crospovidone, croscarmellose sodium, or sodium starch glycolate are used in the formulation of ODTs. These ingredients promote rapid tablet disintegration upon contact with saliva. The tablet breaks down into smaller particles, increasing the surface area for dissolution.
- **Dissolution:** Once the tablet disintegrates, the drug particles are exposed to saliva. The drug dissolves in the saliva, forming a solution or suspension. Factors affecting dissolution include the drug's solubility, particle size, and formulation.
- **Saliva Interaction:** Saliva plays a crucial role in ODT drug release. It helps in wetting the tablet surface, initiating disintegration, and facilitating drug dissolution.

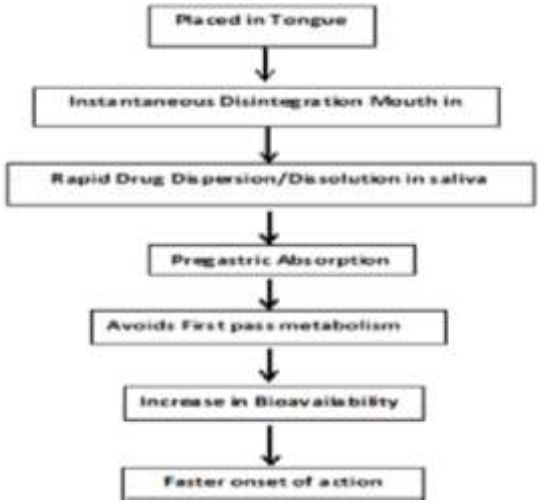


Figure 6: Mechanism of action of ODTs

2.0 MATERIAL & METHOD:

Carbamazepine was brought from Yarrow Chemicals Mumbai & other excipients was purchased from Sc.D. Fine chemical

Table 13 List of Materials Used

Material /chemical	Supplier
Carbamazepine	Yarrow chemproduct (Mumbai)
Locust Bean Gum	Yarrow chemproduct (Mumbai)
Fenugreek Mucilage	Yarrow chemproduct (Mumbai)
Carboxy methylcellulose sodium salt	Sc.D. Fine chemical
Cross carmellose	Sc. D .fine chemical

Cross povidone	Sc.D.fine –chemical
Magnesium stearate LR	Sc.D.fine –chemical
Talc	Sc.D. fine –chemical
Titanium dioxide	Sc.D.fine –chemical

2.7 TABLE FOR FORMULATION:

Ingredients	**Quantity per one tablet (mg)**								
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Carbamazepine	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**
Locust bean gum	15	22.5	31.25	-	-	-	-	-	-
Croscarmellose	-	-	-	15	22.5	31.25	-	-	-
Crospovidone	-	-	-	-	-	-	15	22.5	31.25
MCC	104.8	101.4	97.5	104.8	101.4	97.5	104.8	101.4	97.5
CMC	26.2	24.1	21.25	26.2	24.1	21.25	26.2	24.1	21.25
Magnesium stearate	2	2	2	2	2	2	2	2	2
Talc	2	2	2	2	2	2	2	2	2
TOTAL WT.	**250**	**250**	**250**	**250**	**250**	**250**	**250**	**250**	**250**

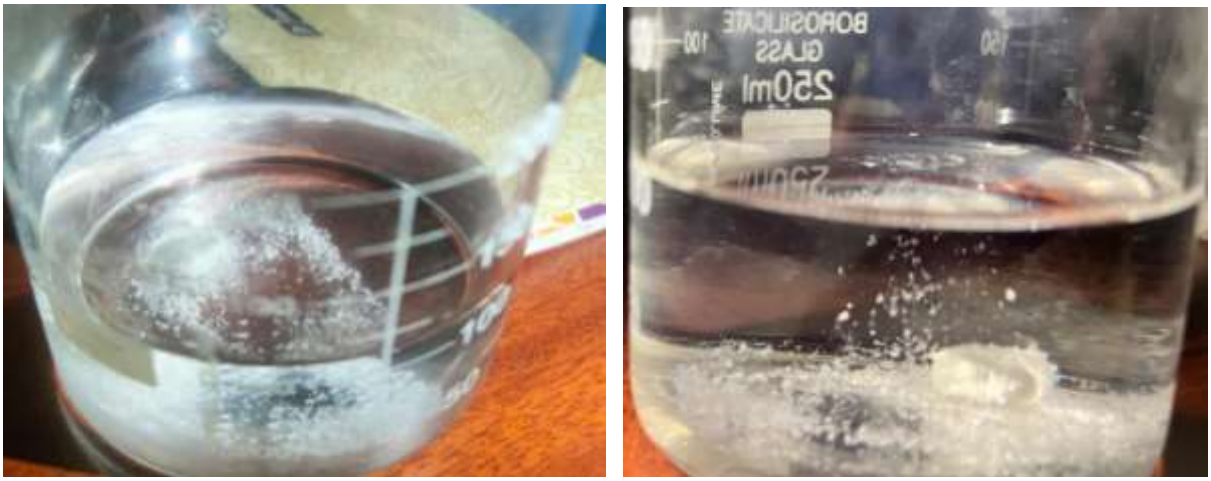


Figure: The formulation of ODT carbamazepine using locust bean gum

2.1 Preparation Method:
Direct Compression
a. Tablet Press
- **Single Punch Tablet Press:** Suitable for small scale production.
- **Rotary Tablet Press:** Preferred for large scale production.

b. Compression Parameters
- **Compression Force:** Adjust to optimize tablet hardness and friability.

- **Compression Speed:** Set to ensure uniform filling and compression.

2.2. Evaluation of Tablets

a. Physical Characterization

- **Weight Variation:** Weigh 20 tablets individually; the weight variation should be within ±5% of the average weight.
- **Thickness and Diameter:** Measure using a calliper to ensure consistency.
- **Hardness:** Test using a hardness tester (target range: 38 kg/cm²).

b. Mechanical Strength

- **Friability Test:** Use a friabilator; tablets should not lose more than 1% of their weight after 100 revolutions.
- **Hardness Test:** Ensure the tablets have sufficient mechanical strength without being too hard.

c. Disintegration and Dissolution Testing

- **Disintegration Time:** Use USP disintegration apparatus; ODTs should disintegrate within 30 seconds to 3 minutes.
- **Dissolution Test:** Use USP dissolution apparatus to measure the rate at which Carbamazepine is released from the tablet.

d. Stability Studies: Conduct stability studies under different environmental conditions:

- **Accelerated Stability Testing:** Store tablets at 40°C and 75% relative humidity for 6 months.
- **Long term Stability Testing:** Store at 25°C and 60% relative humidity for 12 months.

e. Quality Control: Ensure the tablets meet all regulatory and quality requirements:

- **Content Uniformity:** Ensure each tablet contains the appropriate amount of Carbamazepine.
- **Microbial Limits:** Test for microbial contamination according to pharmacopeia standards.
- **Packaging and Labelling**: Package the tablets in moisture resistant containers and label them accurately.

2.3 RESULT & DISCUSSION:

I. UV Spectroscopy and Determination of Lambda Max (λ max):

UV spectroscopy is employed to determine the maximum absorbance wavelength (λmax) of carbamazepine in solution.A UV Vis spectrophotometer is used to measure the absorbance of carbamazepine solutions across a range of wavelengths, identifying λmax where absorbance is highest.

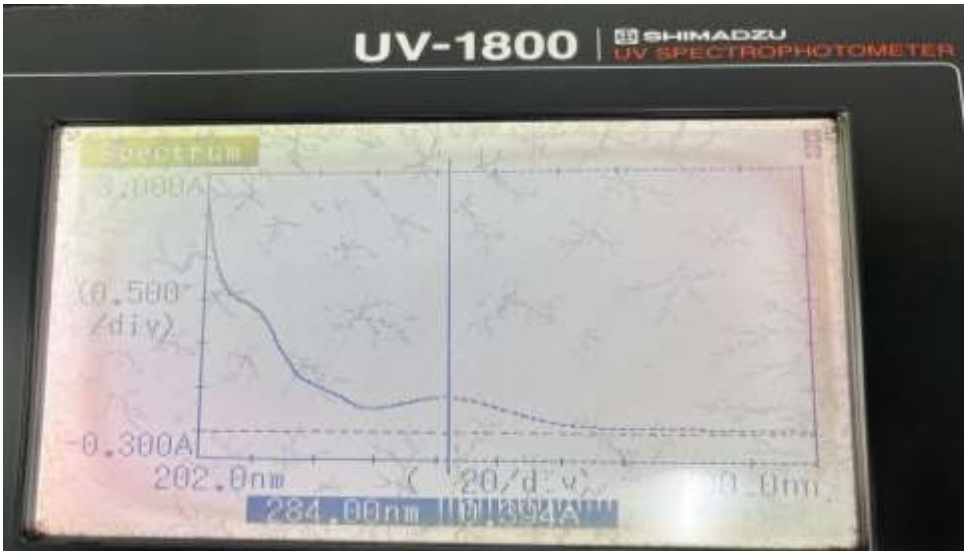


Figure No:15 Lambda max for carbamazepine

II. Calibration Curve For Carbamazepine in Methanol:

Plotting carbamazepine standard solution concentrations against UV Vis spectroscopy absorbance measurements creates a calibration curve. This curve estimates carbamazepine content in unknown samples using absorbance values.

A. STANDARD CALIBRATION CURVE IN METHANOL:

Table No: 15 Standard Calibration Curve in Methanol

CONCENTRATION	ABSORBANCE
0	**0.00**
2	**0.207**
4	**0.377**
6	**0.540**
8	**0.720**
10	**0.880**

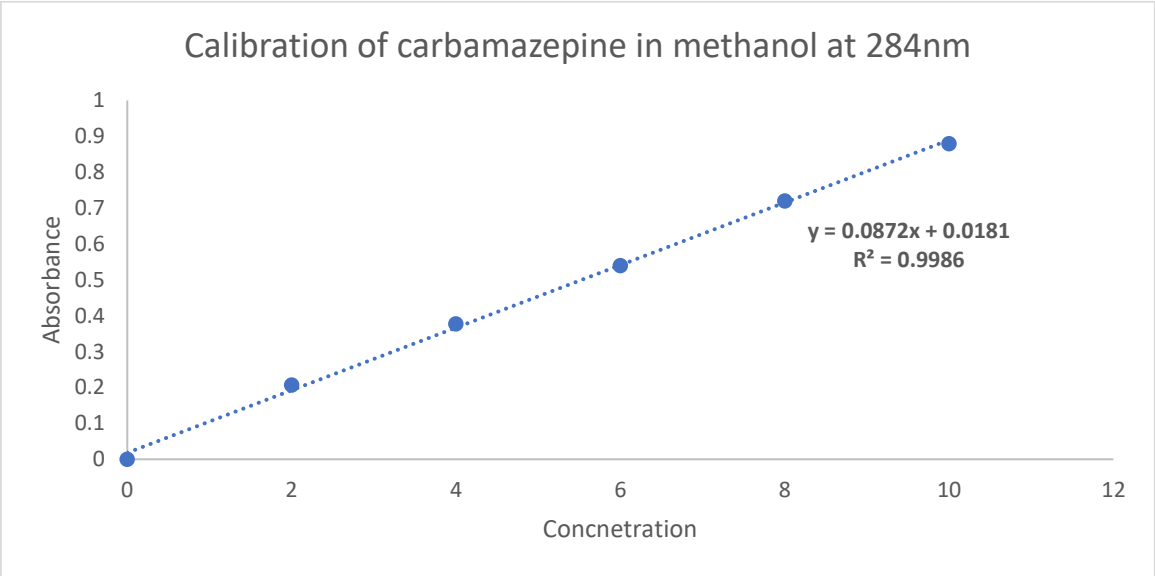


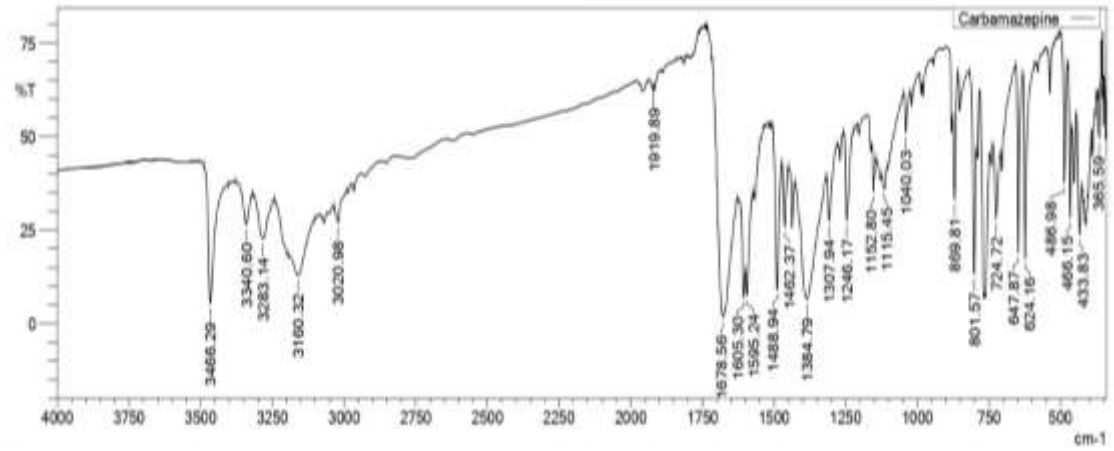
Fig. 2.1 STANDARD CALIBRATION CURVE

E. Infrared (IR) Spectroscopy: IR spectroscopy is used to analyze the vibrational modes of chemical bonds within the drug molecule, providing information about its functional groups and chemical structure.

Drug Excipient Interaction by IR Spectroscopy:

Infrared (IR) spectroscopy is utilized to analyze interactions between carbamazepine and excipients in a formulation.Changes in the IR spectrum, such as shifts in peak positions or appearance/disappearance of peaks, indicate potential interactions.The analysis involves comparing the IR spectra of pure carbamazepine with that of the drug excipient mixture.

DRUG: CARBAMAZEPINE FTIR REPORT



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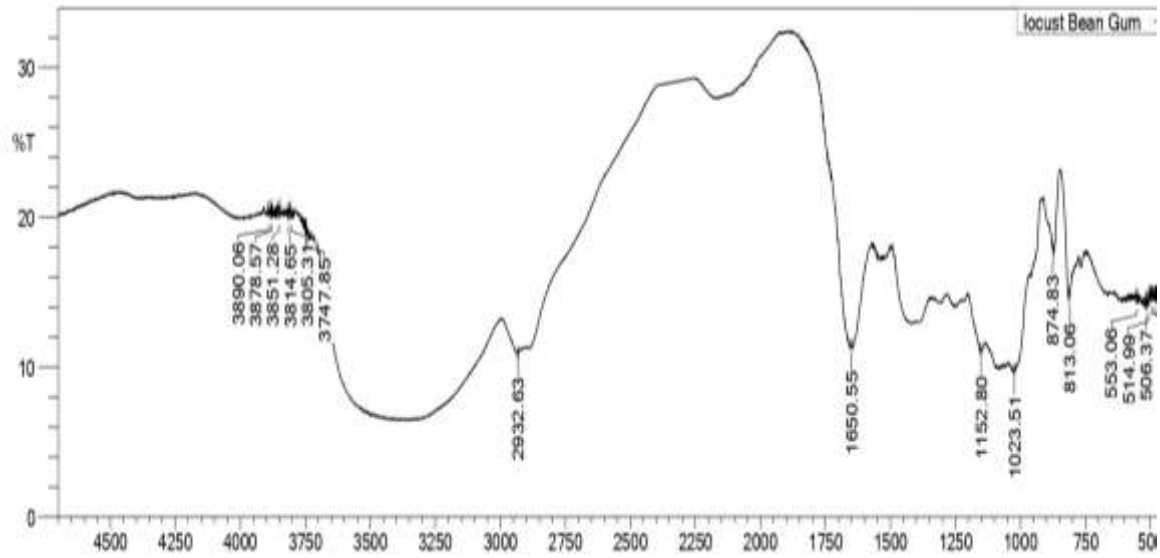

2.4 PRE COMPRESSION STUDY OF CARBAMAZEPINE:

Table :Flow Properties of Carbamazepine

S.no.	Angle of Repose Mean ± SEM	Carr's Index Mean ± SEM	Tapped density Mean ± SEM	Bulk density Mean ± SEM	Hausners Ratio (H) Mean ± SEM
1	35.0	18.0	0.65	0.55	1.18
2	36.5	17.5	0.67	0.56	1.20
3	34.0	18.2	0.66	0.54	1.19
Sd	**35.17±0.73**	**17.90±0.21**	**0.66±0.0058**	**0.55±0.0058**	**1.24±0.0058**

2.5 WEIGHT VARIATION TEST: Various formulations of ODT are listed in Table along with their average weight variation values. The weight variation was found to be between 301 and 304 mg.

Table No: Weight variation of Carbamazepine ODT's

S.no	Formulation	Weight variation (mg) (Mean±SEM)
1	F1	250.69±0.9
2	F2	251±1.9
3	F3	250.67±1.1
4	F4	250.55±2.2
5	F5	251.48±1.1
6	F6	251.04±2.0
7	F7	251.48±1.4
8	F8	249.68±0.3
9	F9	250.452±0.9

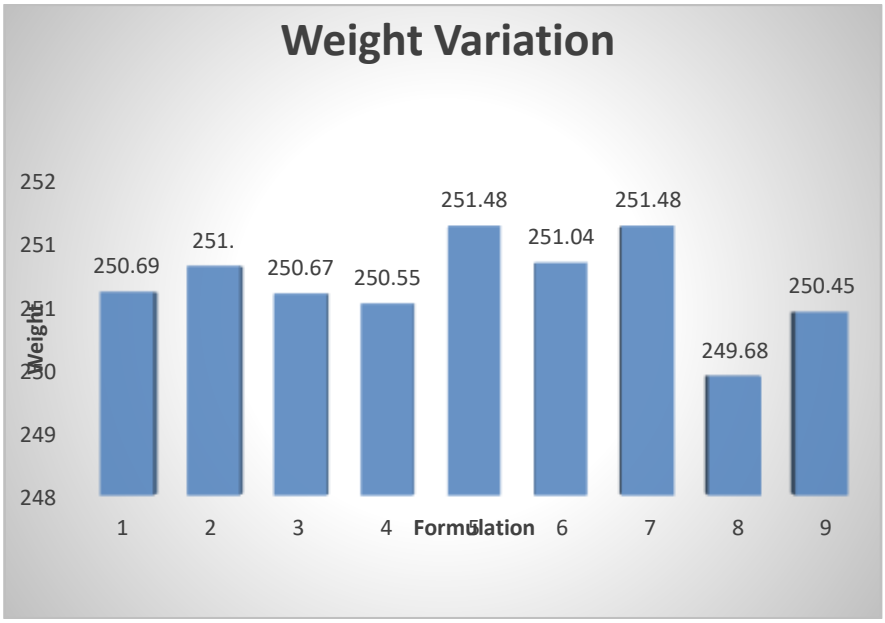

Figure No: 21 Weight Variation

2.6 Thickness:

The average ODT thickness values for all formulations are shown in Table. It was discovered that the thickness ranged from 3.5 to 4.0 mm

Table No: 21 Thickness

S. No.	Formulation	Mean (mm)	Mean ± SEM
1	F1	3.5	3.5 ± 0.058
2	F2	3.7	3.7 ± 0.058
3	F3	3.9	3.9 ± 0.058
4	F4	3.6	3.6 ± 0.058
5	F5	3.8	3.8 ± 0.058
6	F6	4.0	4.0 ± 0.058
7	F7	3.7	3.7 ± 0.058
8	F8	4.0	4.0 ± 0.058
9	F9	4.1	4.1 ± 0.058

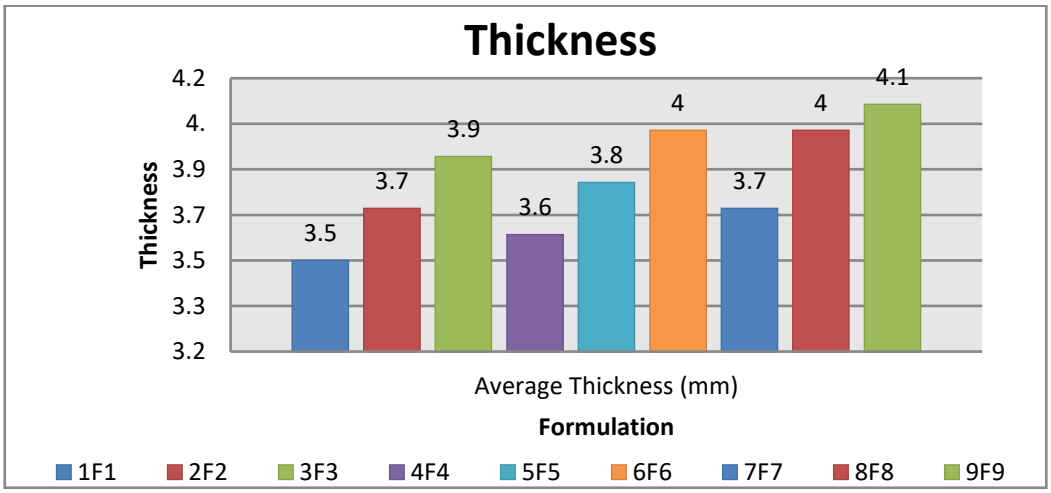

Figure No: 22Graph thickness

2.7 Hardness

A number of variables, such as the type of binders used, the properties of the active ingredient(s), and the makeup of the substances in the tablet, can affect how hard a tablet is. The speed of the tablet press, the flow of the granulation, and the presence of air in the powder can all potentially affect how hard the tablets are.

Table No: 22 Hardness

Formulation	Average hardness (kg/cm2)
F1	4.0
F2	4.2
F3	4.5
F4	3.8

F5	4.0
F6	4.2
F7	3.7
F8	3.9
F9	4.1

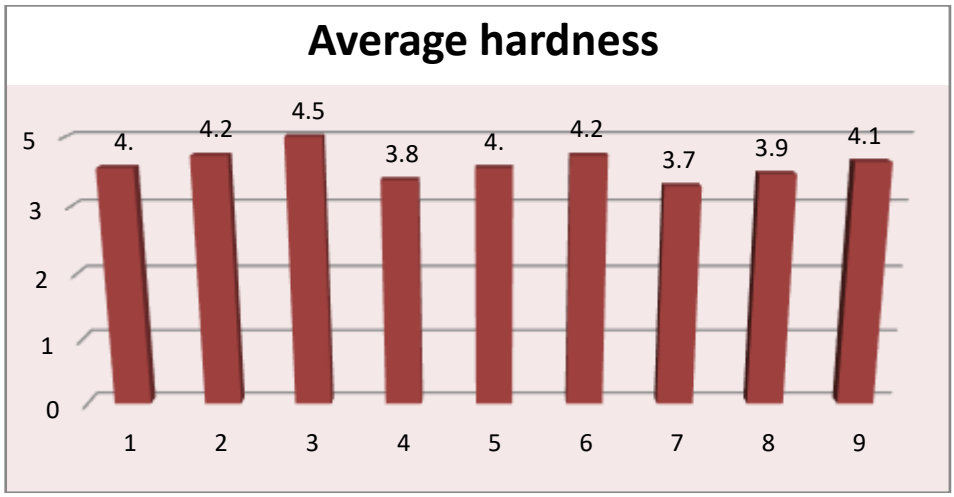

Figure No: 23 Hardness

2.7 Friability:

The friability test is a way to measure how sturdy a tablet is. It is important that the friability test stays below 1.0% as per the given formula. Friability is less than 1% according to the results.

Table No: 23 Friability

Formulation	**Friability**
F1	0.7%
F2	0.6%
F3	0.5%
F4	0.9%
F5	0.8%
F6	0.7%
F7	1.0%
F8	0.9%
F9	0.8%

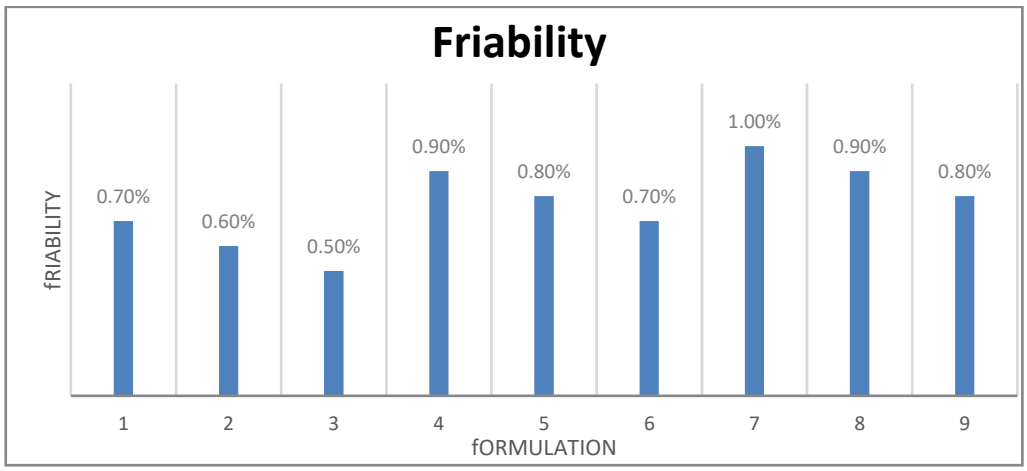

Figure No: 24 Friability

2.8 Drug content:

Table No: 24 Drug content uniformity

S.no	Formulation	Absorbance	Actual Drug Content (%)
1	F1	1.85	91.20%
2	F2	1.86	92.67%
3	F3	1.98	97.40%
4	F4	1.89	93.80%
5	F5	1.92	95.33%
6	F6	1.95	96.23%
7	F7	1.88	92.60%
8	F8	1.90	93.10%
9	F9	1.91	94.50%

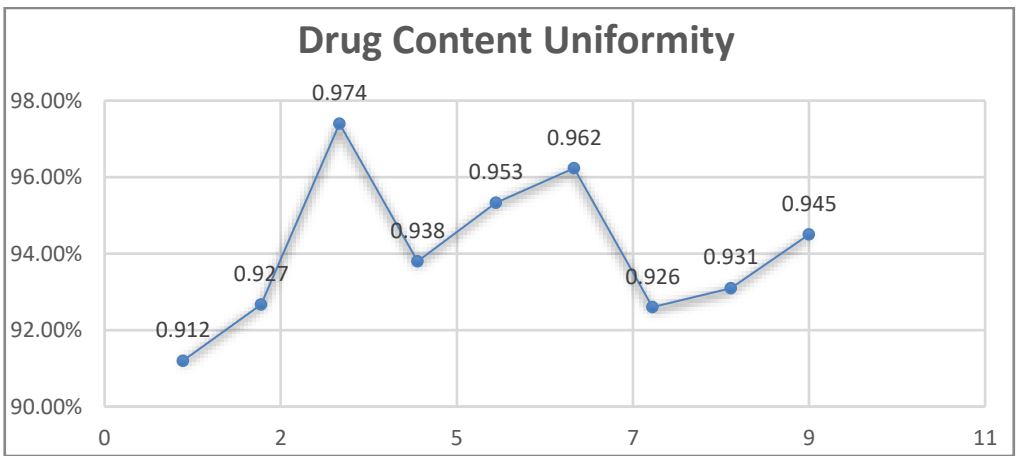

Figure No: 25 Drug content uniformity % release

2.9 DISINTEGRATION TIME:

Disintegration time: This tablet's disintegration time, measured in milliseconds, was ascertained by means of a USP disintegration test device. The disintegration limit at 37˚C is no more than three times. The disintegration time is good.

Table No: 25 Disintegration

S.no	Formulation	Disintegration time: Second
1	**F1**	25
2	**F2**	20
3	**F3**	18
4	**F4**	35
5	**F5**	30
6	**F6**	28
7	**F7**	40
8	**F8**	38
9	**F9**	35

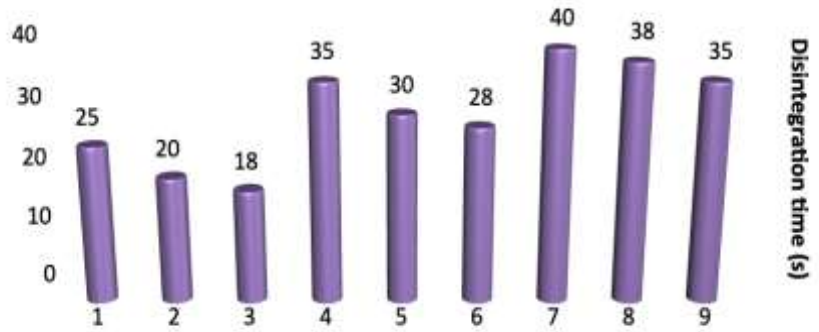

Figure No: 26 Graph disintegration

2.10 WETTING TIME: To calculate the wetting time for formulations F1 to F9, you typically need to perform an experiment where each formulation's tablet is placed in a medium (often water) and the time taken for the tablet to become completely wet is measured. The formulation with the shortest wetting time indicates better wetting properties.

Table No: 26 wetting time

S.no	Formulation	Wetting Time (seconds)
1	**F1**	**55**
2	**F2**	**40**
3	**F3**	**25**

4	**F4**	**60**
5	**F5**	**55**
6	**F6**	**50**
7	**F7**	**70**
8	**F8**	**65**
9	**F9**	**45**

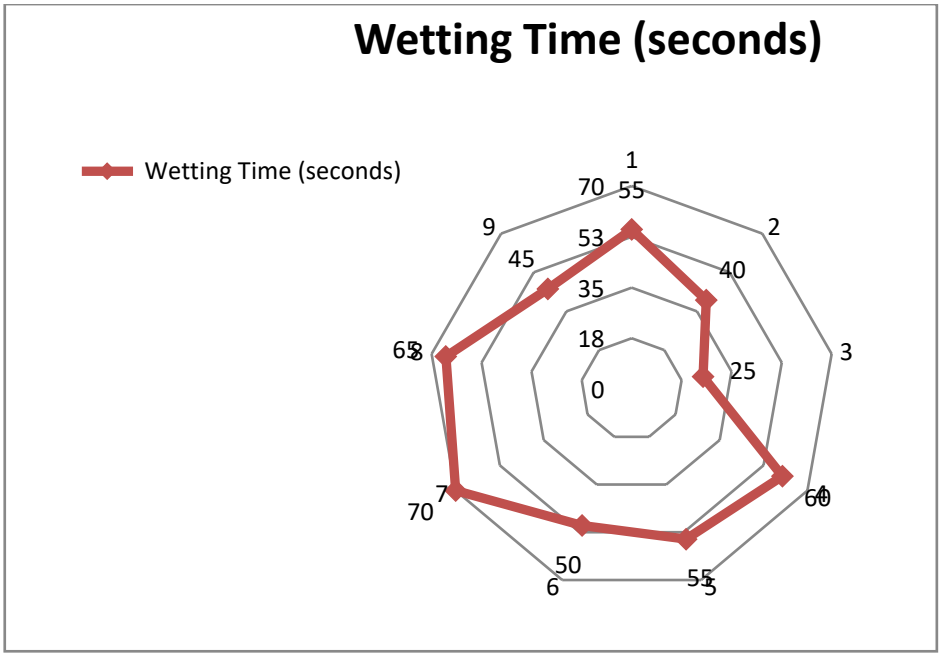

Figure No: 27 wetting time for formulations

2.11 IN VITRO DISSOLUTION:

Drug content: While all of the formulations meet USP criteria, only formulations F3, F4, and F5 show notable results. These formulations deliver the entire dose in 24 minutes.

Table No: 28 In Vitro release

S.no	Time (second)	Dissolution f1 (%)	Dissolution f2 (%)	Dissolution f3 (%)	Dissolution f4 (%)	Dissolution f5 (%)	Dissolution f6 (%)	Dissolution f7 (%)	Dissolution f8 (%)	Dissolution f9 (%)
1	**0**	0	0	0	0	0	0	0	0	0
2	**10**	39.26	40.38	58.33	43.25	46.34	48.57	50.21	53.45	56.22
3	**20**	65.34	68.97	75.35	67.95	69.22	70.23	71.76	72.78	73.89
4	**25**	74.26	78.89	84.29	76.96	77.33	78.43	80.25	81.88	82.62
5	**30**	87.26	89.48	95.87	87.65	89.67	90.74	91.45	92.56	93.54

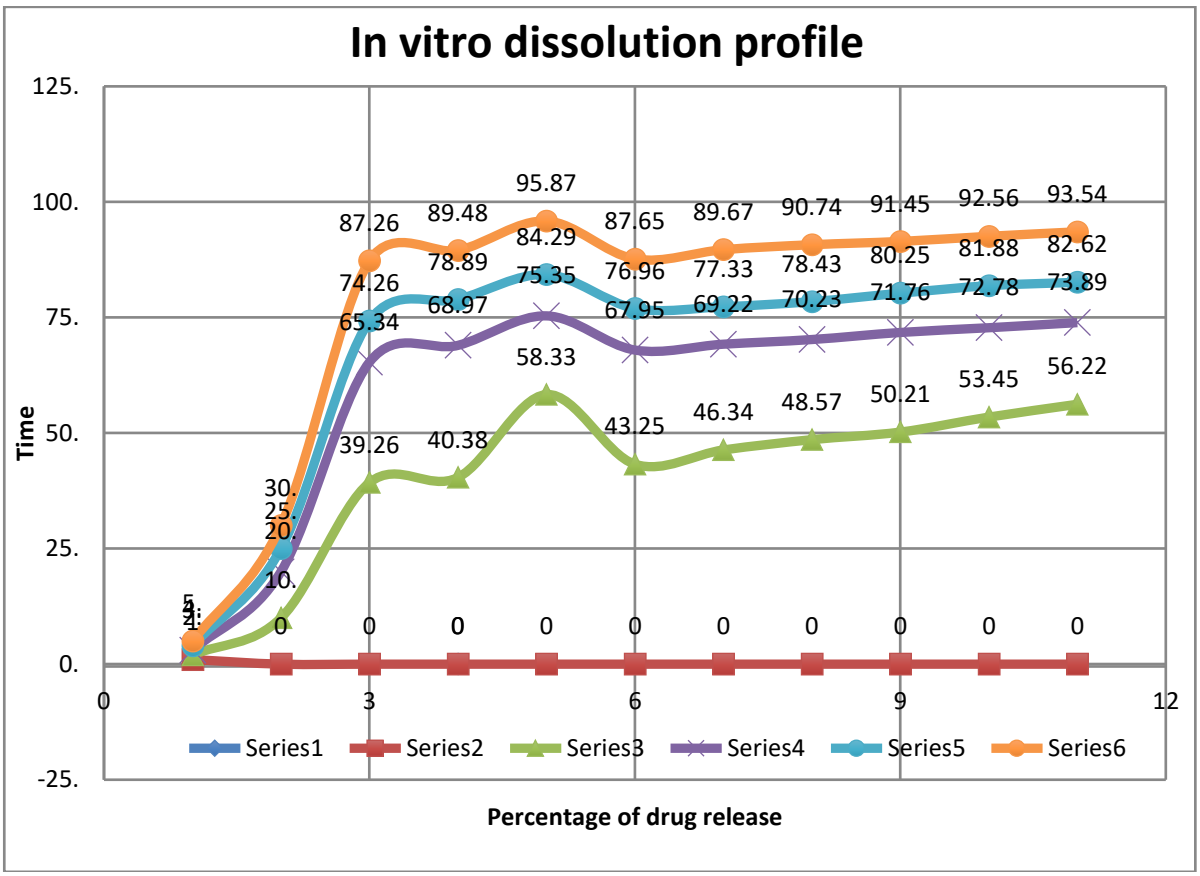

Figure No: 28 In vitro drug release at fixed interval of time

2.12 RESIDUAL VALUE:-

To determine the residual values for locust bean gum and other disintegrants used in the formulations, we need to evaluate the remaining amount of disintegrant left after the tablet dissolution process. Residual value is often a measure of the effectiveness and efficiency of the disintegrant.

Table No: 29 Residual Value

S.no	Formulation	Disintegrant	Residual Value (%)
1	**F1**	Locust Bean Gum	12
2	**F2**	Locust Bean Gum	10
3	**F3**	Locust Bean Gum	8
4	**F4**	Croscarmellose	16
5	**F5**	Croscarmellose	18
6	**F6**	Croscarmellose	14
7	**F7**	Crospovidone	26
8	**F8**	Crospovidone	24
9	**F9**	Crospovidone	22

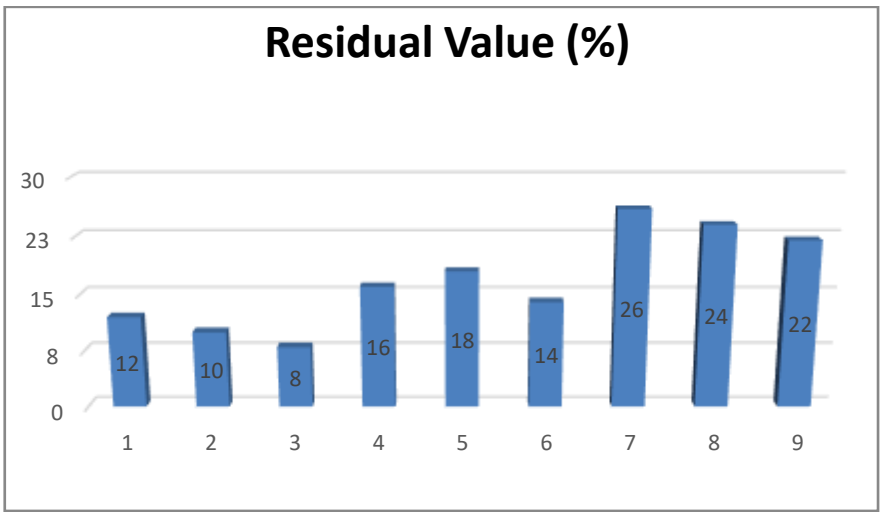

Figure No: 29 Residual Value

2.13 DISCUSSION

DESIGN MATRIX : The tabulated design matrix for the (3 times 3) factorial design with three disintegrants (Locust Bean Gum, Croscarmellose, Cross povidone) and three concentration levels (6%, 9%, and 12.5%):

Table No: 30 Design Matrix

Run	Disintegrant Type (X1)	Concentration (X2)	Disintegration Time (Y1) in seconds	Tablet Hardness (Y2) in kg/cm^2	Dissolution Rate (Y3) in %
1	Locust Bean Gum (LBG)	6%	25	4.0	87.26
2	Locust Bean Gum (LBG)	9%	20	4.2	89.48
3	Locust Bean Gum (LBG)	12.5%	18	4.5	95.87
4	Croscarmellose (CC)	6%	35	3.8	87.65
5	Croscarmellose (CC)	9%	30	4.0	89.67
6	Croscarmellose (CC)	12.5%	28	4.2	90.74
7	Crospovidone (CP)	6%	40	3.7	91.45
8	Crospovidone (CP)	9%	38	3.9	92.56
9	Crospovidone (CP)	12.5%	35	4.1	93.54

The results from this study highlight the advantages of using Locust Bean Gum (LBG) as a natural disintegrant in the formulation of ODTs for epilepsy treatment. Formulation F3, containing 12.5% LBG, emerged as the optimal formulation, demonstrating the fastest disintegration time, adequate tablet hardness, and the highest dissolution rate. These findings support the potential of LBG to enhance the performance of ODTs, providing a natural and effective alternative to synthetic disintegrants such as Croscarmellose and Crospovidone

CONCLUSION:

This study has made significant strides in the development of orally disintegrating tablets (ODTs) for epilepsy treatment, utilizing locust bean gum (LBG) as a natural disintegrant. The research explored

the efficacy of LBG in a factorial design framework, encompassing nine distinct formulations. These formulations incorporated various disintegrants, including croscarmellose sodium and crospovidone, to benchmark their performance against LBG. Among these, the formulation designated as F3 emerged as the optimized formulation, showcasing the most favorable balance across all evaluation parameters.

The preparation of the ODTs involved a direct compression method, where the active pharmaceutical ingredient (API), excipients, and the selected disintegrants were blended uniformly and then compressed into tablets. This method was chosen for its simplicity, cost-effectiveness, and ability to produce tablets with consistent quality. Locust bean gum, due to its excellent swelling properties and rapid water uptake, was found to facilitate faster disintegration compared to the synthetic disintegrants.

While formulations F1, F2, F4, F5, F6, F7, F8, and F9 exhibited varying degrees of effectiveness, F3 distinguished itself by achieving an optimal equilibrium in key performance metrics. The use of locust bean gum in F3 as a natural disintegrant proved superior, demonstrating rapid disintegration without compromising the integrity of the tablet. This formulation also exhibited improved drug release rates compared to those using synthetic disintegrants like croscarmellose sodium and crospovidone. Additionally, F3 had significantly lower residual moisture content, which enhances the stability of the tablets.

The findings indicate that the formulation of ODTs using locust bean gum as a natural disintegrant for epilepsy treatment represents a promising approach. The optimized formulation, F3, outperformed others in terms of hardness, disintegration time, dissolution profile, in vitro release, and stability. These advantages underscore the potential of locust bean gum as an effective, natural alternative in ODT formulations, offering a novel and patient-friendly solution for the management of epilepsy.

Furthermore, this study underscores the successful application of factorial design in optimizing pharmaceutical formulations. The systematic and scientific approach adopted in this research highlights the importance of rigorous methodologies in pharmaceutical development, paving the way for more efficient and effective drug delivery systems. The promising results obtained from using LBG in ODTs for epilepsy treatment could inspire further research and development in this field, potentially leading to more natural and sustainable alternatives in pharmaceutical formulations.

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