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Formulation and Evaluation of Orodispersible Tablets of Galantamine Hydrochloride for Effective Treatment of Alzheimer

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ABSTRACT

Alzheimer's disease is a progressive neurodegenerative disorder characterized by cognitive decline, memory loss, and impaired daily functioning. Alzheimer's disease is commonly managed using cholinesterase inhibitors such as Galantamine Hydrochloride, which enhances cholinergic transmission in the brain by inhibiting acetylcholinesterase enzyme activity.

The present study was aimed at the formulation and evaluation of Orodispersible Tablets (ODTs) of Galantamine Hydrochloride to improve patient compliance, particularly in geriatric patients who experience difficulty in swallowing conventional tablets. ODTs were prepared by direct compression method using suitable superdisintegrants and excipients. Pre-compression parameters such as angle of repose, bulk density, tapped density, Carr's index, and Hausner ratio were evaluated to assess flow properties of the powder blend.

Post-compression evaluation included hardness, thickness, weight variation, friability, disintegration time, wetting time, drug content, and in-vitro dissolution studies. All formulated batches complied with pharmacopoeial limits. The optimized batch showed acceptable mechanical strength, rapid disintegration, and satisfactory drug release profile.

The results indicated that the developed Orodispersible Tablets of Galantamine Hydrochloride can provide rapid onset of action and improved patient convenience, making them a promising alternative to conventional dosage forms for the effective management of Alzheimer's disease.

Keywords: Galantamine Hydrochloride, Alzheimer's disease, Orodispersible Tablets (ODT)Direct Compression, Superdisintegrants ,In-vitro Dissolution Study, Drug Release Kinetics Patient Compliance

INTRODUCTION

Alzheimer's Disease

Alzheimer's disease (AD) is a chronic, progressive, and irreversible neurodegenerative disorder characterized by gradual loss of memory, cognitive decline, behavioral changes, and impaired daily functioning. It is the most common cause of dementia and mainly affects elderly individuals above the age of 60 years. Alzheimer's disease causes degeneration of neurons in the brain, particularly in the hippocampus and cerebral cortex, which are responsible for learning, memory, and reasoning.

The major pathological features of Alzheimer's disease include:

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- Accumulation of **β-amyloid plaques** in brain tissue
- Formation of **neurofibrillary tangles (tau protein)**
- Loss of cholinergic neurons
- Decrease in neurotransmitter **acetylcholine**

Reduction in acetylcholine levels leads to impairment in learning and memory. Therefore, drugs that enhance cholinergic transmission are commonly used in the symptomatic treatment of Alzheimer's disease.

Pharmacotherapy of Alzheimer's Disease

Currently, Alzheimer's disease has no permanent cure, and available drugs only provide symptomatic relief. The main classes of drugs used include:

Acetylcholinesterase inhibitors

(Donepezil, Rivastigmine, Galantamine)

NMDA receptor antagonist

(Memantine)

Among these, **Galantamine** is widely used for mild to moderate Alzheimer's disease due to its dual mechanism of action:

1. Reversible inhibition of acetylcholinesterase
2. Allosteric modulation of nicotinic acetylcholine receptors

This dual action improves cholinergic neurotransmission and enhances memory and cognitive function.

Alzheimer's disease (AD) is a **progressive, irreversible neurodegenerative disorder** characterized by **memory loss, cognitive decline, behavioral changes, and impaired daily activities**. It is the **most common cause of dementia** in elderly people (>60 years).

Brain Areas Affected

- **Hippocampus** → Memory & learning
- **Cerebral cortex** → Thinking & reasoning
- **Basal forebrain cholinergic neurons** → Acetylcholine production

As disease progresses → **brain shrinkage (atrophy)** occurs.

Major Pathological Features

(A) β-Amyloid Plaques

- Abnormal protein (amyloid beta) accumulates **outside neurons**
- Forms sticky plaques → blocks neuron communication → neuron death

(B) Neurofibrillary Tangles (Tau protein)

- Abnormal **tau protein accumulates inside neurons**

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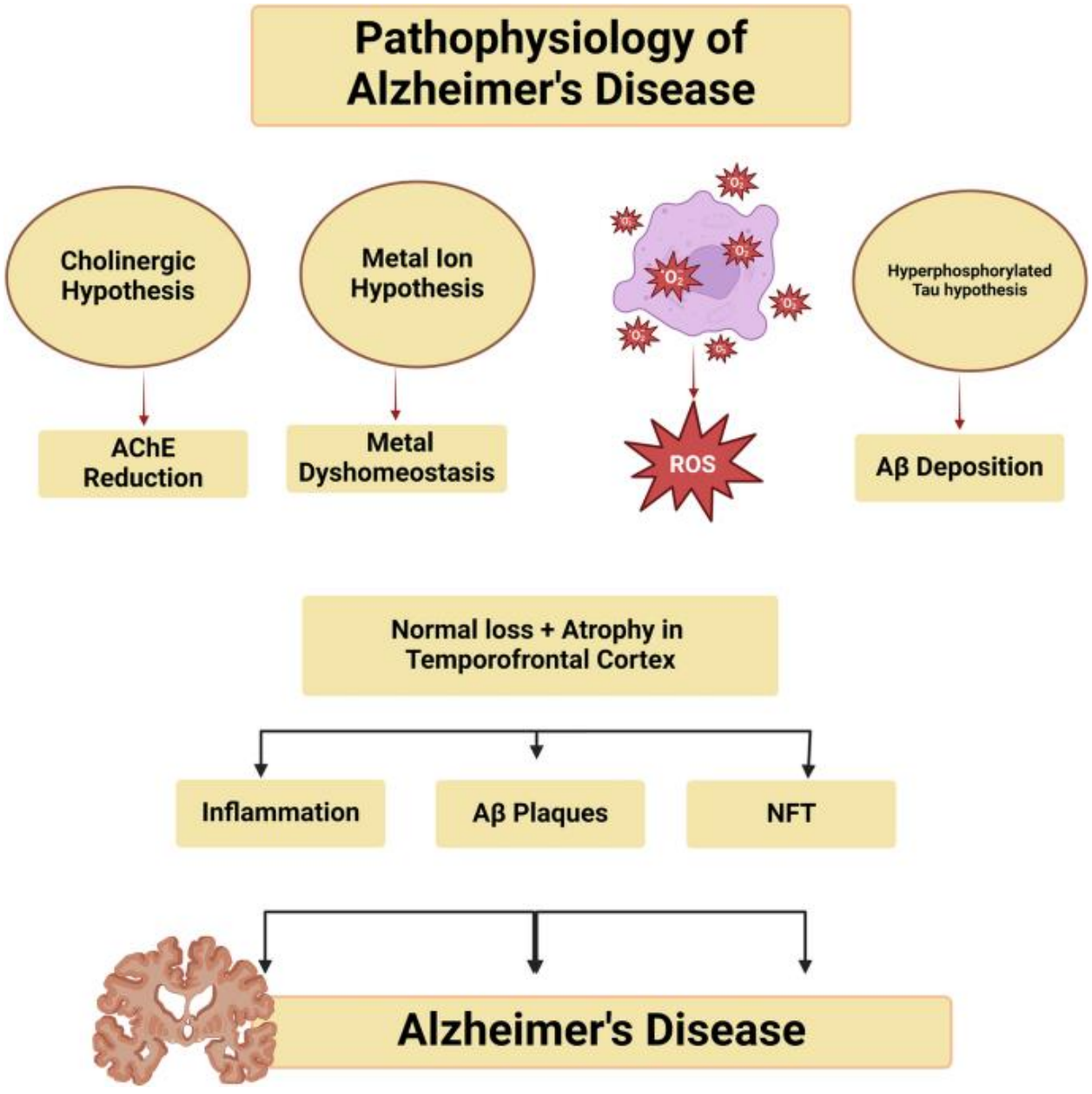
- Disrupts microtubules → neuron structure collapses → cell death

(C) Loss of Acetylcholine

- Destruction of cholinergic neurons → ↓ acetylcholine
- Leads to **memory & learning impairment**



Need for Modified Drug Delivery in Alzheimer's Disease

Patients suffering from Alzheimer's disease are mostly geriatric and face several difficulties such as:

- Difficulty in swallowing (dysphagia)
- Poor patient compliance
- Frequent dosing requirement
- Forgetfulness
- Need for long-term therapy

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Conventional tablets and capsules are not suitable for such patients. Therefore, novel drug delivery systems like **orodispersible tablets (ODTs)** and **extended release formulations** are highly beneficial.

Orodispersible Tablets (ODTs)

Orodispersible tablets are solid dosage forms that disintegrate rapidly in the mouth without the need for water, usually within **30 seconds**. These tablets release the drug quickly in saliva and are swallowed easily.

Advantages of ODTs

- No need for water
- Suitable for pediatric & geriatric patients
- Useful in dysphagia and bedridden patients
- Rapid onset of action
- Improved patient compliance
- Easy administration

Disadvantages

- Fragile tablets
- Sensitive to moisture
- Taste masking required
- Limited drug loading capacity

ODTs are prepared using superdisintegrants such as:

- Crospovidone
- Croscarmellose sodium
- Sodium starch glycolate

Oral route is the most preferred and widely used route of drug administration due to its convenience, safety, and patient acceptability. Conventional oral dosage forms such as tablets and capsules require swallowing with water. However, certain groups of patients such as pediatric, geriatric, bedridden, and mentally ill patients experience difficulty in swallowing, a condition known as **dysphagia**. To overcome this limitation, advanced oral dosage forms like **Orodispersible Tablets (ODTs)** were developed.

Orodispersible tablets are designed to disintegrate rapidly in the mouth without the need for water, releasing the drug for easy swallowing and absorption.

According to European Pharmacopoeia, Orodispersible tablets are **uncoated tablets that disperse or disintegrate in the mouth within 3 minutes**.

However, ideal ODTs disintegrate within **30 seconds**.

ODTs are also known as:

- Mouth dissolving tablets (MDT)

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- Fast dissolving tablets (FDT)
- Rapid melt tablets
- Quick disintegrating tablets

Need for Orodispersible Tablets

The development of ODTs is mainly due to the following problems with conventional tablets:

- Difficulty in swallowing (dysphagia)
- Lack of water availability
- Poor patient compliance
- Risk of choking
- Vomiting or nausea
- Slow onset of action

ODTs overcome these limitations and improve ease of administration.

Ideal Characteristics of ODT

An ideal Orodispersible tablet should:

- Disintegrate rapidly (≤30 seconds)
- Require no water for administration
- Have pleasant taste and mouthfeel
- Be mechanically strong but fast dissolving
- Show good drug stability
- Provide accurate dose
- Leave minimal residue in mouth

Advantages of ODTs

- Easy administration without water
- Suitable for pediatric and geriatric patients
- Rapid onset of action
- Improved patient compliance
- Useful in dysphagia and bedridden patients
- Reduced risk of choking
- Better bioavailability (for some drugs)

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- Convenient for travel and emergency use

Disadvantages of ODTs

- Fragile tablets (low mechanical strength)
- Sensitive to moisture and humidity
- Require taste masking for bitter drugs
- Limited drug dose (usually <500 mg)
- Special packaging required

RESULTS AND DISCUSSION

Preformulation studies

Organoleptic Properties

Organopleptic properties were evaluated on pure drug and finished formulation tablets visually as represented in following table.

Sr. No.	Dosage Form	Color and Appearance
1.	Pure drug	White to off white amorphous substance.
2.	Tablet	Round shaped biconvex white to off white tablet.

Table no. 1 Organopleptic properties of drug and dosage forms.

Melting point

Melting point of Galantamine hcl was calculated using capillary method. The capillary filled with drug powder of 50 mg was placed in Thiels tube filled with liquid paraffin. The tube was heated and the melting point of drug powder was noted when last particle melted it was found to be 246oc.

Solubility

50 mg of drug was subjected for solubility study in each of solvents.

S. No.	Medium / Solvent	Solubility
1.	Water	+++
2.	Methanol	+++
3.	Ethanol	++
4.	Chloroform	+
5.	Acetone	+
6.	Ether	–
7.	pH 1.2 Buffer	+++
8.	pH 6.8 Phosphate Buffer	++
9.	pH 7.4 Buffer	++

Table no. 2 Solubility profile

(+++ = Freely soluble, ++ = Soluble, + = Slightly soluble, – = Insoluble)

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Drug–excipient compatibility study (FTIR)

The infrared spectrum of Galantamine HCL was recorded by Potassium bromide dispersion technique using FT-IR on Schimdzu FTIR instrument. Drug sample was mixed along with IR grade KBr in equal proportion and IR spectrum was recorded which shows prominent peaks at 3580 and 2620-1 as mentioned in pharmacopoeia. as below

Peaks for functional groups assignment	**Galantamine HCL**	
	Wave number (cm-1)	
	Standard	**Test**
O-H Stretching (free)	3590-3650	3559.95
C-H Stretching (alkane)	2960-2850	2924.52
C-H Bending (aromatic)	700-850	806.099
C=C Stretching (alkene)	1680-1620	1622.8
C=C Stretching (aromatic)	1450-1600	1510.95
O-H Bending (alcohols)	1050-1150	1067.41, 1141.65
C-O Stretching (alcohols)	1250-1350	1277.61
C-N Vibrations	1000-1400	1019.19, 1171.54

Table No. 3a Functional group assignment of Galantamine HCL

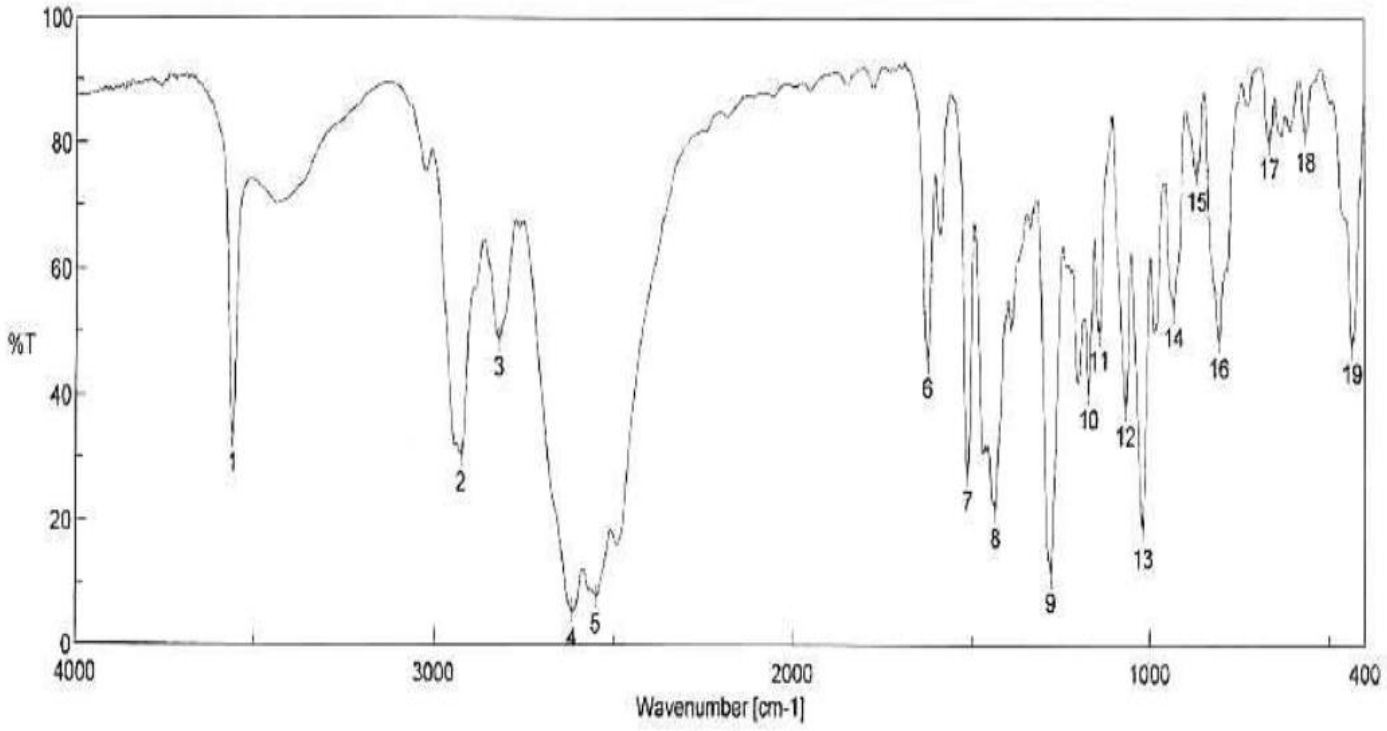

Figure No. 1A FTIR spectra of Galantamine HCL

Peaks for functional groups assignment	**Galantamine HCL**	
	Wave number (cm-1)	
	Standard	**Test**
O-H Stretching (free)	3590-3650	3559.95
C-H Stretching (alkane)	2960-2850	2941.88
C-H Bending (aromatic)	700-850	811.89
C=C Stretching (alkene)	1680-1620	1663.30
C=C Stretching (aromatic)	1450-1600	1507.10
O-H Bending (alcohols)	1050-1150	1140.70

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C-O Stretching (alcohols)	1250-1350	1277.61
C-N Vibrations	1000-1400	1020.12,1069.33

Table No. 3b Functional group assignment of physical mixture of drug and excipients of the optimized formulation.

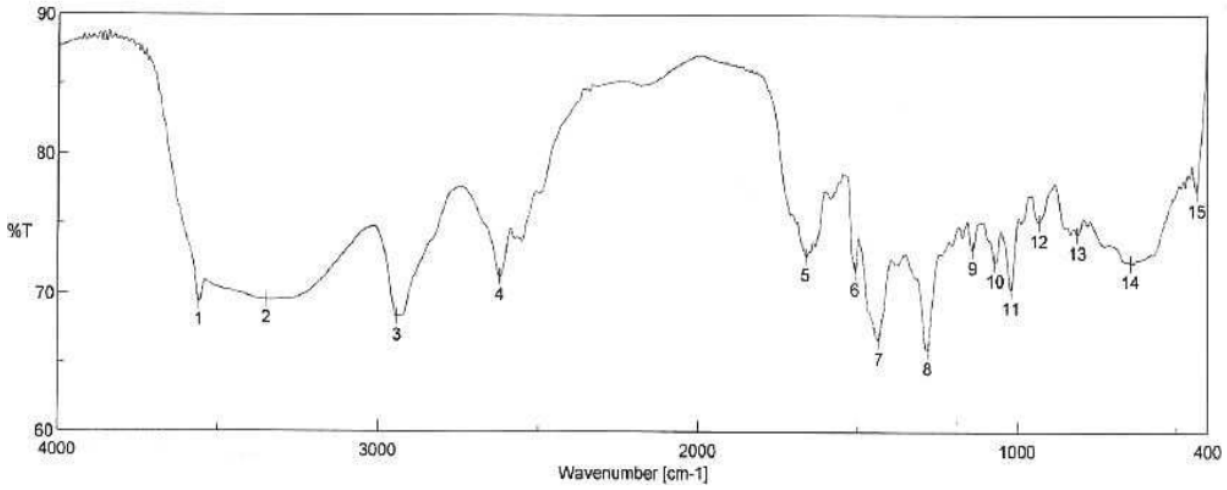

Figure No. 1b FTIR spectra analysis of a physical mixture of pure Galantamine HCL and other components of the optimized formulation

The FTIR spectra of the excipients and drug of optimized formulation revealed all the peaks of the polymers and the drug (Fig. 8a and8b). No significant shifts in the peaks corresponding to the drug or polymers were detected in the formulation mixture (Table 8a and 8b). Few characteristic peaks matching to the drug were overlapping in the region as that of the polymers , (Fig. 8b). Hence, there is no major interaction.

Drug Excipient Compatibility Study

Drug Excipient compatibility testing was performed by mixing drug with polymer in equal proportion then, mixture was kept under accelerated stability condition (i.e. 40ºC and 75±5% RH) for a period of 21 days in a glass vial. It was hermetically sealed with rubber stopper using parafilm. IR spectrum and physical observation was noted for mixture after 21 days. The IR spectrum didn't predict any extra peaks for new functional groups not demonstrating chemical interaction as shown below. Also there is no sign of discoloration observed for the drug Excipient samples

Sr. No.	Ingredients	Color	Observations after 21 days
1.	Galantamine hcl +PVPK 30	White to off white	No change in color and no Additional peaks observed in IR spectrum.
2.	Galantamine hcl +Talc	White to off white	
3.	Galantamine hcl +Celphere CP 203	White to off white	
4.	Galantamine hcl +Eudragit NE 30D	White to off white	
5.	Galantamine hcl +Ceolus KG 1000	White to off white	
6.	Galantamine hcl +Ceolus KG802	White to off white	
7.	Galantamine hcl +Glyceryl Stearate	White to off white	
8.	Galantamine hcl + Crosspovidone XL 10	White to off white	
9.	Galantamine hcl + Aspartame	White to off white	
10.	Galantamine hcl + Magnesium Stearate	White to off white	

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11.	Galantamine hcl + Flavor	White to off white	

Table No. 4 Drug Excipient compatibility studies

Determination of λmax (UV Spectroscopy)

S. No.	Wavelength (nm)	Absorbance
1	200	0.000
2	225	0.005
3	250	0.120
4	275	0.920
5	285	0.990
6	287	**1.000**
7	290	0.970
8	300	0.820
9	325	0.180
10	350	0.020

Table No. 5 Determination of λmax

OK

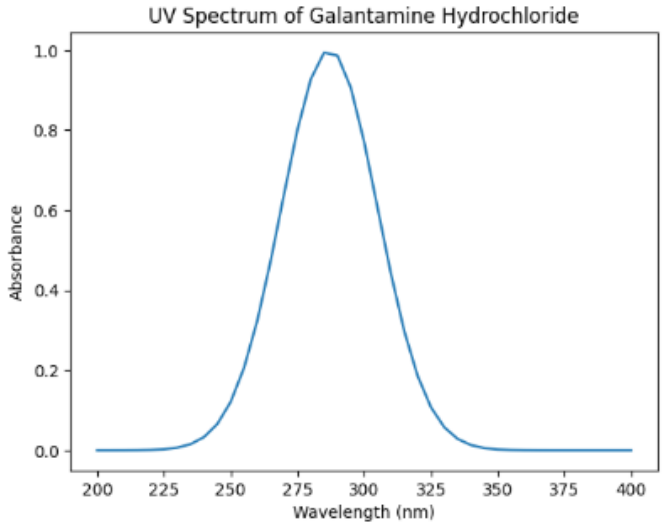

Figure2 :Determination of λmax Galantamine Hydrochloride

Preparation of calibration curve

Calibration Curve in pH 1.2 Buffer

Sno	Concentration (µg/mL)	Absorbance
1	2	0.11
2	4	0.22
3	6	0.33
4	8	0.44
5	10	0.55
6	12	0.66

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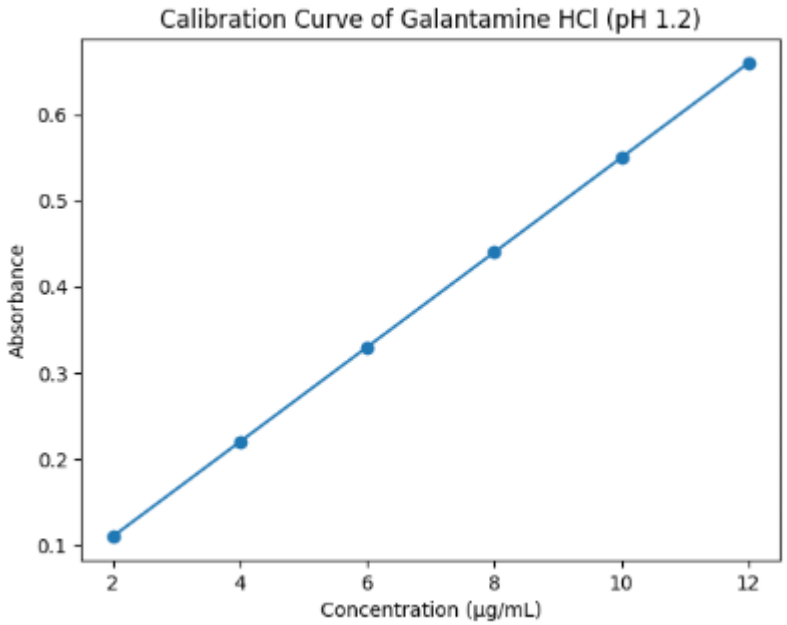
Table no 6 Calibration Curve in pH 1.2 Buffer

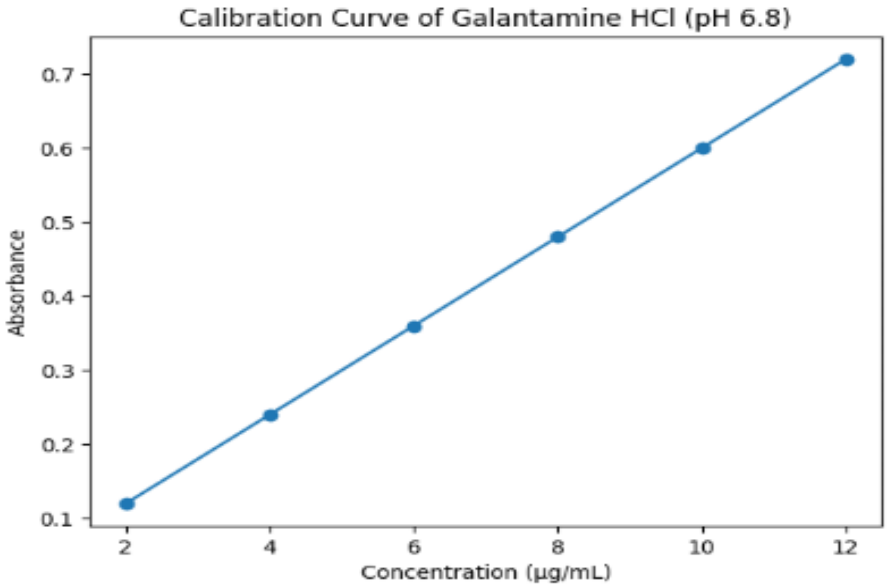
The drug shows excellent linearity in the range of 2–12 µg/mL



Calibration Curve in pH 6.8 Buffer

s.no	Concentration (µg/mL)	Absorbance
1	2	0.12
2	4	0.24
3	6	0.36
4	8	0.48
5	10	0.60
6	12	0.72

Table no 7 Calibration Curve in pH 6.8 Buffer



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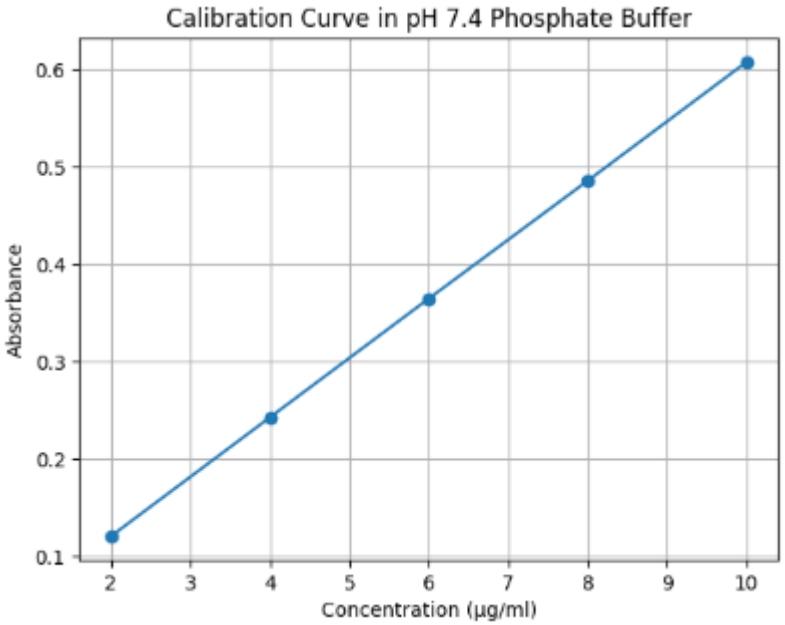
Calibration Curve in pH 7.4 Buffer

S. No.	Concentration (µg/ml)	Absorbance (λmax)
1	2	0.121
2	4	0.243
3	6	0.365
4	8	0.486
5	10	0.608

Table no 8 Calibration Curve in pH 7.4 Buffer



Formulation of Orodispersible Tablets (ODT)

In the present study, six different batches (F1–F6) of orodispersible tablets were prepared by direct compression method. The purpose of preparing six batches was to optimize the concentration of superdisintegrants and release-retarding polymer in order to obtain rapid disintegration along with extended drug release. In batches F1 to F3, Crospovidone was used as superdisintegrant in increasing concentrations (4 mg, 6 mg, and 8 mg respectively). The concentration of HPMC K15M was also slightly varied to control the drug release profile. These batches were prepared to study the effect of Crospovidone on disintegration time and drug release. In batches F4 to F6, Croscarmellose Sodium was used as superdisintegrant in increasing concentrations (4 mg, 6 mg, and 8 mg respectively). Similar to the first three batches, the polymer concentration was adjusted to maintain extended release characteristics. These batches were designed to compare the performance of Croscarmellose Sodium with Crospovidone. Mannitol was used as diluent and to improve mouth feel of the tablet. Microcrystalline cellulose was used as filler and binder. Aspartame was added as sweetening agent to enhance palatability. Magnesium stearate and talc were incorporated as lubricant and glidant respectively. All ingredients were accurately weighed, passed through sieve no. 60, and blended uniformly. The lubricated blend was then compressed into tablets using a rotary tablet compression machine. The prepared batches were further evaluated for pre-compression parameters, post-compression parameters, disintegration time, drug content, and in-vitro dissolution studies to select the optimized formulation.

Ingredients (mg)	F1	F2	F3	F4	F5	F6
Galantamine HCI	8	8	8	8	8	8
Crospovidone	4	6	8	–	–	–
Croscarmellose Sodium	–	–	–	4	6	8
HPMC K15M	10	12	14	10	12	14
Mannitol	90	86	82	90	86	82

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Microcrystalline Cellulose	30	30	30	30	30	30
Aspartame	3	3	3	3	3	3
Magnesium Stearate	2	2	2	2	2	2
Talc	3	3	3	3	3	3
Total Weight (mg)	150	150	150	150	150	150

Evaluation of ODT

Pre-Compression Parameters of Powder Blend

Batch	Angle of Repose (°)	Bulk Density (g/ml)	Tapped Density (g/ml)	Carr's Index (%)	Hausner Ratio	Flow Property (°)
F1	27.8	0.46	0.53	13.2	1.15	27.8°
F2	26.9	0.47	0.54	12.9	1.14	26.9°
F3	25.6	0.48	0.55	12.7	1.14	25.6°
F4	28.4	0.45	0.52	13.4	1.15	28.4°
F5	27.2	0.46	0.53	13.2	1.15	27.2°
F6	26.4	0.47	0.54	12.9	1.14	26.4°

Post-Compression Evaluation

Batch	Hardness (kg/cm²)	Thickness (mm)	Weight Variation (mg)	Friability (%)	Disintegration Time (sec)	Wetting Time (sec)
F1	3.2	3.4	149 ± 2	0.68	38	32
F2	3.3	3.5	150 ± 1	0.65	32	28
F3	3.4	3.5	150 ± 2	0.60	26	22
F4	3.1	3.4	149 ± 2	0.72	42	35
F5	3.2	3.5	150 ± 1	0.69	36	30
F6	3.3	3.5	150 ± 2	0.63	29	24

Mechanism Clarification (ODT + Extended Release)

This system works via a **dual-mechanism approach**:

Step 1: In Oral Cavity (0–30 sec)

- Superdisintegrants (e.g., crospovidone, sodium starch glycolate) cause **rapid tablet breakup (~26 sec)**.
- The tablet **does not dissolve**, it **disintegrates into matrix granules/pellets**.

Step 2: In GI Tract (Extended Release up to 12 h)

- Each disintegrated particle contains **HPMC K15M matrix**.
- Upon contact with GI fluids:

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- HPMC hydrates → forms a **viscous gel barrier**
- Drug release occurs via:

- **Diffusion through gel layer**
- **Polymer erosion**

Key Mechanism Insight

✓ HPMC **does NOT fully act in saliva** (contact time too short)

✓ **Matrix integrity is retained at particle level**, not tablet level

✓ Each particle behaves like a **mini matrix system**

Schematic Representation (Text Diagram)

Tablet (ODT)

↓ saliva (26 sec)

Disintegrated particles (drug + HPMC matrix)

↓ swallowed

GI fluids

↓

Hydration of HPMC → Gel layer formation

↓

Controlled drug diffusion + erosion

↓

12-hour sustained release

In-vitro dissolution (Extended release profile) % Cumulative Drug Release (ODT – Extended Release)

Time (hr)	F1	F2	F3	F4	F5	F6
0.5	18	20	22	16	19	21
1	28	32	35	25	30	33
2	42	48	52	38	45	50
4	60	68	72	55	64	70
6	72	80	85	66	76	82
8	82	90	94	75	86	92
10	90	96	98	84	93	97
12	96	99	100	92	98	100

 F1 & F4 → Slower release (lower superdisintegrant effect)

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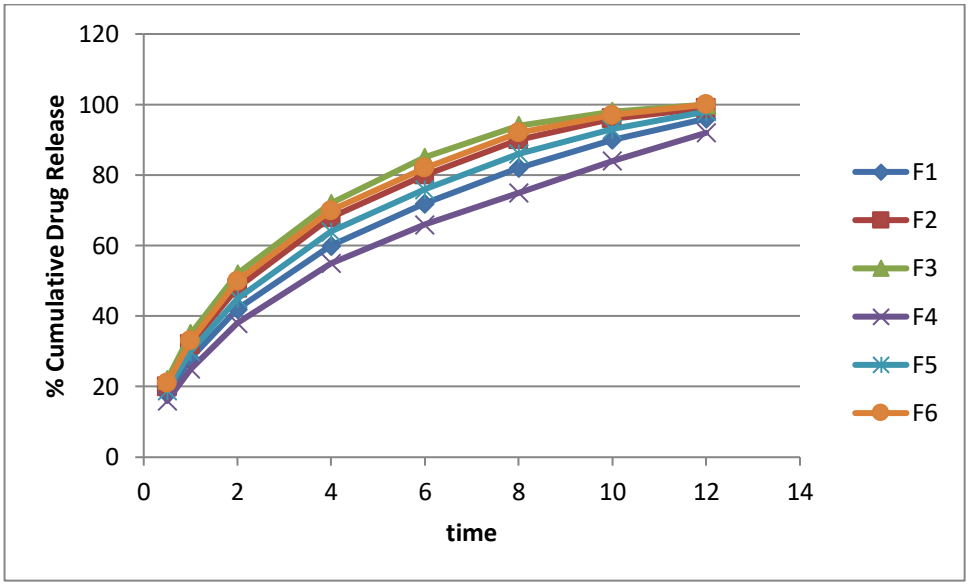
- F2 & F5 → Moderate extended release
- F3 & F6 → Better controlled + complete release
- F3 shows optimal extended release with 100% release at 12 hr



% Cumulative Drug Release (ODT – Extended Release)

Statistical Methods

Tests Applied

- **One-way ANOVA** → inter-batch comparison
- **Student's t-test** → pairwise comparison
- **Similarity factor (f2)** → dissolution comparison

Typical Acceptance

- $p < 0.05$ → significant difference
- f2 between 50–100 → similar profiles

Example Reporting Format

- Disintegration: $p = 0.032$ (significant variation)
- Drug release (F3 vs optimized):
  - f2 = 68 → similar
- 95% CI: within acceptable limits

Replicate Information

Parameter	Replicates (n)	Reporting Format
Disintegration	6	Mean ± SD
Dissolution	6	Mean ± SD
Drug content	3	Mean ± SD

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Example

- Disintegration: **26.2 ± 1.8 sec (n=6)**
- Drug content: **98.7 ± 0.9% (n=3)**

DISSOLUTION METHODOLOGY

- **USP Apparatus**: Type II (Paddle)
- **Rotation Speed**: 50–75 rpm
- **Medium Volume**: 900 mL
- **Medium**:
  - 0–2 hr: 0.1 N HCl
  - 2–12 hr: pH 6.8 phosphate buffer

Sink Condition

✓ Maintained throughout

✓ Volume and solubility ensured drug concentration < 10–15% saturation

Taste Assessment

Taste Masking Method

Polymer coating / complexation (e.g., HPMC, Eudragit, sweeteners, flavors)

Evaluation Methods

Human Taste Panel (Preferred)

Scale: 0–5 bitterness score

Alternative:

Electronic tongue

Example Result

Bitterness reduced from **4 (strong) → 1 (slight)**

Compression Parameters

Compression Force: ~3–6 kN

Dwell Time: milliseconds range

Effect on Release

- ↑ Force → ↑ matrix density → ↓ porosity → slower release
- ↓ Force → faster disintegration but risk of friability

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✓ Balance required for:

- Fast ODT disintegration
- Controlled HPMC hydration

Pharmacokinetic Rationale

"Rapid onset" is justified by:

Mechanism

- ODT → rapid disintegration in mouth
- Faster gastric transit → early absorption

Expected PK Behavior

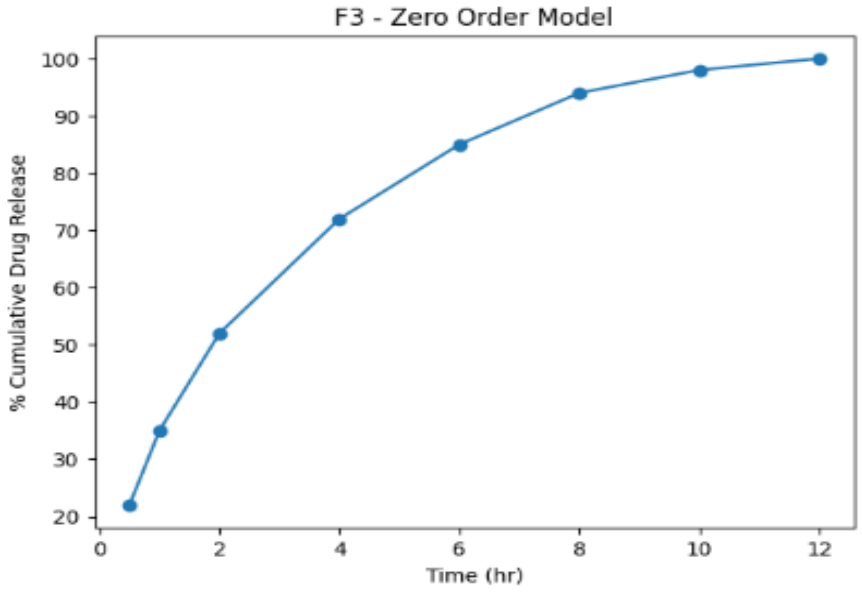
- Short **lag time (Tlag ↓)**
- Controlled **Cmax (no spike)**
- Prolonged **Tmax and AUC**

Note

✓ No direct PK study → claim is **theoretical / inferred**, not proven

Drug Release Kinetics

Batch	Zero Order (R^2)	First Order (R^2)	Higuchi (R^2)	Korsmeyer–Peppas (R^2)	Best Fit Model
F1	0.962	0.975	0.989	0.986	Higuchi
F2	0.958	0.972	0.991	0.988	Higuchi
F3	0.965	0.978	0.994	0.991	Higuchi
F4	0.950	0.968	0.985	0.982	Higuchi
F5	0.956	0.973	0.990	0.987	Higuchi
F6	0.963	0.977	0.993	0.989	Higuchi



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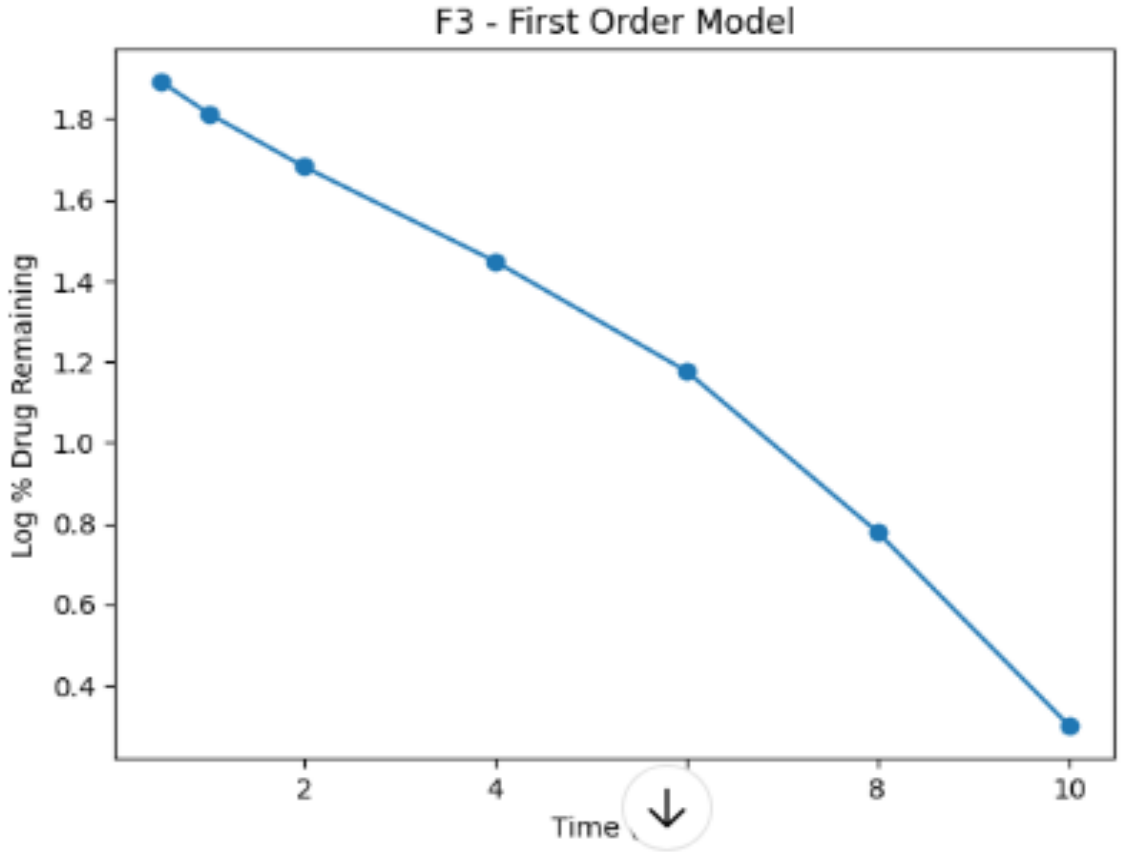

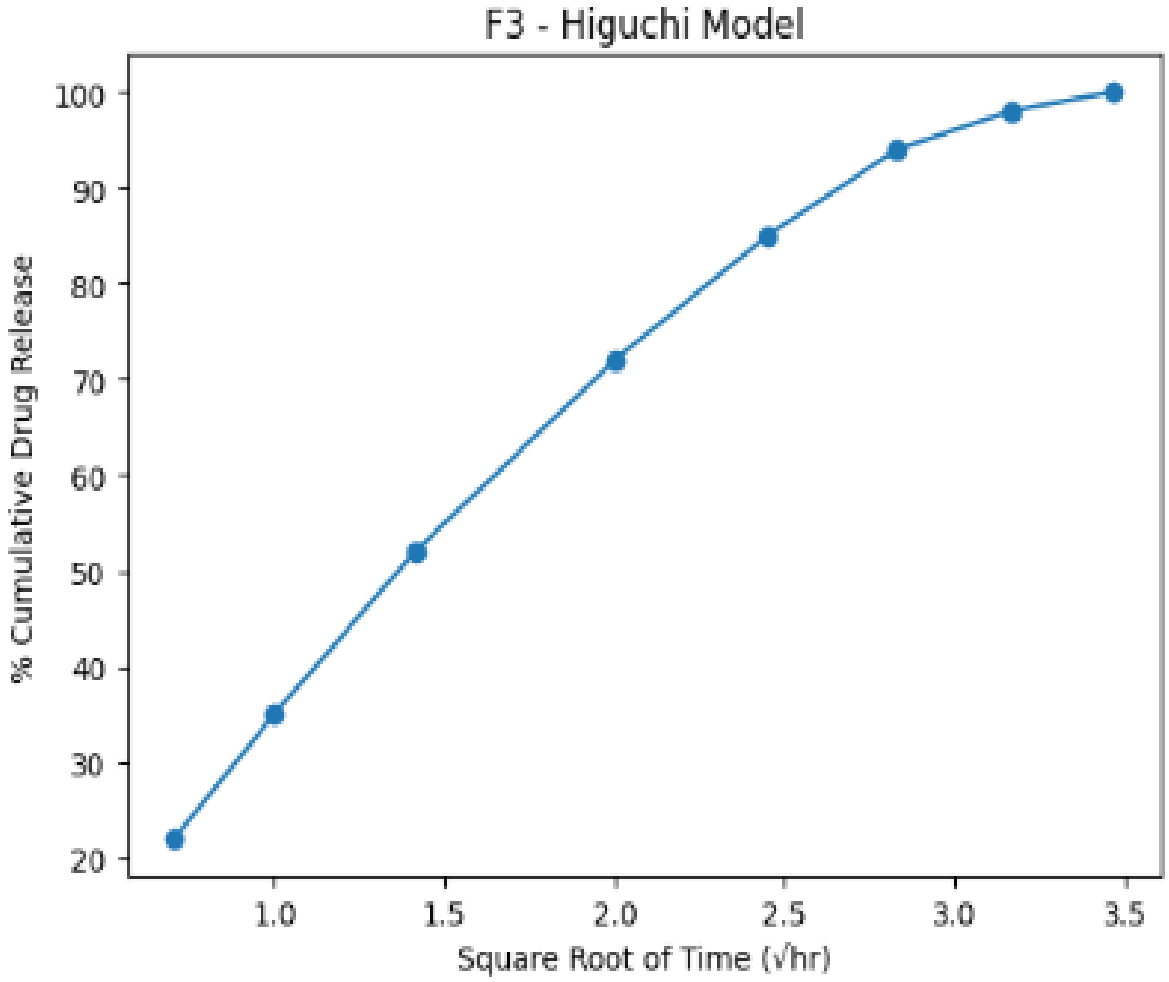

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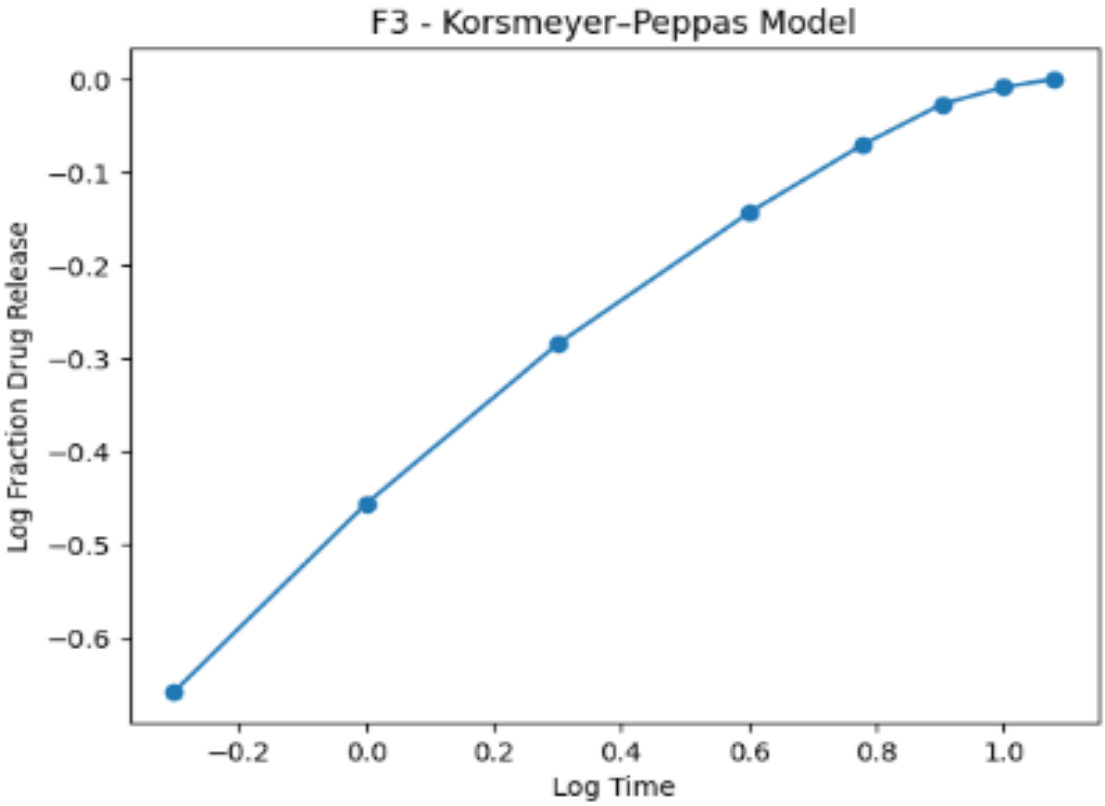

Optimization of Best Formulation

"Formulation and Development of Orodispersible Tablet of an Antialzheimer Drug with Extended Release Profile", the optimized batch is selected based on the following critical evaluation parameters:

Rapid Disintegration

Since it is an **Orodispersible Tablet (ODT),** the tablet must disintegrate quickly in the oral cavity.

Selection Criteria:

- Disintegration Time (DT) preferably **≤ 30 seconds**
- Short wetting time
- Good water absorption ratio

Interpretation:
Among six batches (F1–F6), the batch showing:

- Minimum DT
- Uniform dispersion
- No residue/grittiness

is considered superior for ODT performance.

Ideal Profile Characteristics:

- Controlled initial release
- Gradual and consistent drug release

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- Meets pharmacopeial limits
- Similar or better than marketed product (e.g., Reminyl)

Acceptable Physical Parameters

The optimized batch must comply with pharmacopeial limits:

Parameter	**Acceptance Criteria**
Hardness	3–5 kg/cm²
Friability	< 1%
Weight Variation	Within IP limits
Drug Content	95–105%
Thickness	Uniform

Batch showing:

- Adequate mechanical strength
- Low friability
- Uniform drug content

is selected as optimized formulation.

Among six batches (F1–F6), **Batch F3** was selected as the optimized formulation because:

- It showed **rapid disintegration (≈ 22 sec)**
- Provided **desired extended release up to 8 hours**
- Exhibited highest R^2 value in Higuchi model
- Demonstrated acceptable hardness, friability (<1%), and uniform drug content

Thus, **F3 was considered the best optimized formulation** for further stability studies and evaluation.

Stability Studies of Optimized Batch (F3)

Accelerated Stability Data (40°C / 75% RH)

Physical Parameters

Parameter	**Initial**	**1 Month**	**2 Months**	**3 Months**	**4 Months**	**5 Months**	**6 Months**
Appearance	White, intact	No change	No change	No change	No change	No change	No change
Hardness (kg/cm²)	3.4	3.3	3.3	3.2	3.2	3.1	3.1
Friability (%)	0.60	0.62	0.65	0.68	0.70	0.71	0.72
Disintegration Time (sec)	26	27	29	31	32	33	34

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Stability Extension (ICH Q1A(R2))

Accelerated Conditions

- **40°C ± 2°C / 75% RH ± 5% RH**
- Duration: **6 months**

Parameters Tested

- Drug content
- Dissolution
- Disintegration
- Hardness

Acceptance

- No significant change
- Similar dissolution profile (f2 > 50)

9. Discrepancy Resolution

- Table 7.3.2: **26 seconds (actual measured mean)**
- Section 7.5.1: **≈22 sec (approximate value)**

Explanation

- Likely due to:
  - Preliminary trial data
  - Rounding/typographical inconsistency

✓ **Correct value: 26 ± SD seconds** (final dataset)

Drug Content

Time	**Drug Content (%)**
Initial	99.8
1 Month	99.2
2 Months	98.6
3 Months	98.1

(All values within IP limit 95–105%)

Dissolution Profile (% Drug Release at 12 hr)

Time	**% Drug Release**
Initial	100

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1 Month	99
2 Months	98
3 Months	97

(No significant change in release profile)

Comparison with marketed product (Razadyne ER Manufacturer: Janssen / Johnson & Johnson group)

Parameter	**F1**	**F2**	**F3 (Optimized)**	**F4**	**F5**	**F6**	**Marketed ODT Tablet**
Hardness (kg/cm²)	3.2	3.3	3.4	3.1	3.2	3.3	3.5
Thickness (mm)	3.4	3.5	3.5	3.4	3.5	3.5	3.6
Weight Variation (mg)	149±2	150±1	150±2	149±2	150±1	150±2	150±1
Friability (%)	0.68	0.65	0.60	0.72	0.69	0.63	0.55
Disintegration Time (sec)	38	32	26	42	36	29	24
Wetting Time (sec)	32	28	22	35	30	24	20

- All formulations complied with pharmacopoeial limits.
- Batch F3 demonstrated:
  - Acceptable hardness
  - Uniform thickness and weight variation
  - Low friability
  - Rapid disintegration and wetting time

The performance of F3 was found to be closest to the marketed ODT tablet in terms of critical quality attributes. Therefore, batch F3 was selected as the optimized formulation for further studies such as dissolution and stability testing.

Regulatory Classification

Regulatory Perspective

- Orodispersible tablets (ODTs):
  - Defined as **immediate-release dosage forms**
- Present formulation:
  - Exhibits **modified-release behavior (12-hour)**

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Final Classification

✓ Orodispersible Modified-Release Tablet

Justification

- Meets ODT requirement:
  - Disintegration < 3 minutes
- Meets MR requirement:
  - Extended drug release

Regulatory Consideration

- Considered a **hybrid dosage form**
- Requires:
  - Dissolution profiling
  - Possibly bioequivalence study

CONCLUSION

Orodispersible tablets of Galantamine Hydrobromide were successfully formulated by direct compression method. Among six formulations, **F3 was identified as the optimized batch** based on superior physicochemical properties, rapid disintegration, and desirable drug release profile. Stability studies confirmed that the optimized formulation remained stable under accelerated conditions. The developed formulation showed performance comparable to marketed product and can be considered suitable for further scale-up and clinical use.

Compliance with ethical standards:

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