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FORMULATION AND EVALUATION OF THE ORO- DISPERSIBLE TABLETS OF AMBROXOL HYDROCHLORIDE USING NATURAL DISINTEGRANTS BANANA POWDER

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ABSTRACT

The objective of this study was to evaluate the formulation efficiency and long-term stability of Ambroxol HCl orally dissolving tablets (ODTs). The experimental methodology involved an assay of 20 randomly selected tablets, which were crushed and processed in a phosphate buffer at a pH of 6.8. Drug concentration was quantified using UV/Visible spectrophotometry by measuring absorbance at 345 nm, utilizing 10 ppm dilutions of both the test sample and a 50 mg standard for comparative calculation. *In-vitro* dissolution profiles were established using a Type-2 dissolution apparatus. Among the formulations tested, batch F8 exhibited the most superior performance, achieving a cumulative drug release of 99.76% within an 18-minute interval. This accelerated release rate is attributed to the synergistic disintegrating effects of Banana Extract and Croscarmellose Sodium. Furthermore, the tablets underwent a rigorous three-month stability program under accelerated stress conditions. Throughout the evaluation period, the formulations were monitored for critical changes in physical dimensions, weight variation, hardness, friability, and disintegration time. The results indicated no significant degradation in physical characteristics or chemical potency. The stability data, combined with the efficient drug release from formulation F8, suggests that this delivery system is both robust and effective for clinical applications.

Keywords: ODT, oral, cavity, ambroxol, natural.

INTRODUCTION

While the conventional tablet remains the most ubiquitous solid oral dosage form—favored for its ease of self-administration, chemical stability, and cost-effective manufacturing—it presents significant clinical hurdles for specific demographics. Notably, pediatric and geriatric patients frequently suffer from dysphagia, making the ingestion of standard solid units a primary cause of poor therapeutic adherence. To mitigate these challenges, pharmaceutical scientists have engineered innovative delivery systems known as **"Oro-Dispersible Tablets" (ODTs)**. These formulations, frequently referred to in literature as "fast-melt," "rapid-disintegrating," "quick-dissolving," or "mouth-dissolving" tablets, are specifically designed to liquefy or disintegrate within the oral cavity upon contact with saliva, eliminating the absolute requirement for water.[1,2]

ORO-DISPERSIBLE TABLETS (ODTs):

ODTs are increasingly recognized as a cornerstone of patient-centric drug delivery. Their rise as a mainstream dosage form is particularly vital for pediatric patients, whose musculoskeletal and nervous systems may not be fully developed, and for geriatric patients suffering from neurodegenerative conditions like Parkinson's disease or hand tremors. Beyond manufacturing feasibility, these formulations offer rapid drug release and enhanced bioavailability.

Commonly termed quick-dissolving or fast-crumbling tablets, these uncoated delivery systems are engineered to disperse within the buccal cavity before deglutition. They are ODTs. To facilitate this, the formulation incorporates specific taste-masking agents and super-disintegrants. Saliva triggers the process. Water intake and mastication are rendered obsolete. These tablets achieve structural breakdown in a timeframe spanning 15 seconds to 3 minutes.[3,4]

Fluid ingress into the tablet matrix generates a porous internal structure. This induces immediate fragmentation. Such rapid oral degradation stems from accelerated water penetration. Consequently, the functional efficacy of ODTs remains contingent upon the specific formulation techniques leveraged during production.

Mechanism of drug release of ODTs: The primary methodology for ODT advancement necessitates the integration of super-disintegrants, such as Polyvinyl pyrrolidones (Polyplasdone), carboxymethylcellulose (Croscarmellose), and sodium starch glycolate

(Primogel, Explotab). These agents facilitate instantaneous tablet fragmentation upon oral placement, thereby releasing the therapeutic compound into the saliva. This rapid degradation, which must occur in less than three minutes, is driven by the swift infiltration of moisture into the tablet's internal matrix.[5]

Challenges in Formulation of ODTs

- **Taste masking:** Numerous medications are severe in taste. A tablet of intense medication dissolving/breaking down in Oral will genuinely influence quiet consistence and acknowledgment for the dose frame. So successful taste veiling of theunpleasant medications must be done as such that the essence of the medication isn't felt in the oral depression.
- Disintegration time and mechanical strength:

The extremely rapid breakdown of orally disintegrating tablets is typically engineered so that disintegration occurs in less than one minute, often within only a few seconds. The Aim of present work is to "Formulation and Evaluation of the Oro-Dispersible tablets of Ambroxol Hydrochloride using Natural Disintegrants Banana Powder". It is a paucity of articles reporting the use of Natural Disintegrants Banana Powder super- disintegration agents. This has prompted me to take this study with the objective to investigate the disintegration property by using the cross linked starch (super-disintegration agents like) CCS.[6,7]

MATERIAL & METHODS-

Materials: - The following materials that were best possible grade available here used as supplied by the manufacturer or supplier.

Methods

PREFORMULATION ASSESSMENT:-

Preformulation assessment marks the foundational step in rationally designing a dosage form from an active pharmaceutical ingredient. Such investigations generate essential physicochemical data on the compound to guide subsequent formulation strategies and ensure optimal performance.

METHOD SOURCING

For this investigation, Ambroxol HCl served as the primary active agent. Banana powder, croscarmellose sodium, and sodium starch glycolate functioned as superdisintegrants;

aspartame provided sweetness; magnesium stearate acted as the lubricant.

DRUG IDENTITY CONFIRMATION:-

Sensory Properties

Visual appearance, aroma, and flavor of the drug sample were systematically observed and documented.[8]

Melting Temperature Measurement

A sealed capillary tube containing the powdered drug was inserted into a calibrated digital melting point device. Operation followed standard protocols, recording the onset of liquefaction as the melting point (per IP 2010 guidelines).[9]

Functional Moiety Identification via FTIR

KBr pellets were compressed under 6–8 tons hydrostatic force. Spectral scans spanned 400–4000 cm^{-1} to detect characteristic absorption bands (IP 2010).

Aqueous Solubility Profiling

Excess Ambroxol HCl was introduced incrementally into 10 mL volumes of water, ethanol, methanol, and chloroform within sealed beakers. Suspensions equilibrated undisturbed for 24 hours, followed by ultracentrifugation (5 min), filtration (Whatman paper), and UV-Vis quantification of the supernatant.[10]

λ_max Determination Across Solvents

Spectral profiles pinpointed optimal detection wavelengths for Ambroxol HCl.

Orodispersible Tablet Production

This work generated Ambroxol HCl ODTs (30 mg label strength) through direct compression (F1–F2) and wet granulation (F3–F9), incorporating graded superdisintegrants—banana powder, SSG, crospovidone, croscarmellose sodium—in varied proportions. Aspartame imparted core sweetness.

Direct Compression Workflow (F1, F2)

Individually presieve constituents (#60). Incrementally amalgamate drug, disintegrants, fillers to uniform powder bed; reserve. Accrete remaining components geometrically by mass. Final blend punched at 200 mg/fill on 10-station rotary apparatus.[11]

Wet Granulation Workflow (F3–F9)

Presieve non-actives (#60), drug (#100); homogenize. Introduce binder; knead to coherent mass. Oven-dry granules (40°C, tray), mill (#20). Lubricant blend (#60-sieved) incorporates terminally. Compress resultant lubricated mass (200 mg, 7.5 mm dia. tooling) employing identical press.[12]

Table 1: Formula for Oral dissolves tablets of Ambroxol HCl

INGREDIENTs	FORMULATION CODE								
	F-1	F-2	F-3	F-4	F-5	F-6	F-7	F-8	F-9
Ambroxol HCl	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0
Banana Powder	2.0	3.0	2.0	4.0	8.0	8.0	10.0	12.0	14.0
Di Calcium Phosphate (DCP)	70.0	79.0	80.0	-	-	-	-	-	-
Croscarmellose Sodium	--	2.0	4.0	2.0	4.0	5.0	6.0	6.0	4.0
Sodium Starch Glycolate	-	-	1.0	2.0	-	1.0	-	-	-
Lactose Monohydrate	-	-	-	80.0	78.0	71.0	76.0	70.0	60.0
MCC PH-102	-	-	-	-	-	20.0	22.0	15.0	20.0
PVPK-30	-	0.5	1.0	1.0	2.0	1.0	2.0	2.0	2.0
IPA	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Banana Flavor	5.0	5.0	5.0	5.5	5.5	6.0	5.5	6.0	6.0
Colloidal Silicon DiOxide (Aerosil)	1.0	1.5	1.5	1.5	2.0	2.0	2.0	2.0	2.0
Magnesium Stearate	1.0	1.5	1.5	2.0	2.0	2.0	2.5	2.0	2.0
Mannitol (Plain)	88.5	74.0	66.5	64.5	60	43.5	34.5	45	50
Citric Acid anhydrous	-	-	4.0	3.5	4.0	5.0	4.5	4.0	4.0
Aspartame	2.0	2.5	2.5	3.0	3.5	4.0	3.0	4.0	4.0

Talcum	0.5	1.0	1.0	1.0	1.0	1.5	2.0	2.0	2.0
TOTAL (Mg)	200.0	200.0	200.0	200.0	200.0	200.0	200.0	200.0	200.0

Evaluation Parameters of Oral Dissolving Tablets of Ambroxol HCl: -

The evaluation parameters of Oral dissolving tablets of Ambroxol HCl given as well as following;

Mass Uniformity Check

Randomly select 20 units. Record each mass precisely. Compute mean value. Assess deviation of individuals from average to verify content consistency across batch.

Crushing Strength

Zero the calibrated tester. Apply progressive axial force until diametral rupture occurs. Force magnitude at failure quantifies mechanical resistance, reported as kg/cm² units.

Abrasion Resistance

Load pre-weighed tablets into friabilator drum (Electro-lab). Rotate 100 times (4 min at 25 rpm). Discharge, dedust, reweigh collectively. Compute attrition as % initial mass reduction via equation:

$$F = \frac{(W_{initial}) - (W_{final})}{(W_{intial})} \times 100$$

Dimensional Profiling

Precise gauging of tablet thickness and diameter using digital vernier calipers ensures batch consistency and end-user appeal. Dimensions recorded in millimeters.

Loss on Drying: Determine on 1.0 g by drying in an LOD Apparatus at 60°C Temperature.

RESULT AND DISCUSSION

IDENTIFICATION STUDY:-

Determination of Melting Point

Table 2: Result of Melting Point Determination of Ambroxol HCl.

Observed Melting Point (°C)			**Mean ± S.D. (n =3)**
Sample 1	Sample 2	Sample 3	
233.4	233.0	234.8	233.73 ±0.95

RESULT OF ANALYSIS:

Determination of Wavelength (λ_{max}

Table 3: Standard Plot of Ambroxol HCl in Distilled Water.

S. No.	**Concentration (µg/ml.)**	**Absorbance**			**Mean ± S.D.**
		Sample 1	**Sample 2**	**Sample 3**	
1.	Blank	0.0000	0.0000	0.0000	0.0000 ± 0.0000
2.	2.0	0.1840	0.1842	0.1844	0.1842 ± 0.0002
3.	4.0	0.3479	0.3486	0.3481	0.3482 ± 0.0003
4.	6.0	0.5632	0.5642	0.5634	0.5636 ± 0.0005
5.	8.0	0.7287	0.7280	0.7285	0.7284 ± 0.0003
6.	10.0	0.9044	0.9034	0.9045	0.9041 ± 0.0006

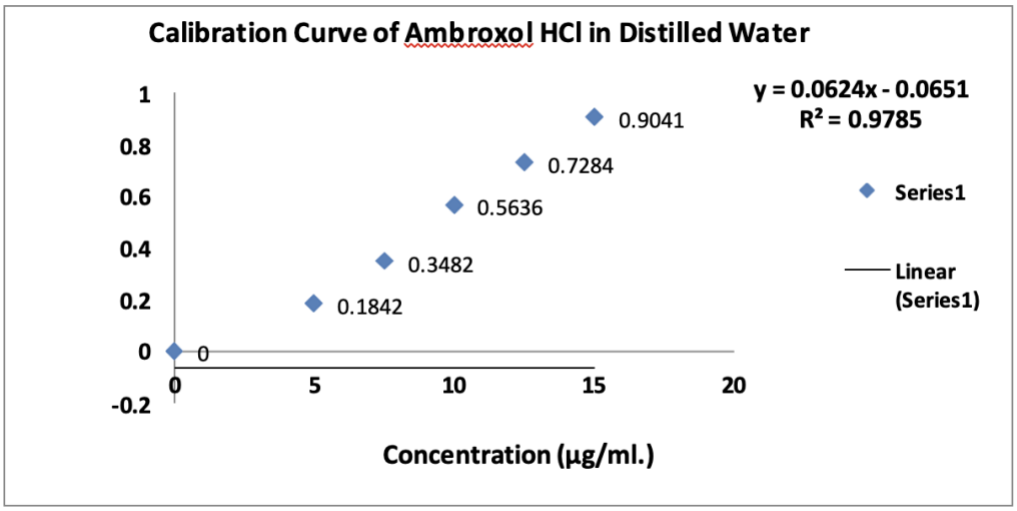

Fig 1: UV spectra of Ambroxol in distilled water

FTIR Spectra of Ambroxol HCl:-

The FTIR spectrum of Ambroxol HCl which is performed by FTIR instruments is given as following and the interpretation of Ambroxol HCl was found to be-

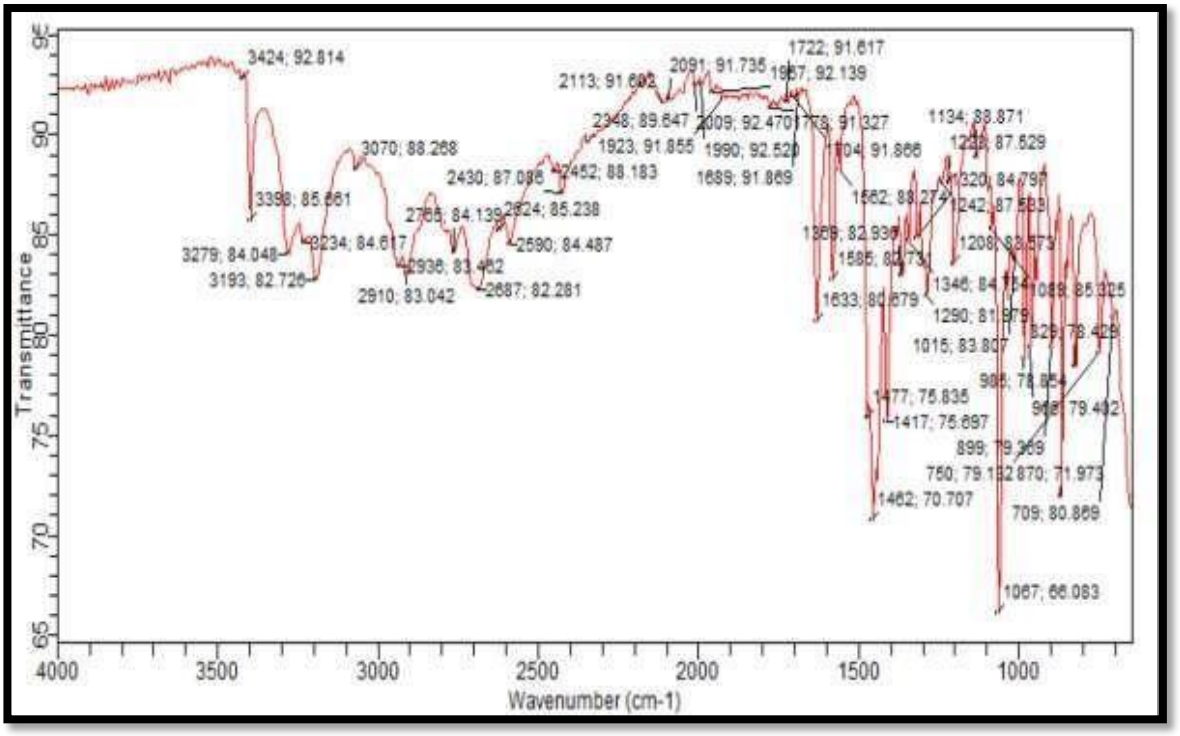

Fig 2: Ambroxol HCl FTIR Spectrum (Sample)

Bulk Density

The bulk density followed expressed by a table of all formulations, it is given as well as following;

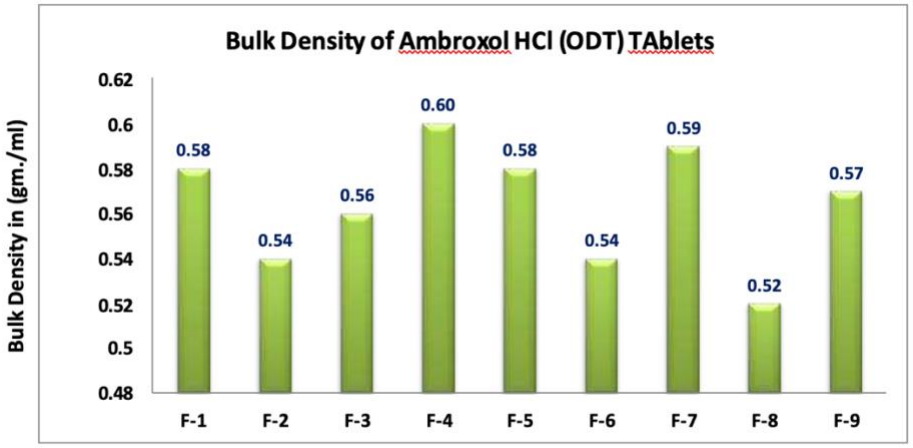

Fig. 3: Graphically Representation of Bulk Density

Tapped Density: - (gm/ml.)

The Tapped density followed expressed by a table of all formulations, it is given as well as following;

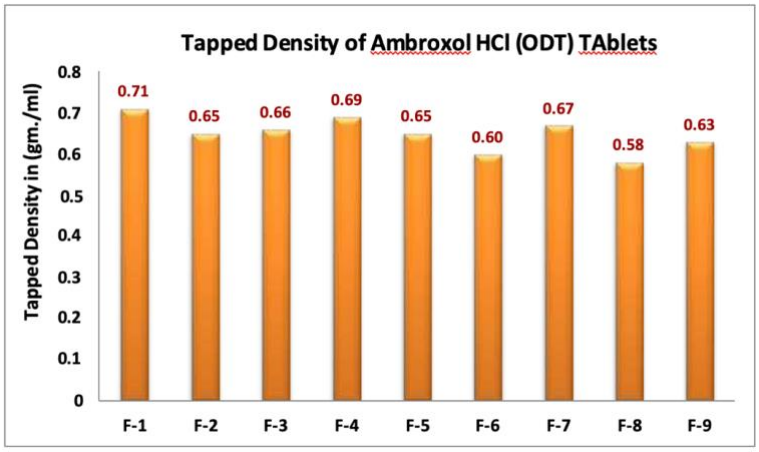

Fig 4. Graphically Representation of Tapped Density

OPTIMIZATION POST- COMPRESSION PARAMETERS OF AMBROXOL HCL (ODT)

Weight Variation : - (mg.)

The Weight variation followed expressed by a table of all formulations; it is given as well as following

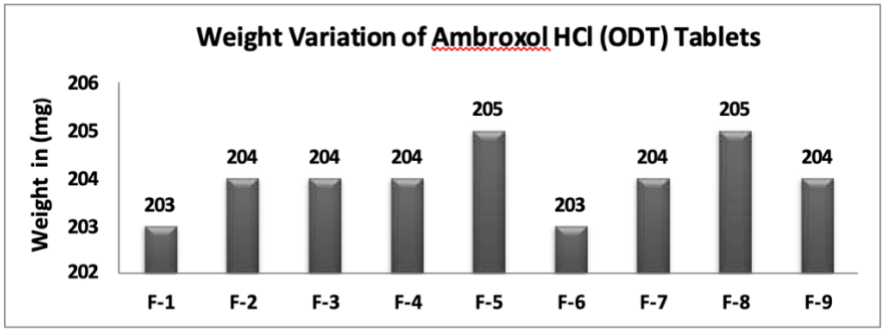

Fig. 5 Graphically Representation of weight variatioion

Thickness

The Thickness of tablets followed expressed by a table of all formulations; it is givenas well as following;

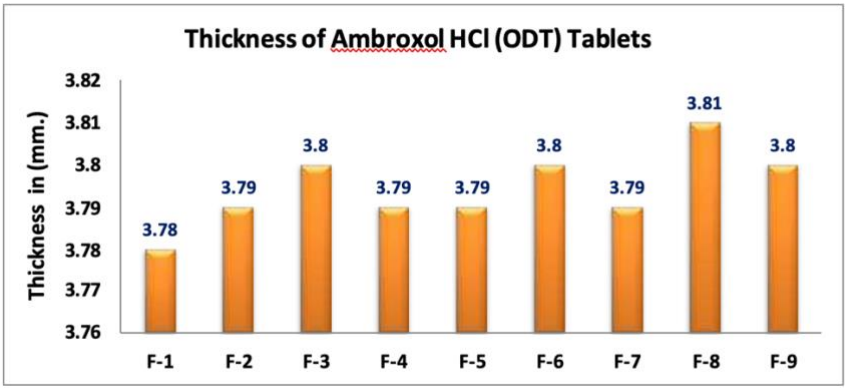

Fig. 6 Graphically Representation of thickness

Hardness: - (kg/cm^2)

The Hardness of tablets followed expressed by a table of all formulations; it is given as well as following;

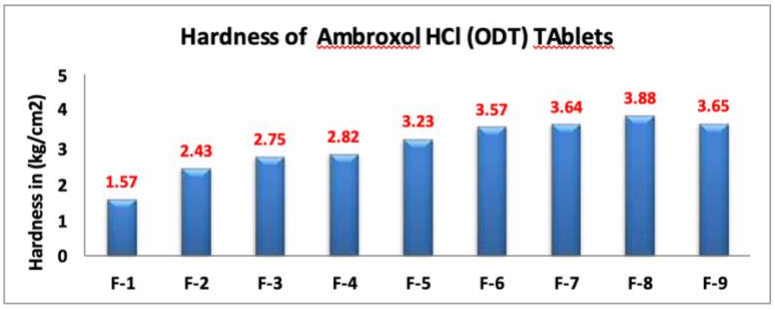

Fig. 7 Graphically Representation of hardness

% Friability:

The % Friability of tablets followed expressed by a table of all formulations; it is given as well as following;

Table 4: % Friability of Ambroxol HCl (ODT)

S.NO.	F-1	F-2	F-3	F-4	F-5	F-6	F-7	F-8	F-9
1.	1.16	1.04	0.94	0.74	0.68	0.51	0.38	0.32	0.28
2.	1.19	1.07	0.92	0.78	0.67	0.54	0.35	0.28	0.31
3.	1,21	1.08	0.89	0.80	0.69	0.53	0.34	0.30	0.27
4.	1.14	1.05	0.94	0.76	0.68	0.55	0.37	0.31	0.30
5.	1.15	1.04	0.96	0.77	0.65	0.49	0.38	0.32	0.26
6.	1.17	1.09	0.91	0.75	0.70	0.52	0.39	0.27	0.32
Mean ± S.D.	**1.17 ± 0.026**	**1.06 ± 0.021**	**0.92 ± 0.025**	**0.76 ± 0.021**	**0.67 ± 0.017**	**0.52 ± 0.021**	**0.36 ± 0.019**	**0.30 ± 0.020**	**0.29 ± 0.023**

In-vitro Disintegration

The Disintegration study of tablets followed expressed by a table of all formulations; it is given as well as following;

Table 5: In-vitro Disintegration

S.NO.	F-1	F-2	F-3	F-4	F-5	F-6	F-7	F-8	F-9
1.	3.24	2.50	2.31	1.56	0.57	1.04	1.48	0.52	0.50
2.	3.04	2.43	2.38	1.52	0.59	1.05	1.28	0.51	0.58
3.	3.20	2.48	2.28	1.49	0.57	1.02	1.36	0.48	0.56
4.	2.58	2.58	2.30	1.59	0.55	1.04	1.32	0.43	0.59
5.	3.04	2.54	2.24	1.54	0.56	1.07	1.27	0.47	0.57
6.	3.28	3.06	2.27	1.57	0.58	1.03	1.31	0.45	0.49
Mean ± S.D.	**3.06 ± 0.25**	**2.59 ± 0.23**	**2.29 ± 0.047**	**1.54 ± 0.036**	**0.57 ± 0.014**	**1.04 ± 0.017**	**1.33 ± 0.076**	**0.47 ± 0.034**	**0.54 ± 0.042**

Wetting Time: -

The Wetting time study of tablets followed expressed by a table of all formulations; it is given as well as following;

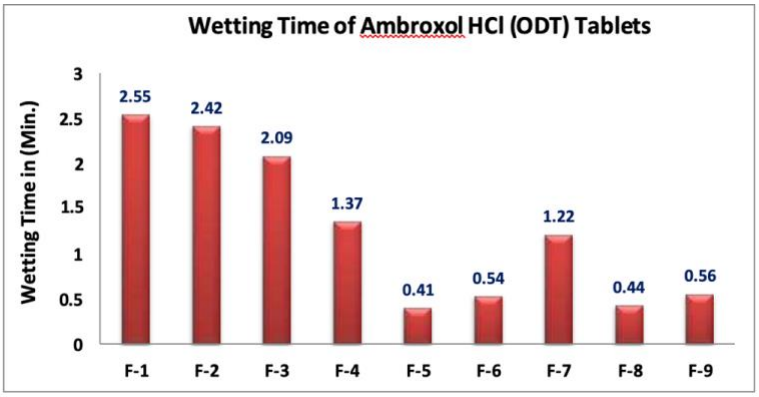

Fig. 8 Graphically Representation of wetting time

% Drug- Content : -

The concentration of Ambroxol HCl was quantified by measuring absorbance at a wavelength of 345 nm using a UV/Visible Spectrophotometer.

Table 6: % Drug Content of Ambroxol HCl (ODT)

Formulations	ssay-1(mg.)	Assay-2 (mg.)	ssay-3 (mg.)	an ± S.D.(mg.)	% Drug-Content
F-1	29.93	29.94	29.92	29.93 ± 0.010	98.54 %
F-2	29.97	29.95	29.93	29.95 ± 0.020	99.09 %
F-3	29.90	29.93	29.92	29.91 ± 0.015	98.24 %
F-4	29.93	29.94	29.98	29.95 ± 0.026	98.93 %
F-5	29.87	29.89	29.85	29.87 ± 0.020	97.34 %
F-6	29.90	29.93	29.95	29.92 ± 0.025	98.35 %
F-7	29.94	29.97	29.98	29.96 ± 0.020	99.13 %
F-8	29.99	29.98	30.00	29.99 ± 0.010	99.75 %
F-9	29.98	29.96	29.98	29.97 ± 0.011	99.44 %

IN-VITRO DRUG RELEASE: - A study was conducted to assess the *in-vitro* release profiles of the prepared Ambroxol HCl oral tablets utilizing **Type-II dissolution equipment**. The data indicates that **batch F8** was the superior candidate, successfully discharging **99.76%** of the active ingredient in an **18-minute** window.

Table 7: % Drug release

S.NO.	TIME (Min.)	F-1 (%)	F-2(%)	F-3(%)	F-4(%)	F-5(%)	F-6(%)	F-7(%)	F-8(%)	F-9(%)
1.	**2.0**	15.81	17.58	18.79	23.07	22.03	19.18	25.80	22.97	30.63
2.	**4.0**	29.01	37.87	32.18	31.55	34.04	36.57	40.40	34.46	43.28
3.	**6.0**	39.46	45.80	48.69	47.28	49.27	51.50	49.86	50.45	54.62
4.	**8.0**	44.75	53.69	61.13	55.25	62.37	58.20	62.76	67.93	66.20
5.	**10.0**	57.81	61.94	71.80	67.39	70.07	73.31	77.40	85.09	79.53
6.	**12.0**	67.55	68.73	79.28	72.69	82.59	87.23	86.07	93.32	88.02
7.	**14.0**	74.46	76.11	85.92	82.16	85.99	89.51	93.03	98.34	93.74
8.	**16.0**	82.76	83.70	91.03	92.43	90.15	94.52	98.01	99.48	98.50
9.	**18.0**	84.63	86.05	93.10	96.42	94.20	97.73	98.22	99.62	99.07

Table 8: Release kinetics study;

mulationCode	Zero Order	First Order	HiguchiMatrix	Korsmeyer Peppas Kinetics
F-1	0.978	0.978	0.965	0.974
F-2	0.948	0.984	0.986	0.974
F-3	0.946	0.990	0.975	0.984
F-4	0.973	0.903	0.977	0.991
F-5	0.943	0.984	0.980	0.988
F-6	0.947	0.952	0.972	0.983
F-7	0.942	0.934	0.982	0.991
F-8	0.920	0.942	0.957	0.971
F-9	0.924	0.924	0.989	0.991

DISCUSSION

Superdisintegrants at different concentration level were used to assist disintegration. The pre-compression parameters results of all formulations are given as well a following.

According to the post compression parameter of all formulations are given as well as following. In the formulation the hardness of all formulations were varies between **1.57-3.88 (kg/cm^2)**

It was observed that when was used sodium Starch glycolate (Plain) from Formulation-1 to formulation-5 and sodium starch glycolate (Primogel) from formulation-6 to Formulation-9 as superdisintegrants, the tablet disintegrate rapidly compared with other tablet prepared using croscarmellose sodium and Crospovidone XL-10.

Oral administration of dosage form should lead to appropriate distribution and show the activity of therapeutic moiety depending on the characteristic of dosage form and drug. Oral dissolving tablets disintegration or dissolve in the saliva and release the drug from tablet.

Ambroxol HCl absorbed from the membrane of Oral and show the effect on seasonal allergies, also known as seasonal allergic rhinitis. The formulation containing sodium Starch glycolate (Plain) from Formulation-1 to formulation-5 and sodium starch glycolate (Primogel) from formulation-6 to Formulation-9 as superdisintegrants, the tablet disintegrate

rapidly compared with other tablet prepared using croscarmellose sodium and Crospovidone XL-10.A stability study was conducted on every formulation to determine how different environmental conditions affect their physical properties. We tracked several variables, ranging from visual characteristics and weight variation to disintegration performance and drug content.

Results indicated that the Ambroxol HCl fast-dissolving tablets remained essentially unchanged after three months of observation. There were no meaningful shifts in the tablets' physical traits, drug concentration, or dissolution rates. These stability trials demonstrate that the prepared tablets are robust when stored at $40^\\circ\text{C}$ with a 75% relative humidity level.

CONCLUSION

Among these formulated Oral dissolving tablets of Ambroxol HCl **Formulation (F-8)** was the best. The formulation containing Banana Extract from Formulation-1 to formulation-5 and sodium starch glycolate (Primogel) from formulation-6 to Formulation-9 as superdisintegrants, the tablet disintegrate rapidly compared with other tablet prepared using croscarmellose sodium and Banana Extract.

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