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FORMULATION AND EVALUATION OF MOUTH DISSOLVING TABLETS OF PERAMPANEL

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Abstract:

*The present study aimed to **Formulate and Evaluate mouth dissolving tablets (MDTs) of Perampanel** to enhance patient compliance and achieve rapid onset of action. Mouth dissolving tablets were prepared by the direct compression method using super disintegrants such as **Crospovidone** and **Croscarmellose sodium**, along with **Avicel PH 102** as a directly compressible diluent. Various formulations were developed and evaluated for both pre-compression and post-compression parameters.*

Pre-compression studies, including angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio, indicated satisfactory flow properties of the powder blends. Post-compression evaluation of tablets, such as weight variation, hardness, thickness, friability, drug content uniformity, wetting time, disintegration time, and in vitro dissolution studies, demonstrated that all formulations complied with Indian Pharmacopoeial (IP) limits.

*Among the developed formulations, **F8** exhibited superior performance with rapid disintegration and maximum drug release of **99.95% within 30 minutes**, and was therefore considered the optimized formulation. The enhanced dissolution was attributed to the synergistic effect of Crospovidone and Croscarmellose sodium, which promoted rapid water uptake and tablet disintegration, while Avicel PH 102 provided adequate mechanical strength and compressibility.*

In conclusion, the study successfully developed Perampanel mouth dissolving tablets with desirable physicochemical properties and rapid drug release, indicating their potential as an effective alternative dosage form for improving patient compliance.

Keywords: *Perampanel, Crospovidone, Croscarmellose sodium and Ac-di-sol*

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INTRODUCTION:

- From almost all the dosage forms mouth dissolving tablet (MDT) is the most widely preferred commercial products. Because of ease in administration, oral cavity is considered to be an attractive site for the administration of drugs. Dosage forms like tablets, capsules, liquid preparations are administered by oral route. In last decade, mouth dissolving tablet (MDT) technologies that make tablets which disintegrate in the mouth without chewing and additional water intake have pulled a great deal of attention.[1-2]
- The effect of varying concentrations of different super disintegrants such as Crospovidone, croscarmellose sodium and sodium starch glycolate on disintegration time and dissolution rate was studied. The MDT is also known as fast melting, fast dispersing, rapid dissolve, rapid melt, and quick disintegrating tablet.
- All MDTs are approved by the Food and Drug Administration (FDA). Recently, the European Pharmacopeia adopted the term Oro dispersible tablet for a tablet that disperses or disintegrates in less than 3 minutes in the mouth before swallowing.
- Such a tablet disintegrates into smaller granules or melts in the mouth and form a hard solid to a gel-like structure, allowing easy swallowing by patients. The disintegration time for good MDTs varies from several seconds to about a minute.
- Mouth disintegrating tablets shows an advantage especially for pediatric and geriatric populations with difficulty in swallowing conventional tablets and capsules.
- Buclizine Hydrochloride (BZ) is an antiallergic drug and also an antiemetic agent. It is good candidate to formulate oral disintegrating tablet which disperse quickly and give onset of action. Hence the formulation will be very useful for pediatric and geriatric patients whose suffer swallowing problem.[3]
- Additionally, pediatric patients may suffer from ingestion problems as a result of underdeveloped muscular and nervous control. Moreover, patients traveling with little or no access to water, limit utility of orally administered conventional tablets or capsules.
- Mouth dissolving of tablet results in quick dissolution and rapid absorption which provide rapid onset of action. Moreover, drug candidates that undergo pregastric absorption when formulated as MDTs may show increased oral bioavailability. It provides good stability, accurate dosing, easy manufacturing. Pre-gastric absorption can result in improved bioavailability and as a result of reduced dosage, improved clinical performance through a reduction of unwanted effects.
- In recent decades, a variety of pharmaceutical research has been conducted to develop new dosage forms. Considering quality of life, most of these efforts have been focused on ease of medication.[4]
- Among the various dosage forms developed to improve the ease of administration, the mouth dissolving tablet (MDT) is the most widely preferred commercial products. The oral cavity is an attractive site for the administration of drugs because of ease of administration. Various dosage forms like Tablets, Capsules, Liquid preparations are administered by oral route.
- During the last decade, mouth dissolving tablet (MDT) technologies that make tablets disintegrate in the mouth without chewing and additional water intake have drawn a great deal of attention. The MDT is also known as fast melting, fast dispersing, rapid dissolve, rapid melt, and or quick disintegrating tablet.[5]
- All MDTs approved by the Food and Drug Administration (FDA) are classified as orally disintegrating tablets. Recently, the European Pharmacopeia adopted the term Oro dispersible tablet for a tablet that disperses or disintegrates in less than 3 minutes in the mouth before swallowing.[5]
- Such a tablet disintegrates into smaller granules or melts in the mouth from a hard solid to a gel-like structure, allowing easy swallowing by patients.

Mouth dissolving tablet (MDT).[6]

It is a tablet that disintegrates and dissolves rapidly in the saliva, within a few seconds without the need of drinking water or chewing. A mouth dissolving tablet usually dissolves in the oral cavity within 15 s to 3min. Most of the MDTs include certain super disintegrates and taste masking agents.

IDEAL PROPERTIES OF MDT.[7-8]

1. It should not require water to dissolve or disintegrate in the mouth in a couple of seconds
2. It ought to permit heavy drug loading
3. It ought to work well with other excipients and flavor masking
4. It ought to feel good in the mouth
5. There should be little to no residual in the mouth after oral administration
6. It ought to be strong enough to endure the strains of manufacture
7. It need to be somewhat insensitive to external factors such as humidity and temperature.
8. It ought to be versatile and compatible with current processing and packaging equipment

9. It ought to make it possible to produce tablets at a reasonable cost using standard packaging and processing machinery.

MOUTH DISSOLVING PHENOMENON.[9-10]

Super disintegrants are given far greater consideration when creating mouth dispersing pills. By inducing swelling and water absorption in the pill, they offer quick disintegration. The swelling mechanism of the super disintegrants wets the carrier's surface, which enhances tablet disintegration and causes increased dissolution to occur. The swelling capacity in the dissolving liquid and matrix density both affect how well super disintegrants act. A greater degree of disintegration is caused by a matrix with a higher swelling capacity and density.

ADVANTAGES OF MDT.[11-13]

1 Administration to the patients who can not swallow, such as the elderly, stroke victims, bedridden patients, patients affected by renal failure & patients who refuse to swallow such as pediatric, geriatric & psychiatric patients.

2 Rapid drug therapy intervention.

3 Achieve increased bioavailability/rapid absorption through pregastric absorption of drugs from mouth, pharynx & esophagus as saliva passes down.

4 Convenient for administration and patient compliant for disabled, bedridden patients and for travelers and busy people, who do not always have access to water.

5 Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patients.

6 The risk of chocking or suffocation during oral administration of conventional formulations due to physical obstruction is avoided, thus providing improved safety.

7 New business opportunity like product differentiation, product promotion, patent extension and life cycle management.

8.Strong enough and long-lasting to endure the rigours of factory handling and the manufacturing process.[14]

9. A pleasing texture to the mouth.

10. Insensitive to temperature and humidity levels in the surroundings.

11. Better flavors with no aftertaste that dissolves into the mouth.

12. Flexible and compatible with current processing and packaging equipment.

13. Economical.

14. Taste masking compatible.

15. Quick intervention with medication therapy

METHODOLOGY:

CONSTRUCTION OF CALIBRATION CURVE OF PERAMPANEL pH 6.8 PHOSPHATE BUFFER.

- Accurately weighed 10 mg of drug was transferred to 10 ml volumetric flask and dissolved in 10ml of methanol, this was considered as stock solution (I).
- To 1 ml of stock solution (I) 9 ml of pH 6.8 phosphate buffer was added and this was considered as stock solution (II).
- From stock solution (II) 1.0ml, 2.0ml, 3.0ml, 4.0ml, and 5.0 ml were taken and was made up the volume to 10ml with pH 6.8 phosphate buffer to get respective concentrations of 10,20,30,40 and 50 µg/ml.
- Prepared samples were analyzed by using ultra violet double beam spectrophotometer at λmax 286nm.
- The calibration curve was plotted by taking concentration on x-axis and absorbance on y-axis.

7.2. PREPARATION OF PERAMPANEL MOUTH DISSOLVING TABLETS

Preparation of Perampanel Mouth dissolving tablets by direct compression method

- Drug and different concentrations of super disintegrates and sweetening agent were accurately weighed and passed through a 40-mesh screen to get uniform size particles and mixed in a glass mortar for 15 minutes.
- The obtained blend was lubricated with magnesium stearate and glidant (Talc) was added and mixing was continued for further 5 minutes.
- The resultant mixture was directly compressed into tablets by using 6mm round flat faced punch of rotary tablet compression machine. Compression force was kept constant for all formulations.

Table 7.1 Composition of Perampanel Mouth dissolving tablet

Materials (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Perampanel	10	10	10	10	10	10	10	10	10
Cross providone	5	10	15	-	-	-	-	-	-
Cross carramellose sodium	-	-	-	5	10	15	-	-	-
Ac-di-sol	-	-	-	-	-	-	5	10	15
Aspartame	8	8	8	8	8	8	8	8	8
Talc	4	4	4	4	4	4	4	4	4
Mg stearate	4	4	4	4	4	4	4	4	4
Mannitol	6	6	6	6	6	6	6	6	6
MCC	63	58	53	63	58	53	63	58	53
Total weight	100	100	100	100	100	100	100	100	100

7.3. EVALUATION OF PRE-COMPRESSION PARAMETERS OF POWDER BLEND

ANGLE OF REPOSE:

- Angle of repose was determined using funnel method. The blend was poured through a funnel that can be raised vertically until a maximum cone height (h) is obtained. Radius of the heap (r) was measured and angle of repose (θ) was calculated using the following formula.

$$\theta = \tan^{-1} h/r$$

Table 7.2 Angle of repose as an indication of powder flow properties

Sr. No	Angle of Repose (°)	Type of Flow
1	< 20	Excellent
2	20 – 30	Good
3	30 – 34	Passable
4	> 34	Very Poor

BULK DENSITY:

- Apparent bulk density (ρ_b) was determined by pouring the powder blend into a graduated cylinder. The bulk volume (V_b) and weight of the powder (M) were determined.

$$\rho_b = M / V_b$$

TAPPED DENSITY:

- The measuring cylinder containing a known mass of blend (M) was tapped for a fixed time (100 tapping). The minimum volume (V_t) occupied in the cylinder and weight of the blend was measured. The tapped density (ρ_t) was calculated using the following formula.

$$\rho_t = M / V_t$$

COMPRESSIBILITY INDEX OR CARR'S INDEX:

- The simplest way for measurement of free flow of powder is compressibility, an indication of the ease with which a material can be induced to flow is given by compressibility index.

$$\text{Carr's Index} = \rho_b - \rho_t / \rho_b * 100$$

Where ρ_t = tapped density

ρ_b = bulk density

Table 7.3 Relationship between compressibility and flow ability

% Compressibility	Flow ability
5 – 12	Excellent
12 – 16	Good
18 – 21	Fair Passable
23 – 35	Poor
33 – 38	Very Poor
< 40	Very Very Poor

HAUSNER'S RATIO (H):

- Hausner's ratio is an indirect index of ease of powder flow. It is calculated by the following formula:

Hausner's ratio (H) = ρt/ρb

Where ρ_t = tapped density

ρ_b = bulk density

7.4. EVALUATION OF POST COMPRESSION PARAMETERS OF PERAMPANEL MDTs:

- Different quality control tests were performed for all the MDT formulations to check whether these have met the specifications given in USP along with other In-vitro tests like wetting time and water absorption ratio.

Various tests performed are:

- Weight variation test
- Thickness measurement
- Hardness
- Friability
- Drug Content uniformity
- Wetting time and Water absorption ratio
- *In vitro* dispersion Time
- *In vitro* disintegration Time
- *In vitro* dissolution studies

WEIGHT VARIATION TEST:

- **Method:** 20 tablets were randomly selected from each formulation and their individual weights and average weight of all 20 tablets was calculated by weighing on an electronic balance (Shimadzu, AUX 220, Shimadzu Corp, Japan). The Mean ± S.D. were noted.

Table 7.4 Weight Variation Limits

IP/BP	Limit	USP
80 mg or less	10%	130mg or less
More than 80mg or less than 250mg	7.5%	130mg to 324mg
250mg or more	5%	More than 324mg

THICKNESS:

- **Method:** Randomly 10 tablets were taken from each formulation and their thickness was measured using a Micrometer. Average thickness and standard deviation values were calculated. The tablet thickness should be controlled within a ± 5% variation of standard value.

HARDNESS:

- **Method:** The tablet hardness of different formulations was measured using the Monsanto hardness tester. The tester consists of a barrel containing a compressible spring held between two plungers. The lower plunger was placed in contact with the tablet, and a zero was taken.
- The upper plunger was then forced against the spring by turning a threaded bolt until the tablet fractures. As the spring is compressed, a pointer rides along a gauge in the barrel to indicate the force. The force of fracture is recorded, and the zero-force reading is deducted from it. Generally, a minimum hardness of 2.5 kg / cm^2 is considered acceptable for uncoated tablets.
- The hardness for MDTs should be preferably 2.5 to 3 kg / cm^2.

FRIABILITY:

- **Method:** This test was performed using a laboratory friability tester known as Roche Friabilator.20 tablets were weighed and placed in a plastic chambered Friabilator

attached to a motor, which revolves at a speed of 25 rpm, dropping the tablets from a distance of 6 inches with each revolution. The tablets were subjected to 100 revolutions for 4 minutes. After the process, these tablets were de - dusted and reweighed. Percentage loss of tablet weight was calculated. Friability values below 1% are generally acceptable.

$$\% \text{ Friability} = \frac{W_1 - W_2}{W_1} * 100$$

Where W_1 = Initial weight of 10 tablets.
W_2 = Final weight of 10 tablets.

DRUG CONTENT:

- **Method:** 3 tablets were randomly selected, weighed and finely powdered and quantity of powder equivalent to one tablet was added to 100 ml of 6.8pH phosphate buffer in a conical flask. A conical flask was then placed on a rotary shaker.
- An aliquot of solution was centrifuged and supernatant was filtered through a 0.22µ filter. Absorbance of the resulted supernatant solution was measured using U.V Visible double beam spectrophotometer at a wavelength of 286nm against 6.8pH phosphate buffer as blank. Concentrations and amount of drug present in one tablet were calculated with the help of calibration curves.

***IN VITRO* DISPERSION TIME:**

- **Method:** *In vitro* dispersion time was determined by placing one tablet in a beaker containing 10 ml of pH 6.8 phosphate buffer at 37±0.5°c and the time required for complete dispersion was determined.
- To check for reproducibility, the measurements were carried out in triplicates (n=3). The dispersion time was recorded using a stopwatch.

IN VITRO* DISINTEGRATION TIME*:

- **Method:** A piece of tissue paper folded twice was placed in a small Petri dish containing 6ml of pH 6.8 phosphate buffer. A tablet was carefully placed on the surface of tissue paper in the Petri dish at room temperature.
- The time required for water to reach the upper surface of the tablets and completely wet them and break down into small particles was noted as the *in vitro* disintegration time. To check for reproducibility, the measurements were carried out in triplicates (n=3). The disintegration time was recorded using a stopwatch.

***IN VITRO* DISSOLUTION STUDIES.**

- **Method:** Dissolution test was carried out by using USP type II apparatus. The paddle was rotated at 50 rpm. 0.1N HCL was used as dissolution medium (900ml) and was maintained at 37 ± 1^0C. Samples of 5ml were withdrawn at predetermined intervals (5, 10, 15, 20 and 30), filtered and replaced with 5ml of fresh dissolution medium.
- The collected samples were suitably diluted with dissolution fluid, where ever necessary and were analyzed for the drug at 286 nm by using ultra violet double beam spectrophotometer. Each dissolution study was performed for three times and mean values were taken.

7.5. CHARACTERISATION:

Fourier Transform Infrared Spectroscopy (FTIR)

- FTIR studies were performed on drug, optimized formulation using Agilent FTIR. The samples were analyzed between wave numbers 4000 and 400 cm^{-1}.

RESULTS AND DISCUSSION:

DETERMINATION OF λ_{max} AND PREPARATION OF CALIBRATION CURVE OF PERAMPANEL

The Maximum wavelength of Perampanel was found to be 286 nm by using UV Visible Spectrophotometer. The regression coefficient was found to be 0.997 which indicates a linearity with an equation of Y = 0.0109x + 0.005. Hence beer - lamberts law was obeyed.

Table.8.1 Calibration curve data of Perampanelin pH 6.8 phosphate buffer at λ max of 286nm

Concentration (µg/mL)	Absorbance
0	0
10	0.117
20	0.224
30	0.336
40	0.439
50	0.546

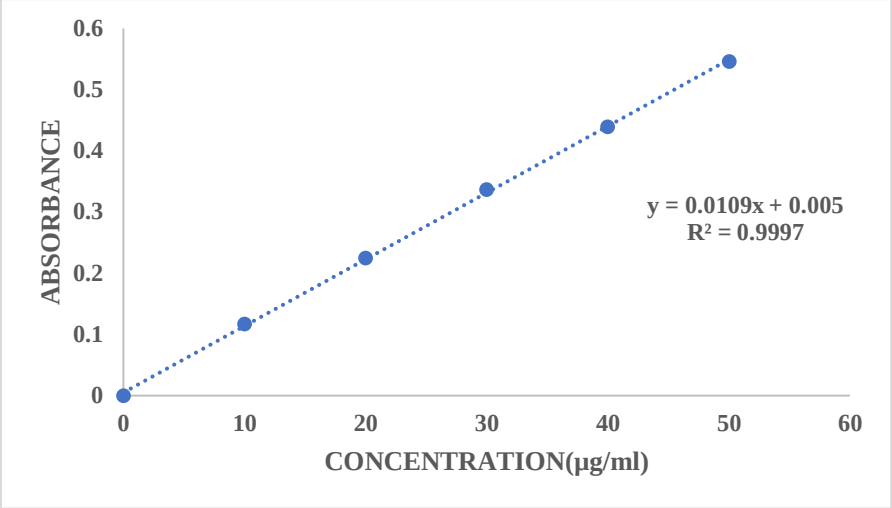


Fig: 8.1 calibration curve of Perampanel

EVALUATION OF PRE - COMPRESSION PARAMETERS OF POWDER BLEND

Table.8.2 Evaluation of pre-compression parameters of powder blend

Formulation	Bulk Density* (gm/cm^3)	Tapped density* (gm/cm^3)	Carr's index* (%)	Angle of Repose* (θ)	Hausner's ratio*
F 1	0.55	0.63	12.68	25.42	1.14
F2	0.53	0.62	14.51	26.77	1.16
F3	0.56	0.66	15.15	27.61	1.18
F4	0.54	0.65	16.92	25.25	1.20
F5	0.52	0.66	21.21	26.45	1.27
F6	0.56	0.65	13.85	26.5	1.16
F7	0.48	0.64	25	27.13	1.33
F8	0.57	0.67	14.93	25.4	1.18
F9	0.58	0.68	14.71	26.56	1.18

* Results are the mean of 3 observations ± SD

Bulk density

Both loose bulk density LBD and tapped bulk density results are shown in table 4 the loose bulk density and tapped bulk density for all the formulations varied from 0.48gm/cm3 to 0.58 gm/cm3 and 0.62 gm/cm3 to 0.68gm/cm3respectively. The values obtained lies within the acceptable range and not large differences found between loose bulk density and tapped density. This result helps in calculating the % compressibility of the powder.

Carr's Index:

The percent compressibility of powder mixture was determined by Carr's compressibility index. The table 6.4 Shows result obtained for percentage compressibility. The percent compressibility for all the nine formulations lies within the range of 12.68 to 25%. All formulations are showing good compressibility.

Hausner's ratio

Hausner ratio of the powder was determined from the loose bulk density and tapped bulk density. Hausner ratio of all the formulation lies within the acceptable range. The Hausner's ratio of all the formulations is in the range of 1.14 to 1.33.

Angle of repose (θ)

Table shows the results obtained for angle of reposes of all the formulations. The values were found to be in the range of 25.4 to 27.61. All formulations showed the angle of repose within 30^0. It indicates that all formulations showed good flow properties.

EVALUATIONS OF POST COMPRESSION PARAMETERS OF PERAMPANELMDTs

Table.8.3 Evaluation of post compression parameters of Perampanel Mouth dissolving tablet (I)

Formulation	Weight variation*	Thickness (mm)**	Hardness** Kg/cm^2	% Friability*	Drug content**
F1	98.34	1.88	2.15	0.27	98.35.
F2	99.48	1.95	2.11	0.44	99.46
F3	96.53	1.84	2.24	0.35	100.88
F4	101.66	1.93	2.17	0.41	97.73
F5	98.83	1.89	2.19	0.25	99.72
F6	99.62	1.91	2.21	0.39	97.64
F7	100.67	1.86	2.14	0.42	99.25
F8	100.39	1.97	2.22	0.28	99.12
F9	99.77s	1.87	2.18	0.33	98.08

* Results are the mean of 10 observations ± SD, **Results are the mean of 5 observations ± SD
**Results are the mean of 3 observations ± SD

- **Weight variation:** The percent weight variation for all the formulation is tabulated in Table. All the tablets passed weight variation test as the % variation was within the pharmacopoeia limit of ±10%. It was found to be from 96.53 mg to 100.67 mg. The weight of all the tablets was found to be uniform. This is due good flow property and compressibility of all the formulations**.**

- **Thickness:** The thickness of the tablets was measured by using Vernier caliper by picking the tablets randomly. The mean values are shown in table 5. The values are almost uniform in all formulations. Thickness was found in the range from 1.84mm to 1.97mm respectively. Uniformity in the values indicates that formulations were compressed without sticking to the dies and punches.

- **Hardness**: The results of hardness are given in table 5 Hardness test was performed by Monsanto hardness tester. Hardness was maintained to be within 2.11kg/cm2 to 2.24 kg/cm2. The lower standard deviation values indicated that the hardness of all the formulations were almost uniform and possess good mechanical strength with sufficient hardness.

- **Friability:** The results are tabulated in table 5 was found well within the approved range (<1%) in all the formulation. Friability was in between 0.25% to 0.44%. Results revealed that the tablets possess good mechanical strength.

- **Drug content:** The content uniformity was performed for all nine formulations and results are shown in table. Three trials from each formulation were analyzed spectrophotometrically. The mean value and standard deviation of all the formulations were calculated. The drug content of the tablets was found between 97.64 % and 100.88 % of Perampanel. The results indicated that in all the formulations the drug content was uniform.

***In vitro* disintegration time:** The internal structure of tablets that is pore size distribution, water penetration into tablets and swelling of disintegration substance are suggested to be the mechanism of disintegration. The results are shown in table this was determined as per I.P for all the formulations. All the formulations show disintegration time less than 60 seconds. Crospovidone has high water uptake and swelling pressure which leads to faster disintegration. Avicel 102 shows disintegration time in between and Croscarmellose sodium shows more disintegration time.

***In vitro* dissolution:**

Table. *In vitro* dissolution study of Perampanel MDT tablets

Time (Minutes)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
5	39.22	56.59	48.65	42.64	37.83	46.38	53.83	57.14	42.52
10	48.74	65.44	63.85	66.49	48.97	64.96	74.93	65.73	59.74

15	56.26	78.12	72.12	75.88	59.27	77.28	85.36	89.56	74.23
20	84.43	84.08	88.48	84.11	74.35	86.22	92.47	94.87	87.48
30	92.88	97.26	95.13	92.17	89.44	94.92	97.56	99.95	94.53

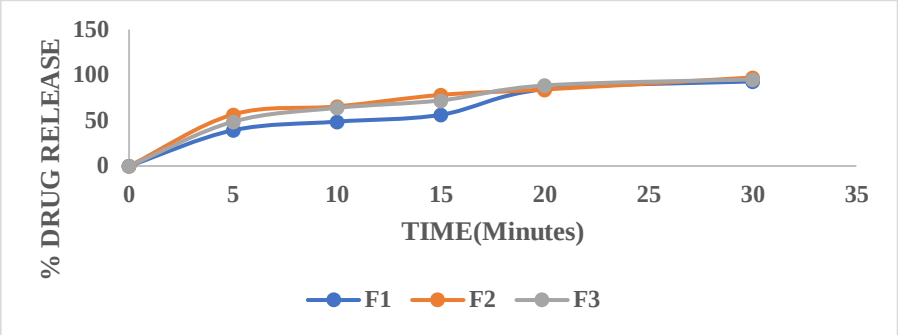


Figure 8.2: *In vitro* drug release of Perampanel MDT tablets containing Crospovidone (F1-F3)

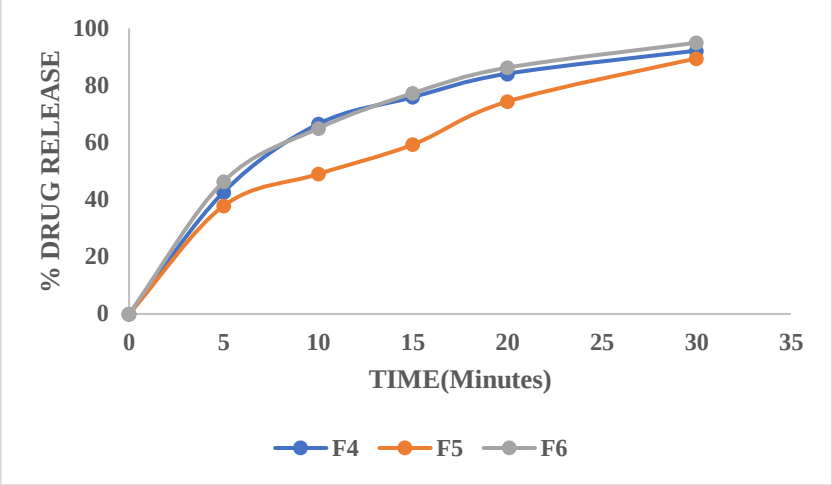


Figure 8.3: *In vitro* drug release of Perampanel MDT tablets containing Croscarmellose sodium (F4-F6)

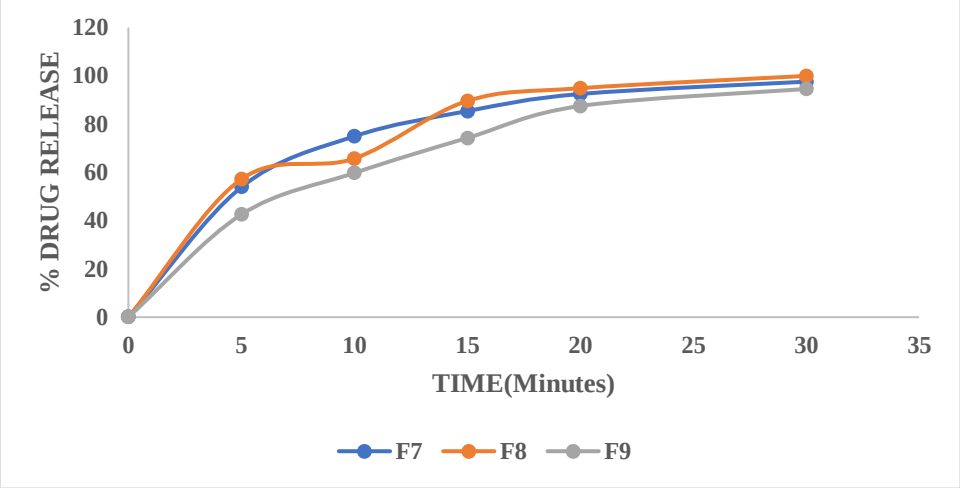


Figure 8.4: *In vitro* drug release of Perampanel MDT tablets containing Avicel 102 (F7-F9)

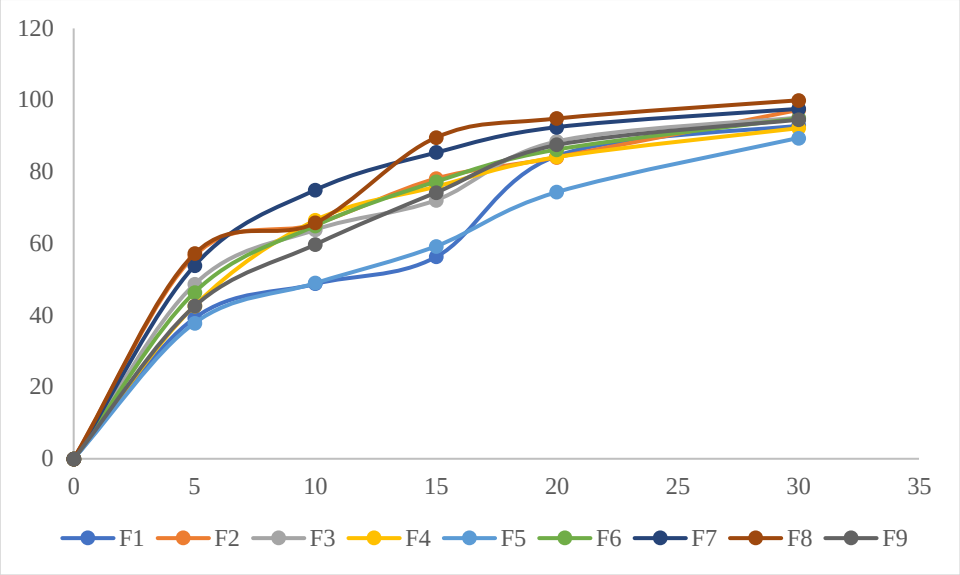


Figure 8.5: *In vitro* drug release of Perampanel MDT tablets for all formulations

From the above dissolution data, the rapid dissolution was observed in formulations F1, F2, F3, release 92.88%,97.26%,95.13, of drug respectively, at the end of 30 minutes and formulation F2 releases 97.26% at the end of 30minutes. formulations F4, F5 and F6 which shows drug release 92.17%,89.44%,94.92% drug respectively at the end of 30 min. F6 releases 94.92 % at the end of 30minutes. Formulations. Formulations F7, F8, F9 releases 97.56%, 99.95%,94.53% respectively at the end of 15 minutes. This rapid dissolution might be due to fast breakdown of particles and rapid absorption of drug. The drug release was completely achieved in a shorter duration of time. In all the formulations the drug release within 30minutes. High dissolution may occur due to faster breakdown.

Best optimized batch was F8because of lesser disintegration time and highest percentage drug release at the end of 30 min among all the formulations.

FTIR RESULTS:

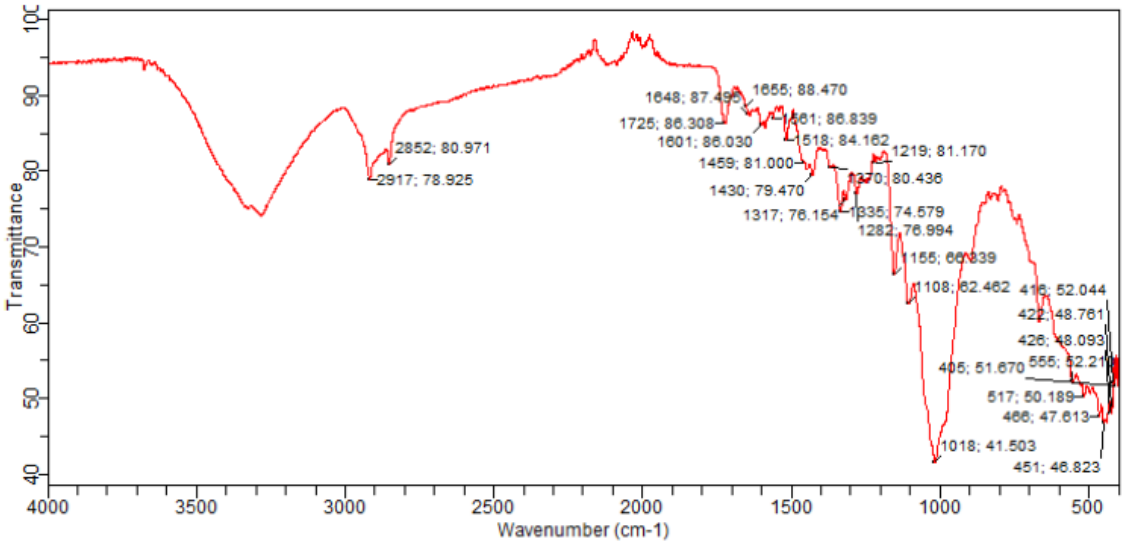


Figure 8.6: FT-IR of pure drug

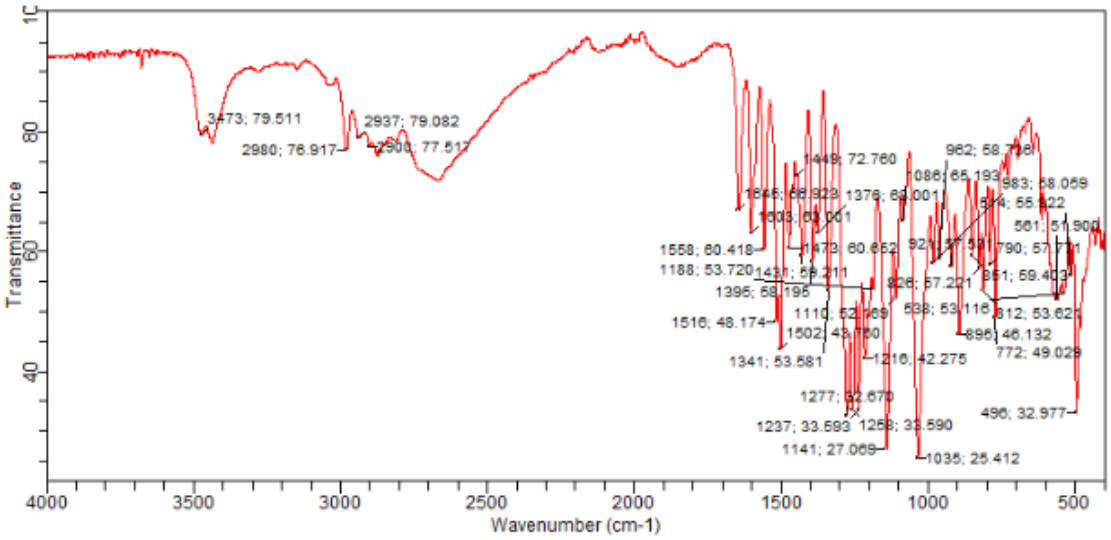


Figure 8.7: FTIR of optimised formula

There is no incompatibility of pure drug and excipients. There is no disappearence of peaks of pure drug and in optimised formulation.

CONCLUSION:

The present study on the formulation and evaluation of mouth dissolving tablets (MDTs) of Perampanel successfully demonstrated that the selection and optimization of super disintegrants and excipients play a critical role in achieving rapid disintegration and enhanced patient compliance.

Mouth dissolving tablets were formulated using super disintegrants such as Crospovidone, Croscarmellose sodium, and the directly compressible diluent Avicel PH 102. The prepared formulations were evaluated for pre-compression parameters (angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio) and post-compression parameters (hardness, friability, weight variation, thickness, drug content uniformity, wetting time, disintegration time, and in vitro dissolution studies).

The results indicated that all formulations showed acceptable flow properties and complied with pharmacopeial limits for physical evaluation tests. Among the super disintegrants used, formulations containing Crospovidone exhibited faster disintegration and enhanced drug release compared to those containing Croscarmellose sodium, owing to its high capillary activity and pronounced swelling without gelling. Avicel PH 102 contributed significantly to tablet hardness, compressibility, and overall mechanical strength while maintaining rapid disintegration.

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