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Synthesis and Evaluation of Fast-Dissolving Telmisartan Tablets

Randal Sir[1], Chavan Jyoti Shamrao[2], Ambhore Ritesh Konduba[3], Jondhale Sachin Vilas[4], Kale Rohit Kalyan[5]
Aditya Diploma Institute of Pharmacy Collage, Beed

Abstract: *Fast dissolving tablets are one of the important novel drug delivery systems designed to dissolve or disintegrate rapidly in the oral cavity without the need of water. This dosage form is especially useful for pediatric, geriatric, bedridden and dysphagic patients who have difficulty in swallowing conventional tablets and capsules. Telmisartan is an anti-hypertensive drug used in the management of high blood pressure. It belongs to the class of angiotensin II receptor blockers and is useful in reducing cardiovascular risk by controlling hypertension. However, Telmisartan is poorly soluble in water, which may affect its dissolution rate and bioavailability.*

The present project is based on the synthesis, formulation and evaluation of fast dissolving tablets of Telmisartan. The synthesis section includes a theoretical overview of the chemical synthesis of Telmisartan, including the formation of benzimidazole derivatives and coupling reactions involved in the preparation of the final drug molecule. The formulation part focuses on the preparation of fast dissolving tablets using the direct compression method. Superdisintegrants such as croscarmellose sodium, Doshion and sodium starch glycolate are used in different concentrations to improve tablet disintegration and drug release.

The prepared tablet formulations are evaluated for pre-compression and post-compression parameters such as angle of repose, bulk density, tapped density, Carr's index, Hausner's ratio, thickness, hardness, friability, weight variation, wetting time, disintegration time, drug content and in-vitro dissolution study.

The results suggest that fast dissolving tablets of Telmisartan can provide rapid drug release, improved patient compliance, faster onset of action and better therapeutic effectiveness in the management of hypertension. Therefore, Telmisartan fast dissolving tablets may serve as a suitable alternative to conventional oral tablets.

Keywords: Telmisartan, Fast Dissolving Tablets, Synthesis, Formulation, Evaluation, Superdisintegrants, Direct Compression, Hypertension.

I. INTRODUCTION

Oral drug delivery is the most widely used and preferred route of drug administration because of its convenience, low cost, patient acceptance and ease of manufacturing. Tablets and capsules are commonly used solid dosage forms because they provide accurate dose, good stability and easy handling. However, some patients experience difficulty in swallowing conventional tablets and capsules. This problem is commonly observed in pediatric patients, geriatric patients, mentally ill patients, bedridden patients and patients suffering from dysphagia.

To overcome these problems, fast dissolving tablets were developed. Fast dissolving tablets are solid dosage forms that disintegrate or dissolve rapidly in the mouth within a short period of time, generally without the need of water. These tablets are designed to release the drug quickly after coming in contact with saliva. They are also known as orally disintegrating tablets, mouth dissolving tablets, quick dissolving tablets, rapid disintegrating tablets and orodispersible tablets.

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Fast dissolving tablets are useful when rapid onset of action is required. In patients with sudden rise in blood pressure, rapid drug action is important. Telmisartan is an anti-hypertensive drug used for the treatment of hypertension. It belongs to the class of angiotensin II receptor blockers. Telmisartan blocks the action of angiotensin II at AT1 receptors, resulting in relaxation of blood vessels and reduction in blood pressure.

Telmisartan is poorly soluble in water. Due to poor solubility, the drug may dissolve slowly in the gastrointestinal tract, which can reduce its bioavailability. Therefore, formulating Telmisartan as a fast dissolving tablet can improve its dissolution rate and may enhance its therapeutic effect.

II. HYPERTENSION

Hypertension is a chronic medical condition in which the blood pressure in the arteries remains persistently elevated. It is one of the major risk factors for cardiovascular diseases such as heart attack, stroke, kidney failure and heart failure. Hypertension is often called a silent killer because many patients do not show symptoms in early stages.

The treatment of hypertension requires long-term medication and patient compliance. If the dosage form is convenient and easy to take, patient compliance can be improved. Fast dissolving tablets are helpful because they can be taken without water and are suitable for patients who have swallowing difficulty.

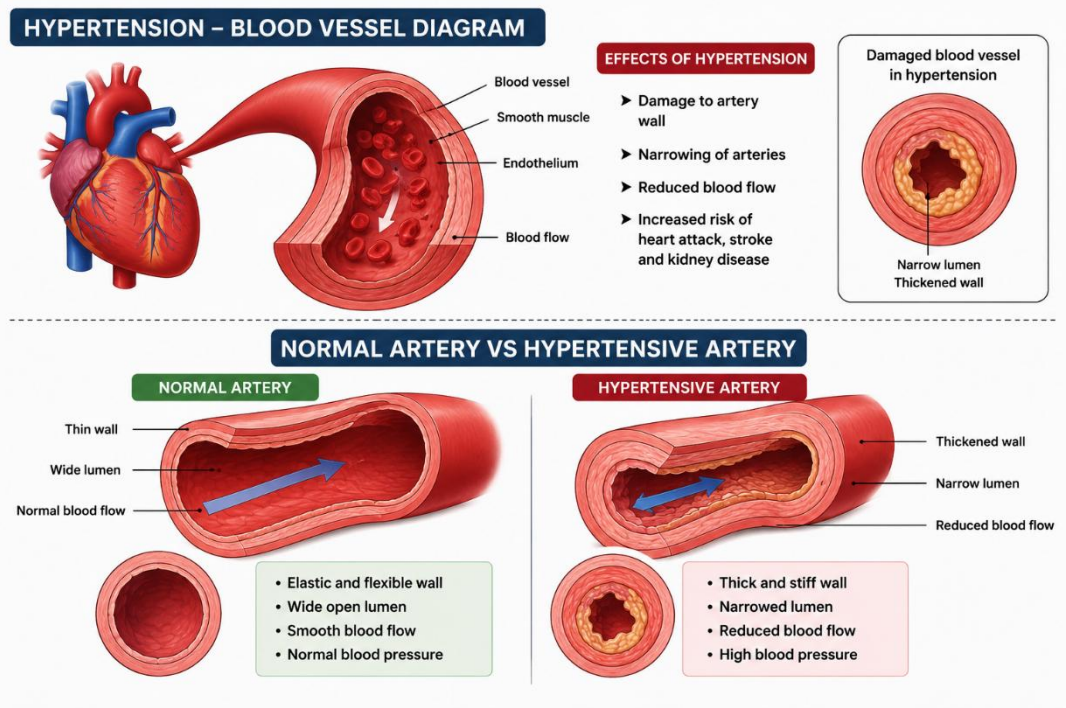

Fig. No. 1: Hypertension blood vessel diagram & Normal artery vs hypertensive artery image

III. TELMISARTAN

Telmisartan is an angiotensin II receptor blocker used in the treatment of hypertension. It selectively blocks the angiotensin II type 1 receptor. Angiotensin II is responsible for vasoconstriction and aldosterone secretion. By blocking this receptor, Telmisartan causes vasodilation and helps reduce blood pressure.

Telmisartan has poor aqueous solubility, which creates a challenge in formulation development. Poor water solubility can reduce dissolution rate and delay absorption. To improve drug release, fast dissolving tablets are prepared with suitable superdisintegrants.

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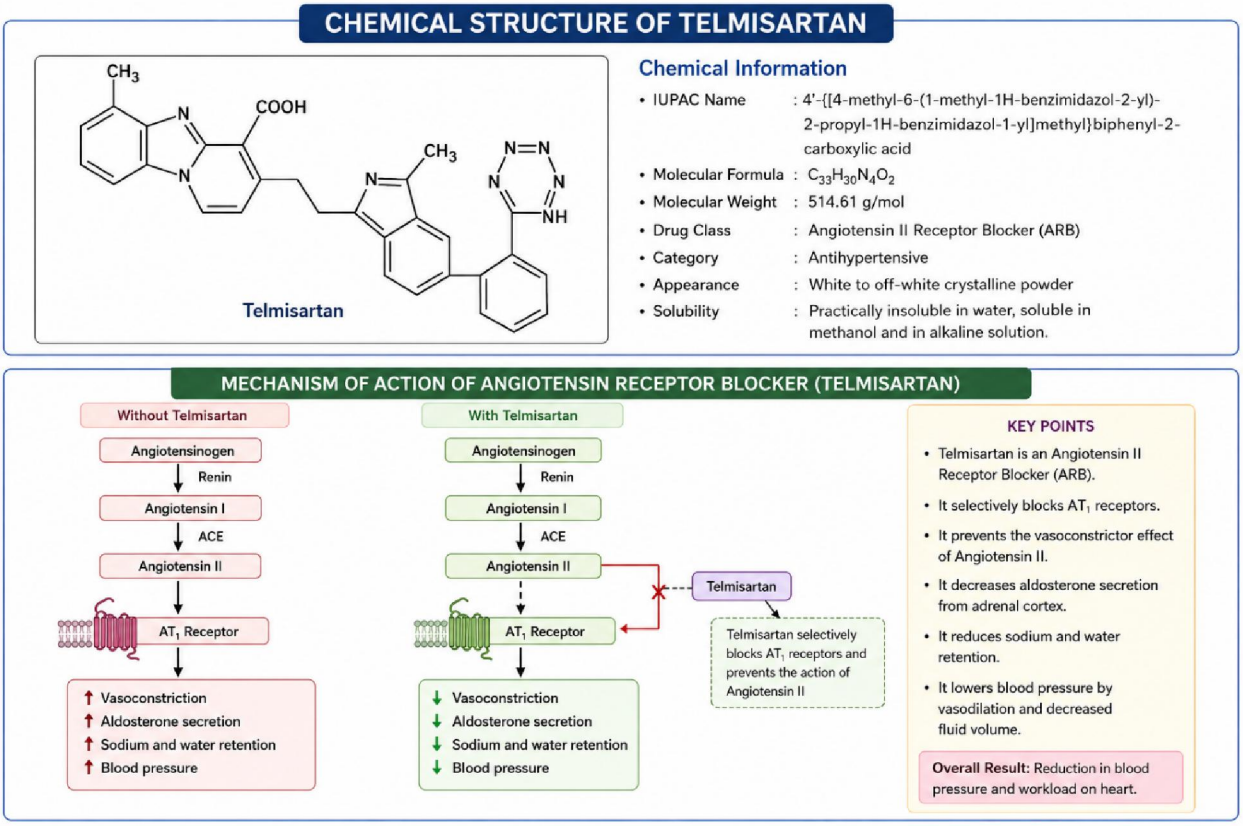

Fig. No. 2: Chemical structure of Telmisartan & Mechanism of action of angiotensin receptor blocker

IV. FAST DISSOLVING TABLETS

Fast dissolving tablets are designed to disintegrate rapidly in the oral cavity. When the tablet comes in contact with saliva, it breaks into smaller particles and releases the drug. The drug may then be absorbed through the oral mucosa or swallowed with saliva and absorbed from the gastrointestinal tract.

A fast dissolving tablet should have:

- rapid disintegration
- pleasant taste
- sufficient mechanical strength
- good stability
- accurate dose
- easy manufacturing process

The European Pharmacopoeia uses the term orodispersible tablet for tablets that disperse rapidly in the mouth before swallowing. These tablets are especially useful for patients who cannot swallow conventional tablets easily.

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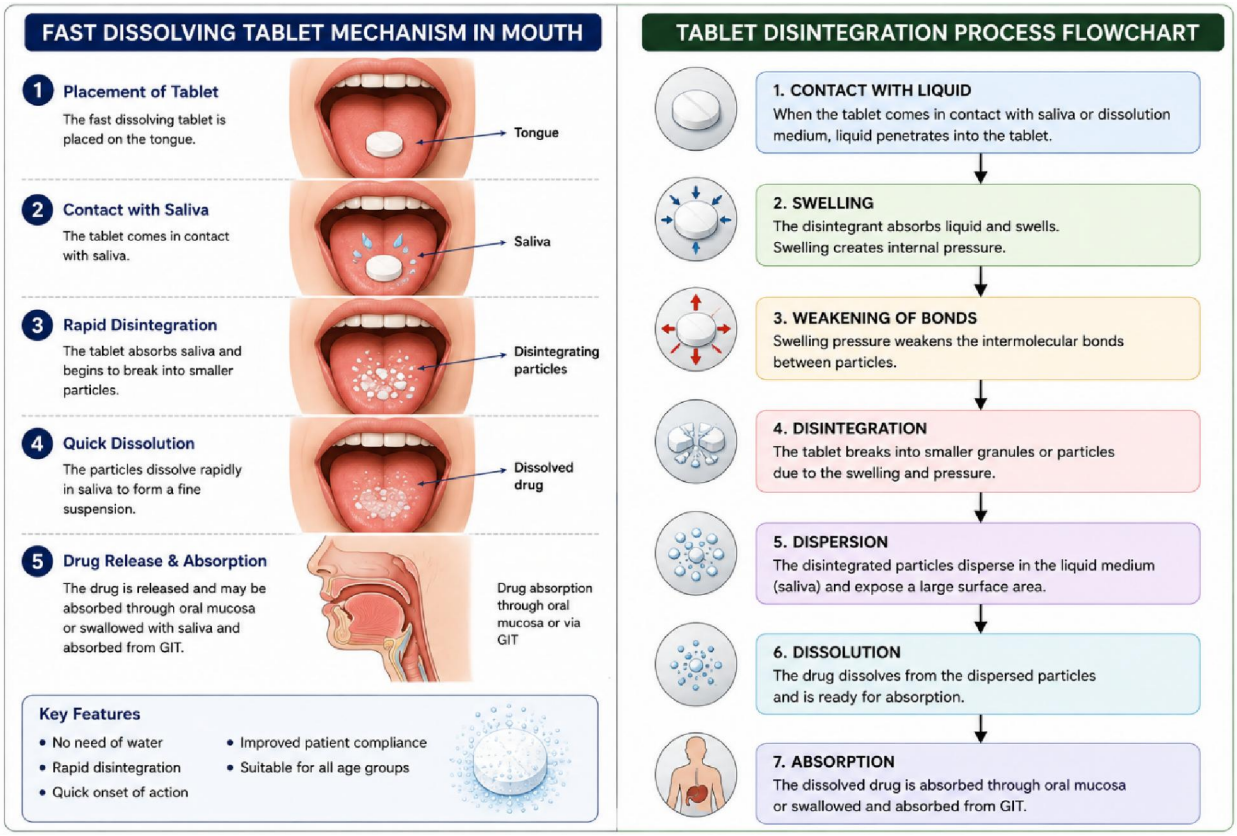

Fig. No. 3: Fast dissolving tablet mechanism in mouth & Tablet disintegration process flowchart

V. ADVANTAGES OF FAST DISSOLVING TABLETS

1. They can be taken without water.
2. They are suitable for pediatric and geriatric patients.
3. They provide faster onset of action.
4. They improve patient compliance.
5. They are useful during travel.
6. They reduce difficulty in swallowing.
7. They may improve bioavailability for some drugs.
8. They are easy to administer.
9. They provide accurate dosing compared to liquid dosage forms.
10. They are useful for emergency conditions where rapid action is required.

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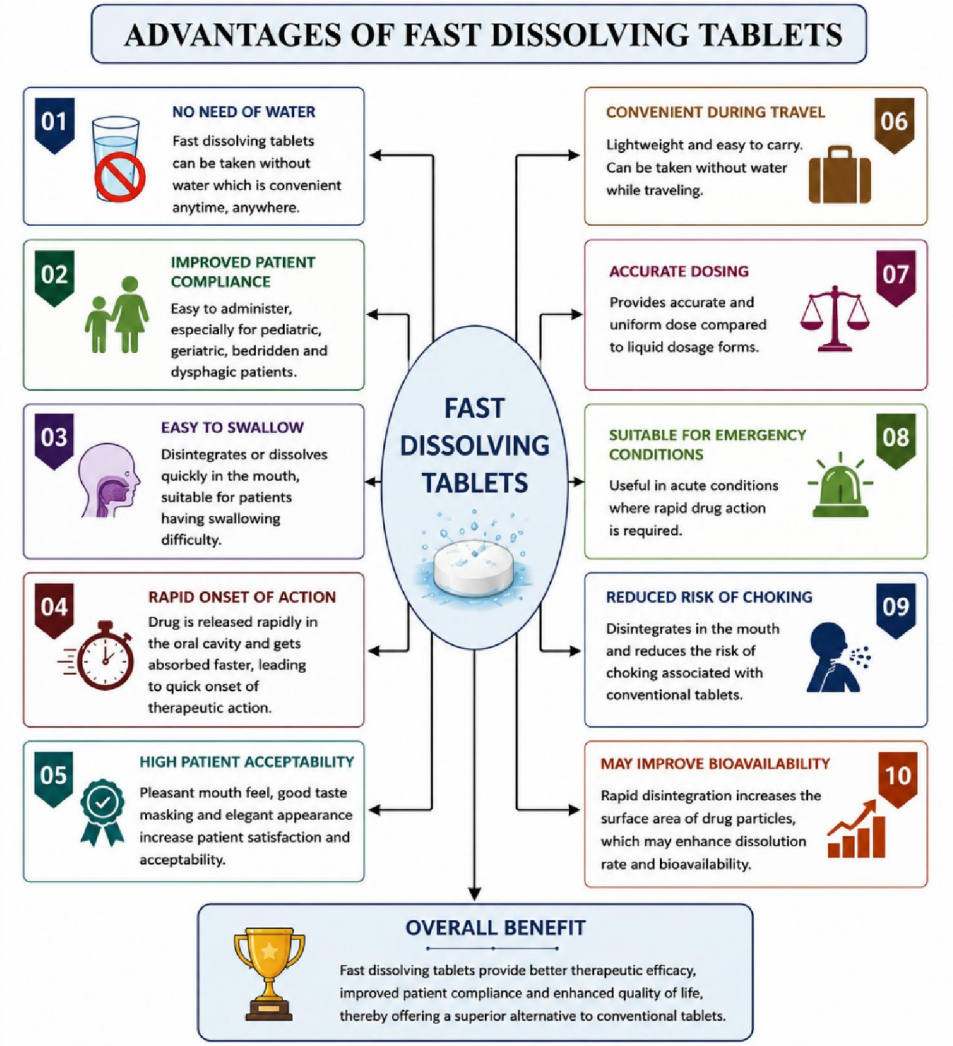

Fig. No. 4: Advantages of fast dissolving tablets flowchart

VI. AIM AND OBJECTIVES

Aim

The aim of the present project is to study the synthesis, formulation and evaluation of fast dissolving tablets of Telmisartan for improving dissolution rate, rapid disintegration and patient compliance.

Objectives

1. To study the drug profile and pharmacological action of Telmisartan.
2. To describe the theoretical synthesis pathway of Telmisartan.
3. To formulate fast dissolving tablets of Telmisartan using direct compression method.
4. To use superdisintegrants such as croscarmellose sodium, Doshion and sodium starch glycolate.
5. To evaluate pre-compression parameters of powder blend.
6. To evaluate post-compression parameters of prepared tablets.
7. To perform in-vitro disintegration and dissolution studies.
8. To compare different formulations and select the optimized batch.

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9. To study stability of optimized formulation.
10. To prepare a patient-friendly dosage form of Telmisartan.

VII. LITERATURE REVIEW

Literature review is an important part of formulation development because it provides information regarding previous research work carried out on the drug and dosage form. Various researchers have developed fast dissolving tablets using different methods and superdisintegrants to improve dissolution rate, disintegration time and patient compliance. The following studies were reviewed for the present project work.

1. Seager H. (1998)

Seager H. reported that fast dissolving drug delivery systems provide rapid disintegration and improved patient compliance. The study explained the advantages of orally disintegrating tablets in pediatric and geriatric patients. It was concluded that fast dissolving tablets improve convenience of administration and rapid onset of action.

The study also highlighted that orally disintegrating tablets can be prepared using specialized technologies to achieve quick tablet disintegration within seconds in the oral cavity.

2. Bradoo R., Shahani S. and Poojary S. (2001)

Bradoo and co-workers reviewed the importance of fast dissolving drug delivery systems in modern pharmaceutics. They explained that difficulty in swallowing conventional tablets is one of the major reasons for poor patient compliance.

The researchers concluded that fast dissolving tablets are useful for:

- pediatric patients
- geriatric patients
- bedridden patients
- mentally ill patients
- dysphagic patients

The study emphasized that fast dissolving tablets improve patient convenience and reduce administration problems associated with conventional oral dosage forms.

3. Indurwade N.H. et al. (2002)

Indurwade and co-workers studied various approaches used for the preparation of fast dissolving tablets. They explained different technologies such as:

- direct compression
- freeze drying
- sublimation
- molding method
- spray drying

The study reported that direct compression is one of the easiest and most economical methods for preparing fast dissolving tablets because it requires less processing steps and provides better scalability.

The researchers also explained the role of superdisintegrants in improving tablet disintegration and dissolution rate.

4. Ghosh T.K. and Pfister W.R. (2005)

Ghosh and Pfister studied intraoral drug delivery systems and explained that oral cavity drug delivery can improve therapeutic effectiveness and patient convenience.

The study discussed:

- buccal drug delivery
- sublingual drug delivery

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- oral cavity absorption
- rapid drug action

The authors concluded that fast dissolving tablets can improve drug absorption and patient compliance because they dissolve rapidly in saliva without water.

5. Yarwood R. (1990)

Yarwood reported the development of Zydis technology for fast dissolving dosage forms. The study explained that fast dissolving tablets are designed to disintegrate rapidly in the oral cavity and provide quick drug release.

The author concluded that fast dissolving dosage forms are useful in improving patient acceptability and therapeutic efficiency.

6. Allen L.V. and Wang B. (1996)

Allen and Wang studied methods for preparing rapidly dissolving tablets using particulate support matrices. The study explained that porous tablet structures help improve penetration of saliva into tablets, resulting in rapid tablet disintegration.

The researchers concluded that porous structures improve wetting and disintegration properties of tablets.

7. Allen L.V. and Wang B. (1997)

In another study, Allen and Wang developed methods for manufacturing rapidly dissolving tablets. They explained that rapidly dissolving tablets should possess:

- sufficient mechanical strength
- rapid disintegration
- acceptable taste
- rapid drug release

The study concluded that formulation variables and processing conditions significantly affect the quality of fast dissolving tablets.

8. Heinmann H. and Rothe W. (1975)

Heinmann and Rothe studied porous tablet preparation methods. The researchers concluded that highly porous tablets disintegrate rapidly because saliva can easily penetrate the tablet matrix.

The study highlighted the importance of tablet porosity in fast dissolving tablet formulations.

9. Shirwaikar A.A. and Ramesh A. (2004)

Shirwaikar and Ramesh prepared fast disintegrating tablets by dry granulation method. They evaluated:

- hardness
- friability
- disintegration time
- dissolution rate

The study concluded that the use of suitable superdisintegrants significantly improves tablet disintegration and dissolution properties.

10. Chauhan K., Parashar B., Chandel A. and Thakur V. (2013)

Chauhan and co-workers formulated and evaluated fast dissolving tablets of Telmisartan using direct compression method. In this study, superdisintegrants such as:

- croscarmellose sodium
- Doshion

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- sodium starch glycolate

were used in different concentrations.

The tablets were evaluated for:

- weight variation
- hardness
- friability
- wetting time
- disintegration time
- dissolution study
- stability study

The study concluded that fast dissolving tablets of Telmisartan showed improved dissolution rate and better drug release. The optimized formulation showed satisfactory stability and rapid disintegration.

The researchers also reported that direct compression method is simple, economical and suitable for large scale manufacturing of fast dissolving tablets.

VIII. MATERIALS AND METHOD

Materials: -

Telmisartan was used as the active pharmaceutical ingredient in the present study. Microcrystalline Cellulose was used as diluent and binder. Croscarmellose Sodium, Doshion, and Sodium Starch Glycolate were used as superdisintegrants for improving tablet disintegration and dissolution rate. Mannitol was used as sweetening and diluent agent to provide pleasant mouth feel. Sodium Lauryl Sulphate was used as surfactant for improving wetting and solubility of the drug. Magnesium Stearate was used as lubricant to reduce friction during compression. Menthol was used as flavoring agent to improve patient acceptability.

All the chemicals and reagents used in the study were of analytical grade.

Method: -

The formulation of fast dissolving tablets of Telmisartan was carried out using the direct compression method. All the required ingredients were accurately weighed and passed through sieve no. 60 to obtain uniform particle size. The drug and excipients were thoroughly mixed to obtain a homogeneous powder blend.

The blend was lubricated using Magnesium Stearate and Menthol to improve flow properties and prevent sticking during compression. The final powder blend was compressed into tablets using a tablet compression machine.

The prepared tablets were further evaluated for various physicochemical parameters such as hardness, friability, weight variation, wetting time, disintegration time and in-vitro drug release study.

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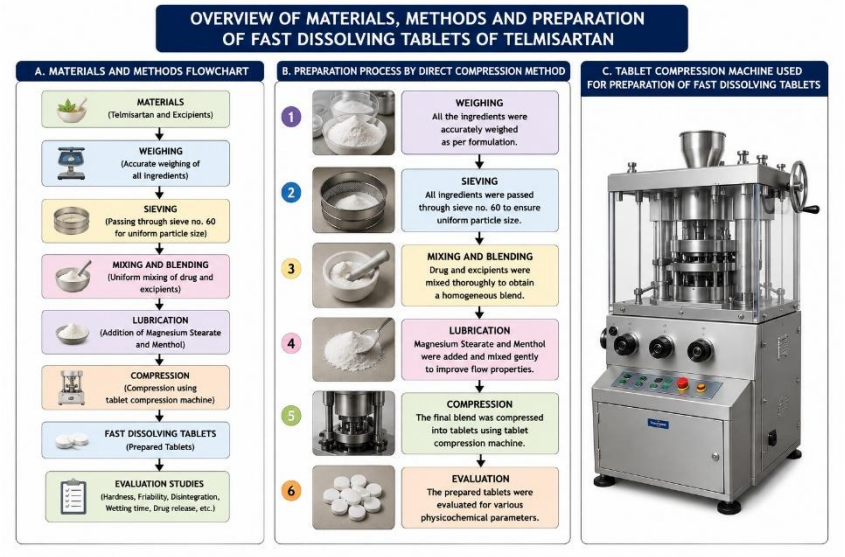

Fig. No. 5: Flowchart and Preparation Process of Fast Dissolving Tablets of Telmisartan

IX. INGREDIENTS AND FORMULATIONS

Ingredients

The formulation of fast dissolving tablets of Telmisartan was carried out using various pharmaceutical excipients selected based on their functional properties.

Telmisartan was used as the active pharmaceutical ingredient (API) due to its effectiveness in the treatment of hypertension and cardiovascular disorders.

Microcrystalline Cellulose (MCC) was used as a diluent and binder to improve compressibility and provide mechanical strength to tablets.

Croscarmellose Sodium, Doshion, and Sodium Starch Glycolate were used as superdisintegrants to enhance rapid tablet disintegration and improve drug release.

Mannitol was used as a diluent and sweetening agent to improve mouth feel and provide a pleasant taste.

Sodium Lauryl Sulphate (SLS) was used as a surfactant to improve wetting property and increase dissolution rate of Telmisartan.

Magnesium Stearate was used as a lubricant to reduce friction during tablet compression and improve tablet ejection.

Menthol was used as a flavoring agent to improve patient acceptability and provide cooling sensation.
All the excipients used in the study were of analytical grade and were compatible with the drug.

Formulations

Different formulations of fast dissolving tablets were prepared by varying the concentration of superdisintegrants to study their effect on tablet disintegration and drug release behavior.

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The formulations were prepared using different concentrations of:

- Croscarmellose Sodium
- Doshion
- Sodium Starch Glycolate

A total of nine formulations (F1–F9) were prepared and evaluated for:

- hardness
- friability
- wetting time
- disintegration time
- drug release study

The formulations F1 to F3 contained Croscarmellose Sodium in increasing concentrations.
The formulations F4 to F6 contained Doshion in different concentrations.
The formulations F7 to F9 contained Sodium Starch Glycolate in varying concentrations.
Among all formulations, the optimized formulation showed:

- rapid tablet disintegration
- improved wetting time
- acceptable hardness
- lower friability
- enhanced drug release behavior

Thus, the concentration of superdisintegrants plays an important role in determining the performance of fast dissolving tablets of Telmisartan.

Table: Composition of Fast Dissolving Tablets of Telmisartan

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Telmisartan	10	10	10	10	10	10	10	10	10
Microcrystalline Cellulose	50	50	50	50	50	50	50	50	50
Croscarmellose Sodium	2.5	3.75	5	-	-	-	-	-	-
Doshion	-	-	-	2.5	3.75	5	-	-	-
Sodium Starch Glycolate	-	-	-	-	-	-	2.5	3.75	5
Sodium Lauryl Sulphate	1	1	1	1	1	1	1	1	1
Menthol	2	2	2	2	2	2	2	2	2
Magnesium Stearate	3	3	3	3	3	3	3	3	3
Mannitol	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s

X. METHODS AND PREPARATION

Fast dissolving tablets of Telmisartan were prepared by direct compression method. Direct compression is one of the simplest and most economical methods used for tablet manufacturing. This method requires fewer processing steps and is suitable for moisture sensitive and heat sensitive drugs.

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In the present study, superdisintegrants such as Croscarmellose Sodium, Doshion and Sodium Starch Glycolate were used in different concentrations to improve tablet disintegration and drug release.
The prepared formulations were compressed into tablets and evaluated for various physicochemical parameters.

Method Used

Direct Compression Method

Direct compression method involves direct mixing and compression of powdered ingredients without granulation process.

The method mainly includes:

- weighing of ingredients
- sieving
- mixing and blending
- lubrication
- compression

Advantages of direct compression method:

- simple process
- economical manufacturing
- less processing time
- suitable for heat sensitive drugs
- better stability
- easy large scale production

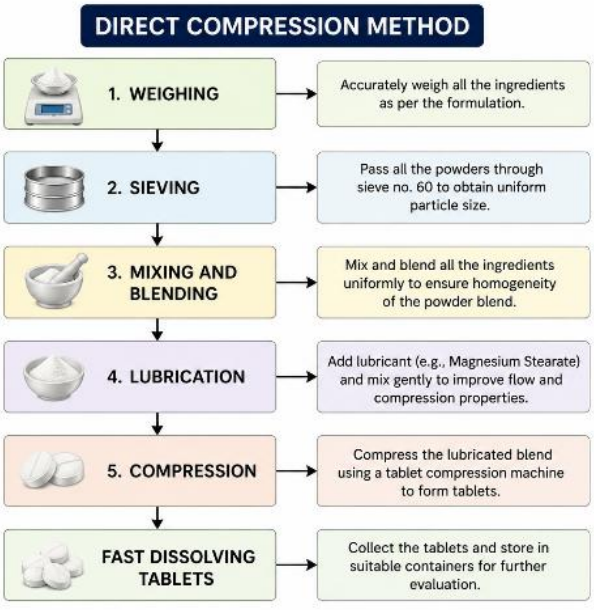

Fig. No. 6: Direct compression method flowchart

Procedure for Preparation of Fast Dissolving Tablets

Step 1: Weighing of Ingredients

All the ingredients required for formulation were accurately weighed according to formulation table using digital weighing balance.

Ingredients weighed included:

- Telmisartan

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- Microcrystalline Cellulose
- Croscarmellose Sodium
- Doshion
- Sodium Starch Glycolate
- Mannitol
- Sodium Lauryl Sulphate
- Magnesium Stearate
- Menthol

Proper weighing ensures uniformity of formulation and accurate drug content.

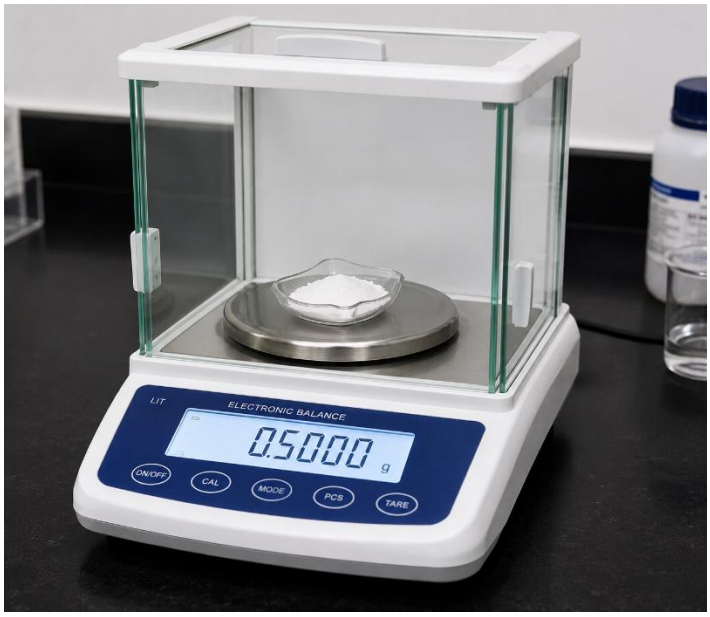

Fig. No. 7: Digital weighing balance image

Step 2: Sieving

All ingredients were passed through sieve no. 60 separately to obtain uniform particle size and remove lumps.

Sieving improves:

- powder flow property
- blending efficiency
- uniformity of powder mixture

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Fig. No. 8: Pharmaceutical sieving process

Step 3: Mixing and Blending

The accurately weighed ingredients were mixed thoroughly using mortar and pestle to obtain homogeneous powder blend.

The drug and excipients were blended uniformly to ensure proper distribution of active pharmaceutical ingredient throughout the formulation.

Fig. No. 9: Powder mixing and blending process

Step 4: Lubrication

Magnesium Stearate and Menthol were added at the final stage and mixed gently with powder blend.

Lubrication helps:

- reduce friction during compression
- improve tablet ejection
- prevent sticking to punches and dies

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Fig. No. 1: Lubrication process in tablet preparation

Step 5: Compression

The lubricated powder blend was compressed into tablets using tablet compression machine.

The compression process was carried out using suitable punch and die arrangement to obtain tablets of uniform size and shape.

The prepared tablets were collected and stored in airtight containers for further evaluation studies.

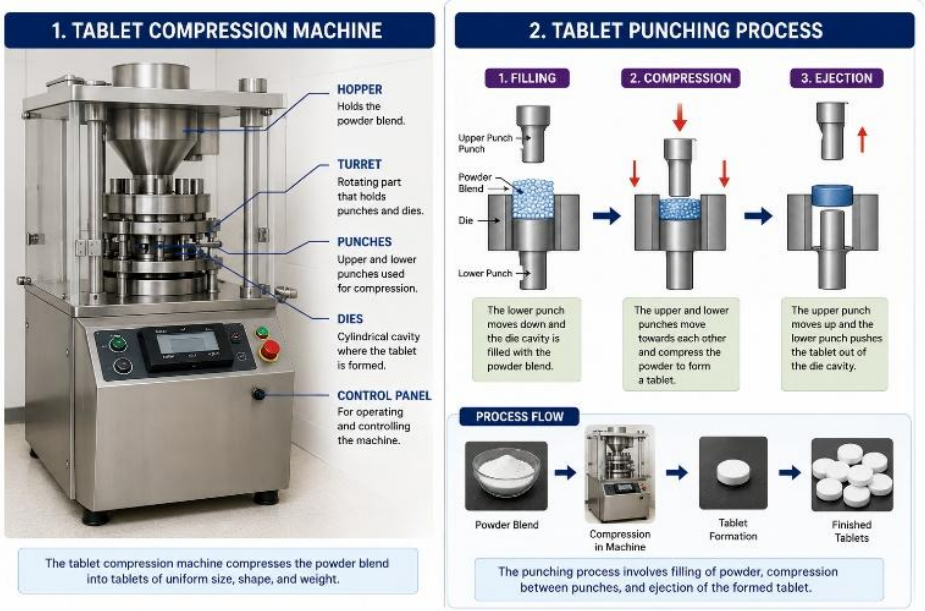

Fig. No. 10: Tablet compression machine & Tablet punching process

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XI. FLOWCHART OF PREPARATION METHOD

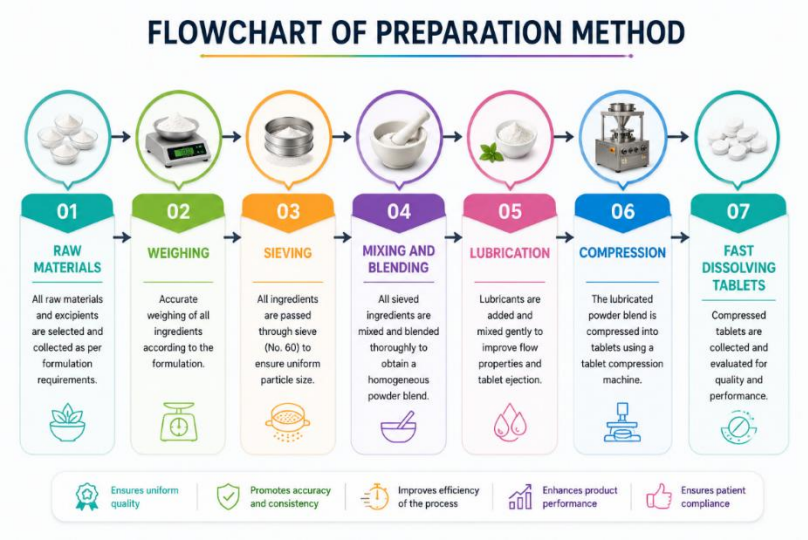

Fig. No. 11: Flowchart of Preparation Method

Characteristics of Prepared Tablets

The prepared tablets were:

- smooth in appearance
- uniform in shape
- mechanically stable
- rapidly disintegrating

The tablets showed good mouth feel and rapid dispersion in saliva.

Storage of Prepared Tablets

The prepared tablets were stored in airtight containers at room temperature and protected from moisture and direct sunlight until further evaluation studies were carried out.

Fig. No. 12: Tablet compression machine & Powder blending process

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XII. RESULT AND DISCUSSION

The prepared fast dissolving tablets of Telmisartan were evaluated for various pre-compression and post-compression parameters to determine the quality, mechanical strength, disintegration behavior and drug release characteristics of the formulations.

Different formulations containing various concentrations of superdisintegrants were prepared and compared to identify the optimized formulation showing rapid disintegration and better dissolution profile.

XIII. PRE-COMPRESSION PARAMETERS

The powder blends prepared for tablet compression were evaluated for angle of repose, bulk density, tapped density, Carr's index and Hausner's ratio.

The angle of repose values of all formulations were found within acceptable limits, indicating good flow property of powder blends. Bulk density and tapped density values showed good packing characteristics and compressibility behavior.

Carr's index and Hausner's ratio values indicated satisfactory flowability and suitability of powder blend for direct compression method.

The results confirmed that all powder blends possessed adequate flow properties for tablet compression.

Table: Pre-Compression Parameters

Formulation	Angle of Repose (°)	Bulk Density (g/ml)	Tapped Density (g/ml)	Carr's Index (%)	Hausner Ratio
F1	24.5	0.42	0.48	12.5	1.14
F2	25.1	0.43	0.49	12.2	1.13
F3	24.8	0.44	0.50	12.0	1.13
F4	25.5	0.41	0.47	12.7	1.15
F5	24.9	0.43	0.48	10.4	1.11
F6	25.0	0.42	0.49	14.2	1.16
F7	24.6	0.44	0.50	12.0	1.13
F8	25.2	0.43	0.49	12.2	1.13
F9	24.7	0.42	0.48	12.5	1.14

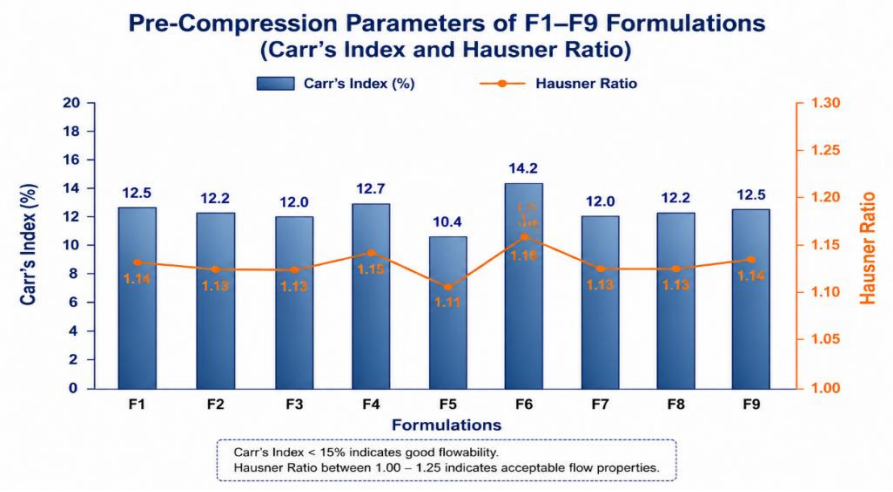

Fig. No. 13: Comparative Pre-Compression Parameter Graph of F1–F9 Formulations

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XIV. POST-COMPRESSION PARAMETERS

The prepared tablets were evaluated for thickness, hardness, friability, weight variation, wetting time and disintegration time. The thickness of all formulations was found uniform, indicating proper compression process. Hardness values showed adequate mechanical strength to withstand handling and transportation. Friability values of all formulations were found below 1%, indicating good mechanical resistance of tablets. Wetting time and disintegration time decreased with increase in concentration of superdisintegrants. Formulations containing higher concentration of superdisintegrants showed rapid tablet disintegration and improved wetting characteristics.

Among all formulations, F3 and F9 exhibited faster disintegration and improved tablet performance.

Table: Post-Compression Parameters

Formulation	Thickness (mm)	Hardness (kg/cm²)	Friability (%)	Wetting Time (sec)	Disintegration Time (sec)
F1	3.2	3.1	0.52	38	42
F2	3.3	3.0	0.48	36	39
F3	3.1	3.2	0.45	32	34
F4	3.2	3.0	0.50	40	44
F5	3.1	3.1	0.47	35	38
F6	3.2	3.0	0.46	31	33
F7	3.3	3.1	0.49	39	41
F8	3.2	3.2	0.45	34	37
F9	3.1	3.1	0.44	30	32

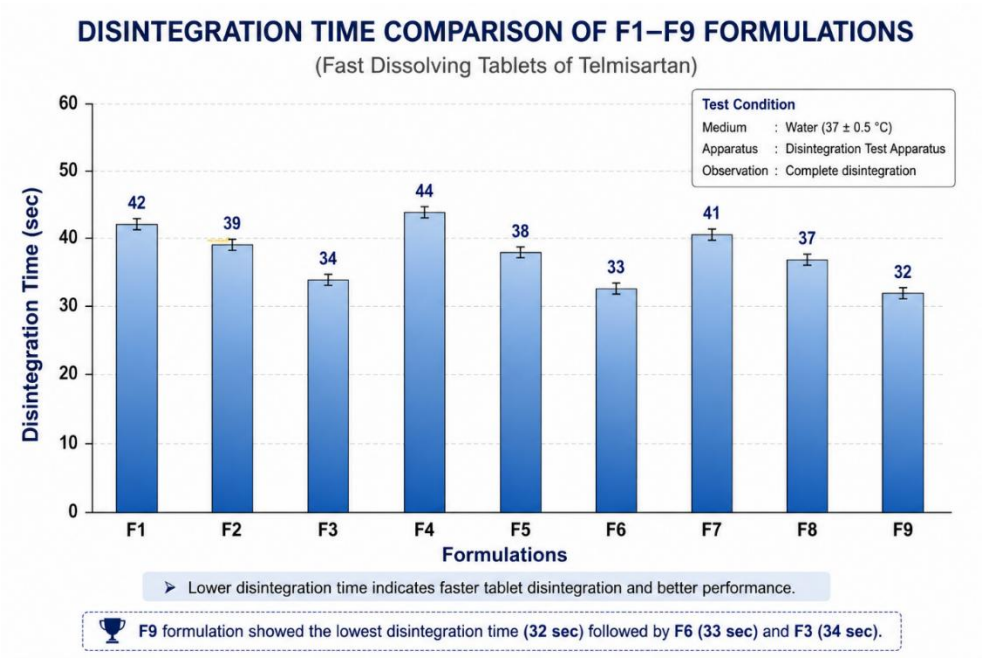

Fig. No. 14: Comparative Disintegration Time Study of F1–F9 Fast Dissolving Tablet Formulations

XV. IN-VITRO DRUG RELEASE STUDY

The in-vitro dissolution study was carried out using USP dissolution apparatus type II in phosphate buffer pH 6.8. The dissolution study indicated rapid drug release from all formulations due to presence of superdisintegrants.

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The formulations containing higher concentrations of superdisintegrants exhibited faster drug release compared to lower concentrations.

Among all formulations, F3 and F9 showed maximum drug release within 25 minutes due to rapid swelling and improved tablet disintegration.

The study confirmed that fast dissolving tablets significantly improved dissolution rate of Telmisartan.

Table: In-Vitro Drug Release Study

Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
5	28	31	35	26	30	34	27	29	33
10	45	50	58	43	48	56	44	47	55
15	62	68	76	60	66	74	61	65	73
20	78	84	92	76	82	90	77	81	89
25	89	94	99	87	92	98	88	91	97

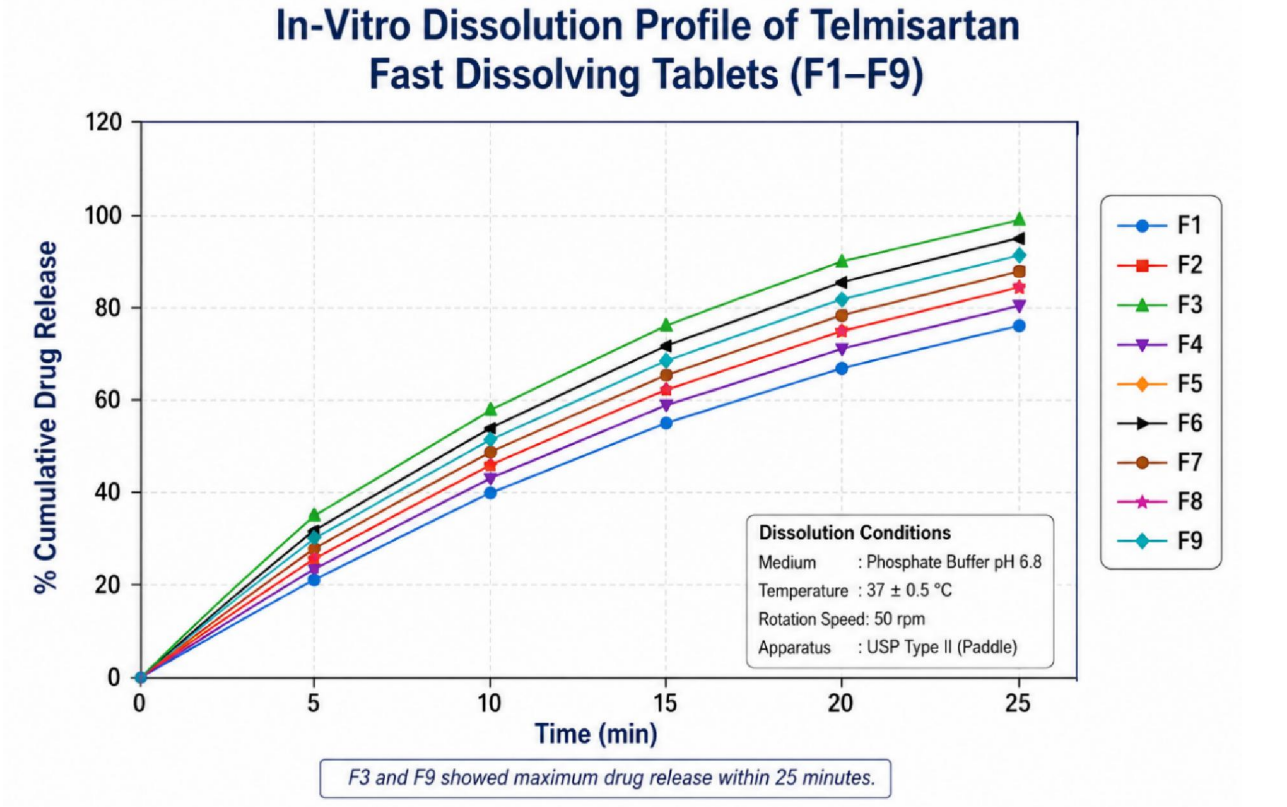

Fig. No. 15: In-Vitro Dissolution Profile of Fast Dissolving Tablets of Telmisartan (F1–F9)

Discussion

The results obtained from the study indicated that direct compression method was suitable for preparation of fast dissolving tablets of Telmisartan.

All formulations showed satisfactory pre-compression and post-compression properties. The tablets possessed acceptable hardness, low friability and uniform weight variation.

The presence of superdisintegrants significantly improved wetting and disintegration characteristics of tablets. Rapid tablet disintegration increased surface area exposure and enhanced dissolution rate of Telmisartan.

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Among all formulations, F3 and F9 showed better performance due to efficient swelling and water absorption characteristics of superdisintegrants.

The study confirmed that fast dissolving tablets of Telmisartan can improve patient compliance, rapid onset of action and dissolution characteristics.

XVI. CONCLUSION

The present study was successfully carried out to formulate and evaluate fast dissolving tablets of Telmisartan by direct compression method using different superdisintegrants.

Fast dissolving tablets were prepared using Croscarmellose Sodium, Doshion and Sodium Starch Glycolate in varying concentrations to improve tablet disintegration and dissolution characteristics.

The prepared formulations were evaluated for various pre-compression and post-compression parameters such as angle of repose, bulk density, tapped density, Carr's index, Hausner's ratio, hardness, friability, wetting time, disintegration time and in-vitro drug release study.

The results of pre-compression studies indicated good flow properties and compressibility behavior of powder blends suitable for direct compression method.

The prepared tablets showed acceptable hardness, low friability and uniform tablet weight, indicating satisfactory mechanical strength and stability.

The formulations containing higher concentrations of superdisintegrants exhibited rapid wetting and faster disintegration due to improved swelling and water absorption properties.

The in-vitro dissolution study demonstrated enhanced drug release profile of Telmisartan fast dissolving tablets. Among all formulations, F3 and F9 showed better drug release and rapid disintegration behavior compared to other formulations.

Thus, the study confirmed that fast dissolving tablets of Telmisartan can improve dissolution rate, rapid onset of action and patient compliance.

The direct compression method was found to be simple, economical and effective for preparation of fast dissolving tablets.

The developed formulation may provide better therapeutic effectiveness and improved patient acceptability in the treatment of hypertension.

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