Available online on 15.04.2026 at http://ajprd.com

Asian Journal of Pharmaceutical Research and Development

Open Access to Pharmaceutical and Medical Research

Open Access Research Article

Development and Evaluation of Multifunctional Co-Processed Excipients for Fast Dissolving Tablet Formulation

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A B S T R A C T

Fast dissolving tablets (FDTs) are novel oral solid dosage forms designed to disintegrate rapidly in saliva without the need for water. They improve patient compliance, especially in pediatric, geriatric, and dysphagic patients. The present study aimed to formulate and evaluate co-processed excipients for fast dissolving tablets using the wet granulation method. Different batches of co-processed excipients were prepared using Crospovidone, microcrystalline cellulose, sodium starch glycolate, mannitol, talc, magnesium stearate, and PVP K30. Pre-compression parameters such as bulk density, tapped density, Carr's index, Hausner ratio, and angle of repose were evaluated to determine flow properties. Post-compression studies included hardness, disintegration time, wetting time, and water absorption ratio. The results demonstrated that co-processed excipients significantly improved the flowability and compressibility compared to physical mixtures. Among all formulations, batch F5 showed optimum performance with excellent flow properties, compressibility, rapid disintegration time (40.58 sec), and wetting time (26 sec). The study concluded that co-processed excipients are an effective approach for improving the overall performance of fast dissolving tablets.

Keywords: Fast dissolving tablet, Co-processed excipients, Wet granulation, Compressibility, Flow properties, Disintegration time.

A R T I C L E I N F O: Received 11 Dec.2025; Review Complete 24 Jan, 2026; Accepted 20 Feb. 2026; Available online 15 April. 2026

Cite this article as:

Raval AM, Ratnakar BP, Utpalkumar PF, Utpalkumar PV, Development and Evaluation of Multifunctional Co-Processed Excipients for Fast Dissolving Tablet Formulation, Asian Journal of Pharmaceutical Research and Development. 2026; 14(2):226-233, DOI: http://dx.doi.org/10.22270/ajprd.v14i2.1751

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INTRODUCTION

Fast dissolving tablets (FDTs) are also known as mouth dissolving tablets, orally disintegrating tablets, rapid melt tablets, or quick dissolving tablets. These tablets dissolve or disintegrate rapidly in saliva without requiring water for administration. FDTs are highly beneficial for pediatric, geriatric, and mentally ill patients who experience difficulty swallowing conventional tablets [1].

The major advantages of FDTs include rapid onset of action, improved patient compliance, enhanced bioavailability, and ease of administration. However, formulation challenges such as poor mechanical strength, taste masking, and sensitivity to humidity remain significant concerns [2].Pharmaceutical excipients play an essential role in formulation development. Conventional physical mixtures of excipients often show poor flowability, segregation, and inconsistent compression behavior. To overcome these limitations, co-processed excipients were introduced. Co-processing involves combining two or more excipients through suitable processing techniques to improve functional properties while maintaining their chemical identity [3].Co-processed excipients offer several advantages including improved flow properties, enhanced compressibility, reduced segregation, better dilution potential, and improved tablet performance. Wet granulation is one of the most commonly used methods for preparing co-processed excipients due to its simplicity and effectiveness [4].

Literature Review

Literature Review on Fast Dissolving Tablets

Venkatesh et al. reported that superdisintegrants are essential for rapid disintegration of FDTs in saliva without water. Reddy et al. highlighted that advanced manufacturing techniques such as lyophilization and 3D printing improve porosity and dissolution characteristics. Sharma et al. discussed patient compliance and identified taste masking as a major challenge in FDT formulation. Kumar et al.

emphasized the use of natural polymers and nanotechnology to improve bioavailability and safety [5-8].

Literature Review on Co-Processed Excipients

Dzoagbe et al. reported that co-processed excipients improve direct compression and reduce manufacturing cost. Ahmed et al. demonstrated the effectiveness of customized excipient blends in overcoming fixed-ratio limitations. Raval et al. developed smart co-processed excipient platforms for high drug-load ibuprofen tablets with improved friability [16]. Burande et al. explored sustainable microwave-assisted wet granulation methods for starch-based co-processed excipients [9-12].

Materials and Methods

Materials

The following materials were used in the formulation:

- Crospovidone
- Mannitol
- Microcrystalline cellulose
- Sodium starch glycolate
- Talc
- Magnesium stearate
- PVP K30

Equipment

The equipment used included:

- Mortar and pestle
- Weighing balance
- Rotary tablet punching machine
- Hot air oven
- Sieve #16 and #40
- Monsanto hardness tester

Preparation of Co-Processed Excipients

Co-processed excipients were prepared using the wet granulation method. Mannitol, microcrystalline cellulose, Crospovidone, and sodium starch glycolate were mixed thoroughly in a mortar for 10-15 minutes. A 2% PVP K30 solution was prepared and added dropwise to the powder blend until a damp mass was formed. The wet mass was passed through sieve #16 to obtain granules. The granules were dried in a hot air oven at 40-45°C and passed through sieve #40. Talc and magnesium stearate were added to the dried granules and mixed properly.

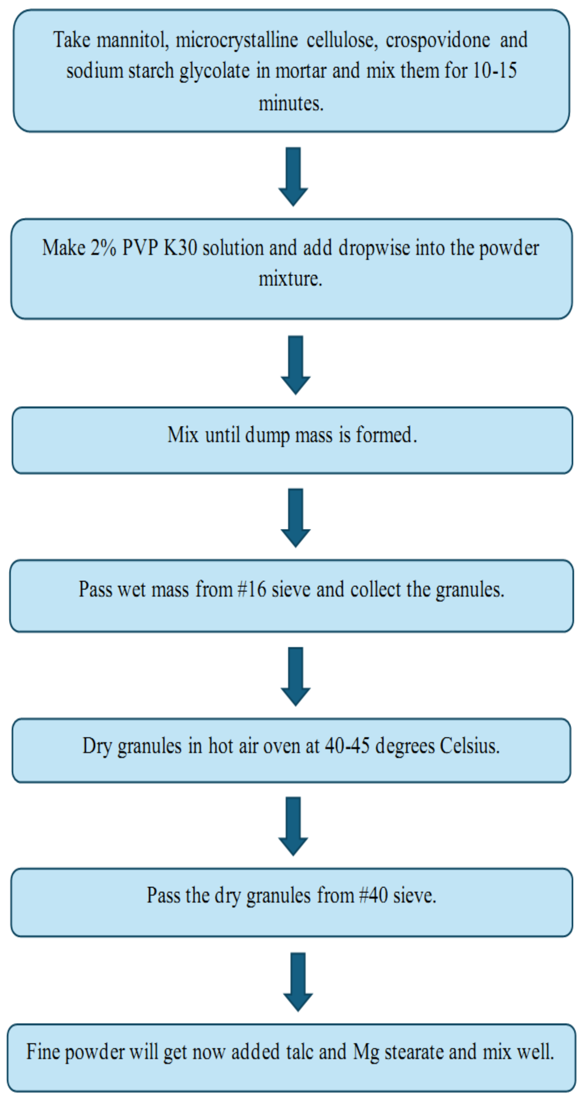

Figure 3: Preparation work during laboratory

Formulation of Different Batches

Table: 1 Formulation of Different Batches

Ingredients	F1	F2	F3	F4	F5	F6
Crospovidone	0.30 g	0.35 g	0.35 g	0.35 g	0.75 g	0.50 g
Microcrystalline cellulose	1.20 g	1.15 g	0.75 g	1.15 g	1.25 g	1.50 g
Sodium starch glycolate	0.15 g	0.35 g	0.35 g	0.35 g	0.50 g	0.25 g
Mannitol	2.50 g	3.15 g	3.30 g	3.15 g	2.25 g	2.50 g
Talc	0.15 g	0.19 g	0.19 g	0.19 g	0.15 g	0.15 g
Magnesium stearate	0.05 g	0.06 g	0.06 g	0.06 g	0.10 g	0.10 g
PVP K30	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

Evaluation Parameters

Pre-Compression Parameters

The prepared co-processed excipients were evaluated using the following parameters:

- Bulk density
- Tapped density
- Carr's index
- Hausner ratio
- Angle of repose

Post-Compression Parameters

Tablets were prepared using co-processed excipients using model drug Aspirin and then, the tablets were evaluated for:

- Hardness
- Disintegration time
- Wetting time
- Water absorption ratio

Results and Discussion

Pre-Formulation Studies of Physical Mixture

Table: 2 Pre-Formulation Studies of Physical Mixture of F1 to F6

Parameters	F1	F2	F3	F4	F5	F6
Bulk Density (g/mL)	0.41 ± 0.02	0.40 ± 0.01	0.38 ± 0.02	0.39 ± 0.01	0.45 ± 0.02	0.39 ± 0.01
Tapped Density (g/mL)	0.50 ± 0.01	0.55 ± 0.02	0.50 ± 0.01	0.60 ± 0.02	0.63 ± 0.01	0.58 ± 0.02
Carr's Index (%)	18.00 ± 0.45	27.27 ± 0.62	24.00 ± 0.51	35.00 ± 0.74	27.41 ± 0.58	34.48 ± 0.69
Hausner Ratio	1.21 ± 0.03	1.38 ± 0.04	1.32 ± 0.03	1.54 ± 0.05	1.37 ± 0.04	1.52 ± 0.05
Angle of Repose (°)	35.52 ± 0.42	40.00 ± 0.55	42.92 ± 0.61	42.00 ± 0.58	41.35 ± 0.49	39.69 ± 0.46

Note: Values are expressed as Mean ± Standard Deviation (n = 3).

Pre-Formulation Studies of Co-Processed Excipients

Table: 3 Pre-Formulation Studies of Co-Processed Excipients of F1 to F6

Parameters	F1	F2	F3	F4	F5	F6
Bulk Density (g/mL)	0.45 ± 0.02	0.45 ± 0.01	0.35 ± 0.01	0.32 ± 0.02	0.45 ± 0.01	0.38 ± 0.02
Tapped Density (g/mL)	0.51 ± 0.01	0.58 ± 0.02	0.46 ± 0.01	0.38 ± 0.01	0.52 ± 0.02	0.47 ± 0.01
Carr's Index (%)	11.76 ± 0.38	22.41 ± 0.54	23.91 ± 0.49	15.78 ± 0.42	13.46 ± 0.36	19.15 ± 0.45
Hausner Ratio	1.13 ± 0.02	1.28 ± 0.03	1.31 ± 0.04	1.18 ± 0.03	1.16 ± 0.02	1.24 ± 0.03
Angle of Repose (°)	33.82 ± 0.44	26.56 ± 0.35	26.56 ± 0.39	26.10 ± 0.31	27.47 ± 0.42	25.64 ± 0.28

Note: Values are expressed as Mean ± Standard Deviation (n = 3).

Evaluation of Optimized Formulation

Table: 4 Evaluation of Optimized Formulation of batch F5 & F6

Parameters	F5	F6
Disintegration Time (sec)	40.58 ± 0.72	45.82 ± 0.81
Wetting Time (sec)	26.00 ± 0.45	38.00 ± 0.63
Water Absorption Ratio (%)	81.81 ± 1.24	68.18 ± 1.08
Hardness (kg/cm²)	3.00 ± 0.12	3.50 ± 0.15

Note: Values are expressed as Mean ± Standard Deviation (n = 3).

Table: 5 Statistical Comparison of Simple Physical Mixture and Co-Processed Excipients Using Experimental Data

Parameter	Physical Mixture (Mean ± SD)	Co-Processed Excipients (Mean ± SD)	Interpretation
Bulk Density (g/mL)	0.40 ± 0.02	0.40 ± 0.05	Comparable bulk density observed
Tapped Density (g/mL)	0.56 ± 0.05	0.49 ± 0.07	Improved packing efficiency
Carr's Index (%)	27.69 ± 6.42	17.75 ± 4.91	Significant improvement in flowability
Hausner Ratio	1.39 ± 0.12	1.22 ± 0.07	Better compressibility after co-processing
Angle of Repose (°)	40.91 ± 2.56	27.69 ± 2.98	Excellent flow property achieved

Table: 6 Statistical Comparison of Optimized Batches (F5 & F6)

Parameter	F5 (Mean ± SD)	F6 (Mean ± SD)	Best Batch
Disintegration Time (sec)	40.58 ± 0.72	45.82 ± 0.81	F5
Wetting Time (sec)	26.00 ± 0.45	38.00 ± 0.63	F5
Water Absorption Ratio (%)	81.81 ± 1.24	68.18 ± 1.08	F5
Hardness (kg/cm²)	3.00 ± 0.12	3.50 ± 0.15	F6

Statistical Interpretation

- Co-processed excipients showed markedly improved flowability and compressibility compared to physical mixtures.
- Lower Carr's index, Hausner ratio, and angle of repose confirmed enhanced micromeritic properties.
- Batch F5 demonstrated superior fast dissolving characteristics with lower disintegration and wetting time.
- Batch F6 showed comparatively higher hardness but slower tablet dispersion behavior.
- Overall, batch F5 was considered the optimized formulation for fast dissolving tablet development.

Table: 7 Comparisons of Simple Physical Mixture and Co-Processed Excipients

Parameters	Simple Physical Mixture	Co-Processed Excipients	Observation
Particle Distribution	Non-uniform	Uniform and integrated	Better homogeneity in co-processing
Flowability	Poor to fair	Good to excellent	Improved powder flow
Compressibility	Lower	Higher	Better tablet formation
Segregation Tendency	High	Low	Reduced separation of particles
Carr's Index	Higher values	Lower values	Indicates improved flow property
Hausner Ratio	Higher values	Lower values	Better packing ability
Angle of Repose	Higher	Lower	Improved flow characteristics
Porosity	Lower	Higher	Enhanced rapid disintegration
Wetting Time	Longer	Shorter	Faster water penetration
Disintegration Time	Slower	Faster	Better FDT performance
Tablet Uniformity	Less consistent	More consistent	Improved content uniformity
Manufacturing Performance	Conventional	Optimized	Better processing efficiency
Stability During Compression	Moderate	Improved	Reduced friability and defects
Patient Compliance	Moderate	Better	Faster tablet disintegration in mouth

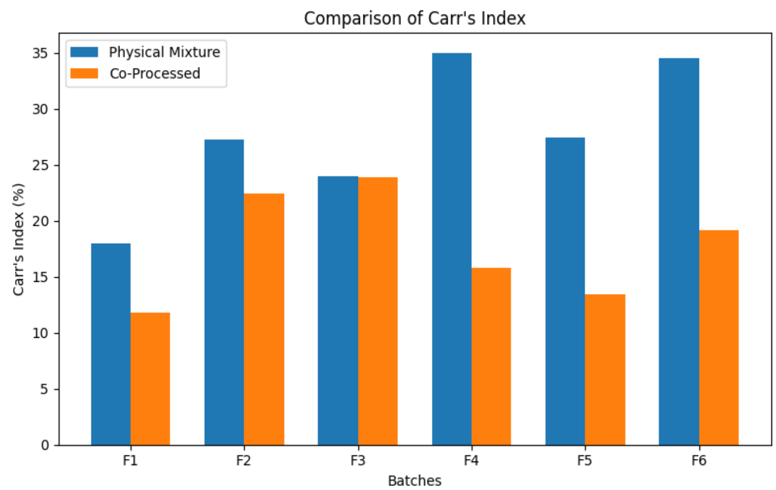

Figure 4: Comparison of Carr's Index

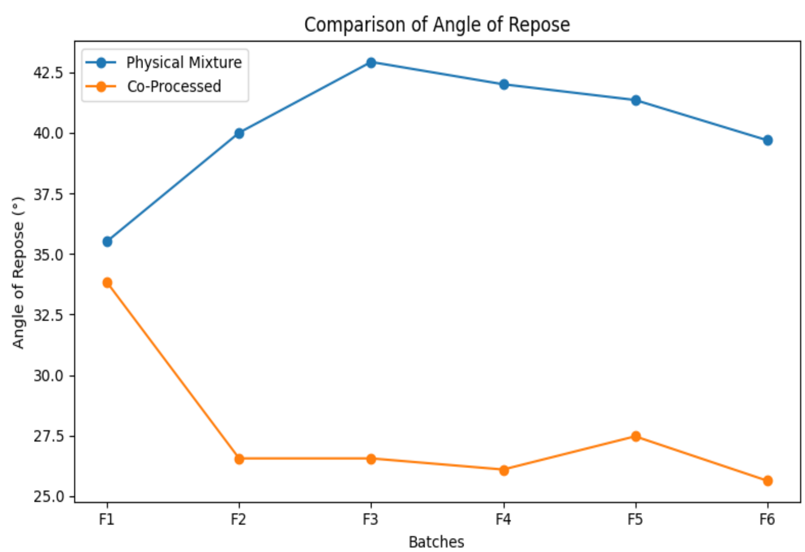

Figure 5: Comparison of Angle of Repose

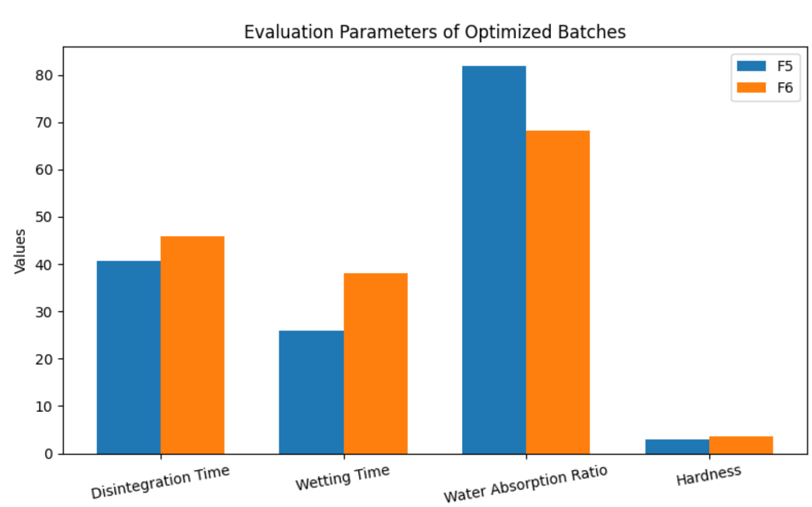

Figure 6: Evaluation Parameters of Optimized Batches (F5 vs F6)

DISCUSSION

The results clearly demonstrated that co-processed excipients improved the flowability and compressibility compared to physical mixtures. Batch F1 was prepared as a trial formulation to compare pre-formulation characteristics between physical mixtures and co-processed excipients.

In batches F2 and F3, a 2% PVP K30 solution in water and ethanol (1:1) was used as the binder. Mannitol concentration was increased in batch F3 to improve porosity. However, ethanol reduced porosity and flowability; therefore, only aqueous PVP K30 solution was used in subsequent batches.

Among all formulations, batch F5 exhibited the best performance with excellent flow properties, compressibility, rapid disintegration time, and improved wetting characteristics. After optimization, Aspirin was incorporated as the API and the formulation maintained excellent pre-compression properties.

CONCLUSION

The present study demonstrated that co-processed excipients significantly improve the performance of fast dissolving tablets compared to conventional physical mixtures. Wet granulation successfully enhanced flow properties, compressibility, wetting time, and disintegration characteristics.

Among all prepared batches, F5 showed the best overall performance with excellent flowability, compressibility, and rapid tablet disintegration. Therefore, co-processed excipients can be considered a promising and effective approach for the development of fast dissolving tablets.

ACKNOWLEDGEMENT

The authors are sincerely thankful to ***Sharda School of Pharmacy, Pethapur, Gandhinagar***, Gujarat, for providing the necessary laboratory facilities, instrumentation support, and academic environment to successfully carry out this research work. The authors also express their gratitude to the Department of Pharmaceutics for continuous guidance and technical assistance during the experimental study and manuscript preparation.

The authors acknowledge the valuable support and encouragement provided by the management and faculty members of Sharda School of Pharmacy throughout the research work. The authors further extend their appreciation to all individuals who directly or indirectly contributed to the completion of this manuscript.

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