Research Article

Effect of Different Disintegration Agents on Tablet Evaluation Parameter

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Received: 06-04-2025; **Revised:** 23-06-2025; **Accepted:** 04-07-2025; **Published online:** 15-07-2025.

ABSTRACT

This study investigates the effect of different disintegration agents—starch, lactose, crospovidone, and methyl cellulose—on the physical and performance parameters of paracetamol tablets. Granules were prepared and evaluated for flow properties, then compressed into tablets and tested for hardness, friability, weight variation, disintegration time, and drug release using UV spectrophotometry. Among all disintegrants, crospovidone demonstrated the best performance with rapid disintegration, excellent flow properties, and the highest drug release (101.98%), making it the most suitable for fast-dissolving formulations.

Keywords: Crospovidone, Lactose, Starch, Methyl Cellulose, Disintegrant.

INTRODUCTION

Oral tablets are the most widely used solid unit dosage form due to their ease of administration, precise dosing, long shelf life, and cost-effective manufacturing. Most tablets are designed for oral delivery and can be formulated for immediate or modified release using appropriate ingredients and manufacturing techniques. A tablet typically contains the active pharmaceutical ingredient (API) along with excipients—substances that, although pharmacologically inactive, are critical to the formulation's performance, manufacturability, stability, and patient acceptability.[1-5]

Excipients perform various roles such as disintegration, binding, lubrication, and enhancing flow properties. To be suitable for pharmaceutical use, excipients must be chemically and physically stable, physiologically inert, and compliant with regulatory standards. Recent trends include the use of co-processed excipients, which combine multiple excipients to improve functionality and reduce formulation complexity.[6-8]

Among all excipients, disintegrants are particularly important because they enable the breakdown of the tablet into smaller fragments upon ingestion, facilitating the dissolution and absorption of the API. The disintegration process typically involves two phases: initial fragmentation into aggregates, followed by deaggregation into primary particles. Traditional disintegrants include starches and celluloses, which function mainly by absorbing moisture and swelling. Modern formulation strategies utilize "super disintegrants" like sodium starch glycolate, croscarmellose sodium, and crospovidone, which provide efficient disintegration at lower concentrations due to enhanced swelling, wicking, and strain recovery properties.[9-13]

Each disintegrant operates via specific mechanisms—such as capillary action, swelling, or gas generation—and often exhibits multiple disintegration pathways synergistically. A sound understanding of disintegrant types, mechanisms of action, and material properties is essential for designing effective tablet formulations that ensure rapid drug release and bioavailability.[14-18]

MATERIALS AND METHODS

MATERIALS:

1] Active pharmaceutical ingredients [API]:

Example - Paracetamol.

2] Disintegrants: Starch, Methyl cellulose, Crospovidone, Lactose

3] Excipients: Starch (Binder), Gum Acasia (Binder), Magenisum stearate (lubricant), Talc (Glidant)

METHODOLOGY:

Formulation of Tablets:

A] *Granules formulation:*

1. Weigh paracetamol powder and sift it through a 100# sieve.

2. Combine paracetamol and starch powder thoroughly using a mortar and pestle.

3. Gradually add starch paste to the mortar until a cohesive mass is achieved; make a note of the amount of starch paste used for granulation.

4. Screen the resulting cohesive mass using a 12# granulating sieve and place it on the granulating tray.

5. Dry the granules in the tray at 50°C for 30 minutes, then pass 50% of the dried granules through a 16# sieve to achieve a uniform particle size, and continue drying for an additional 30 minutes.

6. Proceed to compress the tablet. [11,19-23,35,42]

B] *Preformulation Studies:*

Angle of repose:

Determined using the funnel method to assess powder flow. The height and radius of the powder cone were measured, and the angle was calculated using: [24,25]

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

Bulk Density:

A known weight of powder was added to a graduated cylinder. Bulk density was calculated as:[28,43]

$$\text{Bulk density} = \text{Weight of powder} / \text{Bulk volume}$$

Tapped Density:

The same powder was tapped 500–1250 times using a tap density apparatus. Tapped density was calculated as: [29,30]

$$\text{Tapped density} = \text{Weight of powder} / \text{Tapped volume}$$

Carr's index and Hausner's Ratio:

These parameters assess flow and compressibility.

$$\text{Carr's index} = (\text{Tapped density} - \text{Bulk density} / \text{Tapped density}) \times 100$$

$$\text{Hausner's Ratio} = \text{Tapped density} / \text{Bulk density}$$

C] **Tablet Compression Procedure:**[31-36,40,45]

1. **Fill Die:** Granules added into the die cavity.
2. **Compress:** Powder compressed using punches with set pressure.
3. **Eject:** Tablets released and collected.
4. **Settings:** Weight, size, and pressure kept constant across batches.

EVALUATION PARAMETERS:[39,41-47]

1. Hardness Test:
Measures the force needed to break tablets; affected by excipients and formulation.

2. Friability Test:
20 tablets rotated at 25 rpm for 4 minutes; % weight loss indicates resistance to abrasion.

3. Weight Variation Test:
Weigh 20 tablets individually; check % deviation from average weight.

4. Disintegration Test:
6 tablets tested in water, 0.1HCL, Phosphate Buffer at 37 ± 2°C; must fully disintegrate within the specified time.

5. Assay (UV Spectrophotometer):
Drug content measured by absorbance at 233 nm using standard and sample solutions.

Table 1: Preformulation Study

Sr.No.	Disintegrate Agent	Angle of repose (°)	Bulk density (g/cm³)	Tapped density (g/cm³)	Carr's index (%)	Hausner's ratio	Flow property
1	Starch	35.8	0.49	0.62	20.96	1.27	Fair
2	Lactose	32.1	0.52	0.61	14.75	1.17	good
3	Crospovidone	28.4	0.45	0.52	13.46	1.16	Good to excellent
4	Methyl cellulose	37.6	0.38	0.49	22.45	1.29	Passable

RESULTS

1. Preformulation Study:

Powder properties

1. Angle of Repose less than 30° indicates excellent flow; 30-40° is acceptable.

2. Carr's Index <15% = good flow, 15-25% = fair, >25% = poor.

Hausner's Ratio <1.25 = good flow; >1.25 may indicate poor flow.

2. Hardness Test:

Test: Tablet Hardness test

Product: Paracetamol 500 mg tablet

Instrument Used: Monsanto Hardness Tester

Number of tablets tested: 6

Unit: kg/cm²

Average Hardness: 5.2 kg/cm².

Acceptance Criteria: Should be between 4-8 kg/cm² (as per IP).

Result: All tested tablets comply with specification.

Table 2: Hardness Test

Tablet No.	Hardness (kg/cm²)	Passed/failed
Paracetamol (500mg) (Disintegrant)		
1.Starch	5.2	**Passed**
2.Lactose	5.4	**Passed**
3.Crospovidone	4.8	**Passed**
4.Methyal cellulose	5.5	**Passed**

3. Friability Test:

Limit – Not more than 1.0 %

Table 3: Friability Test

Tablet No. Paracetamol (500mg) Disintegrant	Initial Weight (gm)	Final weight (gm)	% loss.	Result (pass/ Fail)
1. Starch	13.200	13.070	0.7	Pass
2. Lactose	13.200	13.040	0.6	Pass
3. Crospovidone	13.200	13.080	0.5	Pass
4. Methyl Cellulose	13.200	13.079	0.8	Pass

4. Weight Variation Test:

Avg.wt. = sum of individual weight/ NO. of tablets.

i] Acceptance Criteria (for tablet>324mg)

ii] Individual weight should not derivate by more than (+, -) 5%

Table 4: Weight Variation Test

Formulation (Disintegrant)	Mean weight (mg)	% Deviation	Pass/ Fail
Starch	500	±2.5%	Pass
Lactose	498	±2.4%	Pass
Crospovidone	501	±2.6%	Pass
Methyl cellulose	502	±2.7%	Pass

5. Disintegration Tests:

Test: Tablet disintegration test

Instrument used: Disintegration test apparatus.

Medium: Purified water/0.1 N HCl/pH 6.8 phosphate buffer.

Temperature: 37 ± 2°C.

Number of Tablets Tested: 6.

Tablet Specification: 500 mg Paracetamol tablet.

Specification: All tablets disintegrated within 15 minutes (as per USP/BP/IP).

Table 5: Disintegration Test

Disintegrant	Water (Min.)	0.1N HCL (Min)	Phosphate Buffer Ph 6.8 (Min)	Passed/ fail
Starch	7	5	9	Passed
Lactose	9	7	8	Passed
Crospovidone	5	3	6	Passed
Methyl Cellulose	9	6	9	Passed

Table 6: Assay on Spectrophotometer

Disintegrating Agent	Conc. (% w/w)	Absorbance at 243nm	% drug release	Remark
Strach	5	0.712	94.93	Moderate disintegration
Lactose	5	0.634	84.55	Slow disintegration
Crospovidone	5	0.765	101.98	Rapid disintegration
Methyl cellulose	5	0.689	91.93	Gel-forming; moderate
Control (No disintegrant)	0	0.521	96.55	Pour disintegration

Note:

1) A max for paracetamol is typically 243 nm.

2) The higher the absorbance, the greater the drug content released.

3) The standard 500 mg tablet was crushed, dissolved, filtered, and diluted to a known volume before analysis.

CONCLUSION

- Crospovidone was the best disintegrant, showing fastest disintegration, excellent flow, and highest drug release (101.98%).
- Starch performed moderately well with acceptable disintegration and good mechanical strength.
- Methyl Cellulose showed slower disintegration due to gel formation; better suited for sustained release.
- Lactose acted mainly as a filler with poor disintegration and lowest drug release (84.55%).

Overall, Crospovidone is the most suitable for fast-dissolving paracetamol tablets**.**

Source of Support: The author(s) received no financial support for the research, authorship, and/or publication of this article

Conflict of Interest: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

REFERENCES

1. Li JX. Sodium starch glycolate. In: Rowe RC, Sheskey PJ, Cook WG, Fenton ME,eds. Handbook of Pharmaceutical Excipients. 7th ed. London, UK: Pharmaceutical Press; 2012:757-760.
2. Alderborn G. Tablets and compaction. In: Aulton ME, ed. Pharmaceutics: The Science of Dosage Form Design. 2nd ed. Edinburgh, NY: Churchill Livingstone;2001:397-440.
3. Augsburger LL, Zellhofer MJ. Tablet formulation. In: Swarbrick J, ed. Encyclopedia of Pharmaceutical Technology. 3rd ed. New York, NY: Informa HealthcareUSA, Inc; 2007:3641-3652.
4. Bandelin FJ. Compressed tablets by wet granulation. In: Lieberman HA,Lachman L, Schwartz JB, eds. Pharmaceutical Dosage Forms: Tablets. 2nd ed.New York, NY: Marcel Dekker, Inc; 1989:131-193.
5. Garg N, Dureja H, Kaushik D. Co-processed excipients: a patent review. RecentPat Drug Deliv Formul. 2013;7(1):73-83.
6. Moreton RC. Disintegrants in tableting. In: Augsburger LL, Hoag SW, eds.Pharmaceutical Dosage Forms: Tablets. 3rd ed. New York, NY: Informa Healthcare USA, Inc; 2008:217-249.
7. Ingram JT, Lowenthal W. Mechanism of action of starch as a tablet dis-integrant. I. Factors that affect the swelling of starch grains at 37 degree.J Pharm Sci. 1966;55(6):614-617.
8. El- Barghouthi M, Eftaiha A, Rashid I, Al- Remawi M, Badwan A. A novel superdisintegrating agent made from physically modified chitosan with sili-con dioxide. Drug Dev Ind Pharm.

2008;34(4):373-383.

9. Shah U, Augsburger LL. Evaluation of the functional equivalence of crospovidone NF from different sources. I. Physical characterization. Pharm Dev Technol. 2001;6(1):39-51.
10. Zhao N, Augsburger LL. The influence of swelling capacity of super disintegrants in different pH media on the dissolution of hydrochlorothiazide from directly compressed tablets. AAPS PharmSciTech. 2005;6(1):E120-E126.
11. Sallam E, Ibrahim H, Abu Dahab R, Shubair M, Khalil E. Evaluation of fast disintegrants in terfenadine tablets containing a gas-evolving disintegrant. Drug Dev Ind Pharm. 1998;24(6):501-507.
12. Ingram JT, Lowenthal W. Mechanism of action of starch as a tablet disintegrant. I. Factors that affect the swelling of starch grains at 37 degree.J Pharm Sci. 1966;55(6):614-617.
13. El-Barghouthi M, Eftaiha A, Rashid I, Al-Remawi M, Badwan A. A novel superdisintegrating agent made from physically modified chitosan with silicon dioxide. Drug Dev Ind Pharm. 2008;34(4):373-383.
14. Shah U, Augsburger LL. Evaluation of the functional equivalence of crospovidone NF from different sources. I. Physical characterization. Pharm Dev Technol. 2001;6(1):39-51.
15. Zhao N, Augsburger LL. The influence of swelling capacity of super-disintegrants in different pH media on the dissolution of hydrochlorothiazide from directly compressed tablets. AAPS PharmSciTech. 2005; 6(1):E120-E126.
16. Sallam E, Ibrahim H, Abu Dahab R, Shubair M, Khalil E. Evaluation of fast disintegrants in terfenadine tablets containing a gas-evolving disintegrant. Drug Dev Ind Pharm. 1998;24(6):501-507.
17. Quodbach J, Moussavi A, Tammer R, Frahm J, Kleinebudde P. Tablet disinte- gration studied by high-resolution real-time magnetic resonance imaging. J Pharm Sci. 2014;103(1):249-255.
18. Augsburger LL, Brzeczko AW, Shah U, Hahm HA. Super disintegrants: characterization and function. In: Swarbrick J, ed. Encyclopedia of Pharmaceutical Technology. 3rd ed. New York, NY: Informa Healthcare USA, Inc; 2007:3553-3567.
19. Rudnic EM, Lausier JM, Chilamkurti RN, Rhodes CT. Studies of the utility of cross- linked polyvinlpolypyrrolidine as a tablet disintegrant. Drug Dev Ind Pharm. 1980;6(3):291-309.
20. Peck GE, Baley GJ, McCurdy VE, Banker GS. Tablet formulation and design. In: Lieberman HA, Lachman L, Schwartz JB, eds. Pharmaceutical Dosage Forms: Tablets. 2nd ed. New York, NY: Marcel Dekker, Inc; 1989:75-130.
21. List P, Muazzam U. Swellingda driving force in tablet disintegration. Pharm Ind. 1979; 41:1075-1077.
22. Hausler O. Starch. In: Rowe RC, Sheskey PJ, Cook WG, Fenton ME, eds. Handbook of Pharmaceutical Excipients. 7th ed. London, UK: Pharmaceutical Press; 2012:784-790.
23. Schwartz JB, Zelinskie JA. The binding and disintegrant properties of the corn starch fractions: amylose and amylopectin. Drug Dev Ind Pharm. 1978;4(5):463-483
24. Li JH, Vasanthan T, Hoover R, Rossnagel BG. Starch from hull-less barley: Ultrastructure and distribution of granule-bound proteins. Cereal Chem.2003;80(5):524-532.
25. Kibbe AH. Starch, pregelatinized. In: Rowe RC, Sheskey PJ, Cook WG, Fenton ME, eds. Handbook of Pharmaceutical Excipients. 7th ed. London, UK: Pharmaceutical Press; 2012:794-797.
26. Bolhuis GK, Arends-Scholte AW, Stuut GJ, De Vries JA. Disintegration efficiency of sodium starch glycolates, prepared from different native starches. Eur J Pharm Biopharm. 1994;40(5):317-320.
27. Young PM, Edge S, Staniforth JN, Steele DF, Price R. Dynamic vapor sorption properties of sodium starch glycolate disintegrants. Pharm Dev Technol. 2005;10(2):249-259.
28. Sun CC. Cellulose, Microcrystalline. In: Rowe RC, Sheskey PJ, Cook WG, Fenton ME, eds. Handbook of Pharmaceutical Excipients. 7th ed. London, UK: Pharmaceutical Press; 2012:140-144.
29. Al-khattawi A, Alyami H, Townsend B, Ma X, Mohammed AR. Evidence-based nanoscopic and molecular framework for excipient functionality in compressed orally disintegrating tablets. PLoS One. 2014; 9(7):e101369.
30. Guest RT. Croscarmellose sodium. In: Rowe RC, Sheskey PJ, Cook WG,Fenton ME, eds. Handbook of Pharmaceutical Excipients. 7th ed. London, UK:Pharmaceutical Press; 2012:224-226.
31. Barabas ES, Adeyeye CM. Crospovidone. In: Brittain HG, ed. Analytical Profiles of Drug Substances and Excipients. Vol. 24. New York, NY: Academic Press, Inc.;1996:87-163.
32. Kibbe AH. Crospovidone. In: Rowe RC, Sheskey PJ, Cook WG, Fenton ME, eds.Handbook of Pharmaceutical Excipients. 7th ed. London, UK: Pharmaceutical Press; 2012:227-229.
33. Kornblum SS, Stoopak SB. A new tablet disintegrating agent: cross-linked polyvinylpyrrolidone. J Pharm Sci. 1973;62(1):43-49.
34. Shiyani B, Gattani S, Surana S. Formulation and evaluation of bi- layer tablet of metoclopramide hydrochloride and ibuprofen. AAPS PharmSciTech. 2008;9(3):818-827.
35. Kalasz H, Antal I. Drug excipients Curr Med Chem. 2006;13(21):2535-2563.
36. Fromming KH, Ditter W, Horn D. Sorption properties of cross-linked insoluble polyvinylpyrrolidone. J Pharm Sci. 1981;70(7):738-743.
37. Shu T, Suzuki H, Hironaka K, Ito K. Studies of rapidly disintegrating tablets in the oral cavity using co- ground mixtures of mannitol with crospovido ne.Chem Pharm Bull. 2002;50(2):193-198
38. Bele MH, Derle DV. Effect of sorbed water on disintegrant performance of four brands of Polacrilin Potassium NF. AAPS PharmSciTech. 2012;13(1):24-34
39. Shotton E, Leonard GS. Effect of intragranular and extragranular disintegrating agents on particle size of disintegrated tablets. J Pharm Sci. 1976;65(8):1170-1174.
40. Khattab I, Menon A, Sakr A. Effect of mode of incorporation of disintegrants on the characteristics of fluid-bed wet-granulated tablets. J Pharm Pharmacol.1993;45(8):687-691.

41. Gordon MS, Chatterjee B, Chowhan ZT. Effect of the mode of croscarmellose sodium incorporation on tablet dissolution and friability. J Pharm Sci.1990;79(1):43-47.

42. He X, Barone MR, Marsac PJ, Sperry DC. Development of a rapidly dispersing tablet of a poorly wettable compound-formulation DOE and mechanistic study of effect of formulation excipients on wetting of celecoxib. Int J Pharm.2008;353(1-2):176-186.

43. van Kamp HV, Bolhuis GK, Lerk CF. Improvement by super disintegrants of the properties of tablets containing lactose, prepared by wet granulation. Pharm Weekbl Sci. 1983;5(4):165-171.

44. Gould PL, Tan SB. The effect of recompression on the dissolution of wet massed tablets containing 'super' disintegrants. Drug Dev Ind Pharm.1986;12(11-13):1929-1945.

45. Saripella KK, Mallipeddi R, Neau SH. Crospovidone interactions with water. II.Dynamic vapor sorption analysis of the effect of Polyplasdone particle size on its uptake and distribution of water. Int J Pharm. 2014;475(1-2):e174-e180.

46. Saripella KK, Mallipeddi R, Neau SH. Crospovidone interactions with water. I.Calorimetric study of the effect of Polyplasdone particle size on its uptake and distribution of water. J Pharm Sci. 2014;103(2):669-675.

47. Cooper J, Gunn C., Powder flow and compaction In: Carter SJ.Eds Tutorial pharmacy, CBS Publishers and Distributors, New Delhi, India, 1986, pp211-233.

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