



Effect of Microcrystalline Cellulose Particle Size on Flowability and Compressibility in Direct Compression Method

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ABSTRACT

Microcrystalline cellulose is used as a tablet diluent and binder. It also imparts lubrication and self-disintegration properties to the formulation that makes it a multifunctional excipient in tableting by both wet-granulation and direct-compression methods. It is commercially available in different particle sizes, densities and moisture levels that define its different applications. This study aims at evaluating influence of particle size of microcrystalline cellulose on flow and compressibility properties of diclofenac in manufacturing oral tablets by direct compression method. This study demonstrated that out of 4 different grades of microcrystalline cellulose viz. 25, 50, 100 and 200 µm, the grade with 200 µm particle size distribution (HiCel™ LP200) showed superior powder micromeritics to other grades. Whereas the grade with 50 µm particle size distribution (HiCel™ 50M) showed superior tablet characteristics and performance to other grades. This suggested that the particle size of microcrystalline cellulose influenced blend mixing uniformity, flow and density, filling of void spaces in die cavity and compressibility into tablets. This was evident with excellent angle of repose, Carr's index and Hausner's ratio of diclofenac blend containing HiCel™ LP200. The diclofenac blend containing HiCel™ 50M produced tablets with better strength, least weight variations and quick disintegration as compared to the other grades. On the contrary, diclofenac blend containing fine grade of microcrystalline cellulose (HiCel™ 25M) showed poorer micromeritics and produced tablets with unacceptable strength and weight variations. Thus, particle size of microcrystalline cellulose is decisive in ensuring good processability, product quality and performance.

Keywords: microcrystalline cellulose, particle size distribution, direct compression, tablet properties, powder micromeritics.

1. Introduction

Tablets are solid dosage forms in which one or more APIs are blended with excipients and compressed into the final formulation. Conventionally, tablets remain the preferred dosage form due to the advantages, like ease of manufacturing, dosage accuracy, longer shelf life, high patient acceptability and compliance (1). The simplest manufacturing technique, direct compression is acceptable only when the APIs and excipients possess acceptable flow and compression properties without additional processing steps. Belief in advanced commercialisation approaches also, like continuous manufacturing in pharma industry is growing stronger because it addresses the practical challenges in conventional batch manufacturing, such as increased product handling, more manufacturing steps, constraints due to higher plant footprint, time-consuming changeover, and quality control (2). It is a well-known fact that bulk powders inherently exhibit unpredictable flow in feeders, dosing machines, packing machines under the influence of gravity. Such manufacturing processes are significantly influenced by the quality of input materials along with other aspects. Majority of the formulations contain excipient concentration higher than API. Thus, it mandates appropriate selection of starting materials with excellent micromeritics.

Nofrierias *et al* proposed characterization of pharmaceutical powders by means of the SeDeM diagram expert system. Their study comprised of the characterization of Microcrystalline Celluloses (MCC) of different grades (101, 102, 301, 302 and 200) made by four different manufacturers. The SeDeM characterization led to describing and to analysing the differences between each MCC studied based on dimensions, compressibility, flowability, lubricity/ stability and lubricity/ dosage) and the Index of Good Compression (IGC). They concluded that although the MCC manufacturers usually describe similarly in their products, the results indicated that there were large differences between them based on above parameters (3). Ouazzou *et al* have demonstrated the influence of the particle size distribution of maltodextrin powders, the compression pressure and the dwell time on the tensile



strength, porosity, and pore size distribution of the final tablet produced by wet granulation technique (4). Wunsch *et al* had systematically characterized the influence of initial particle size on powder compressibility and compactibility by consideration of in-die compressibility, specific energies, quick elastic recovery, tablet porosity and, tensile strength for the binder microcrystalline cellulose and three APIs. They concluded that the compactibility was increased with decreasing particle size because of the increasing number of bonds in a cross-sectional area of the tablet, as found by the application of the model of Rumpf (5). Microcrystalline celluloses, because of their multifunctional properties like filler, binder, disintegrant and self-lubrication are commonly used in direct compression tablet formulations. Physical properties of such excipients, like density, crystal habit, moisture content, particle size, shape, porosity, static charges and morphology have decisive impact over processability, physicochemical quality attributes, stability, performance and overall therapeutic success of the formulation (6).

The viscoelastic behavior of microcrystalline cellulose also demonstrates greater elastic effects at higher tableting speeds where there is insufficient compaction time for plastic deformation (7). Microcrystalline cellulose has a very high intraparticle porosity with approximately 90–95% of the surface area being internal. Therefore, surface area is not directly influenced by the nominal particle size. The plasticity of microcrystalline cellulose is the main reason of its exceptional binding properties. However, compared to brittle excipients, microcrystalline cellulose is more lubricant sensitive. Lubricated microcrystalline cellulose particles will deform under pressure and will not fracture to create new and clean (lubricant-free) surfaces (8). The presence of high levels of hydrophobic lubricants, such as, magnesium stearate, the use of long blend times and high blend speeds would then result in softer tablets (9). The addition of brittle excipients or colloidal silicon dioxide into the blends containing microcrystalline cellulose can successfully prevent lubricants from occupying the microcrystalline cellulose surfaces, and in turn minimize the negative influence of lubricants on tablet strength. Microcrystalline cellulose has a very high intraparticle porosity with approximately 90–95% of the surface area being internal, this high porosity promotes swelling and disintegration of microcrystalline cellulose tablets by penetration of water into the tablet matrix.

Hence, the influence of particle size distribution as key material attribute of microcrystalline cellulose on processability, quality attributes of powder blend and tablets, and their performance was studied in the present study. Different varieties of spray dried microcrystalline cellulose having particle size distribution ranging from 25- 200 µm with specific densities were used to formulate the pharmaceutical tablets by direct compression technique. The physical blends were evaluated for flow, compressibility and other micromeritics. Out of several formulations, the blend containing coarser grades of microcrystalline cellulose showed better powder micromeritics. Further, the pharmaceutical tablets were evaluated mainly for strength, disintegration and dissolution. Out of several formulations, the tablets containing finer grades of microcrystalline cellulose showed better performance in terms of quicker disintegration and complete dissolution. Thus, it is possible to conclude that the particle size distribution of the major components in tablet formulations has decisive impact over, powder physical properties, processability tablet properties and its performance also.

2. Experimental

2.1 Materials

HiCel™ 25M, HiCel™ 50M, HiCel™ 90M, HiCel™ LP200 were manufactured at SIGACHI® Industries Limited, Dahej, Gujarat, India. Diclofenac sodium was purchased from Pharma Lab Limited, India, colloidal silicon dioxide was purchased from Evonik Industries Germany, Croscarmellose sodium was purchased from Sigachi Industries Limited, Dahej, Gujarat, India, Purified talc powder was purchased from Neelkanth Fine Chem LLP, Jodhpur, Rajasthan, Magnesium Stearate was purchased from Sunshine Organic PVT. LTD. Mumbai, India.

2.2 Methods

2.2.1 Manufacturing of diclofenac sodium tablets by direct compression method

The diclofenac sodium tablet formulations as detailed in the Table No.1, strategically incorporated four distinct grades of HiCel™ (Microcrystalline Cellulose) alongside other critical excipients to achieve desired tableting characteristics and drug delivery profiles. Each HiCel™ grade is selected based on its unique micromeritic properties, which dictate its functional role within the tablet matrix. Supplementary excipients, such as binders, disintegrants, lubricants, and glidants, were selected to collectively optimize powder flow, compaction behavior, tablet integrity, and performance of the final dosage form. Accurately weighed quantities of diclofenac sodium, croscarmellose sodium, microcrystalline cellulose, and colloidal silicon dioxide were co-sifted through a 30# ASTM stainless steel sieve. They were transferred into powder blender of appropriate capacity (Make: Reva Pharma Machinery, India, Model: TRMIX-20). These materials were mixed for 15 min at 25 rpm to ensure blend homogeneity. To this premix, an accurately weighed quantity of talcum powder (previously sifted through a 40# mesh ASTM sieve) was added and mixed for 15 min at 25 rpm. The entire mixture was then subjected to final sifting through a 30# mesh ASTM sieve. Finally, magnesium stearate, previously



sieved through a 60# mesh ASTM sieve, was added into the blended material and mixed for 2 min to facilitate lubrication. Then, this final lubricated blend was compressed into tablets by using a 12-station tablet compression machine (Make: Eliza Press, India, Model: EP-200) fitted with 9.50 mm diameter standard rounded shaped “D” tooling set.

2.3 Evaluation of Pre-Compression Parameter

The final lubricated blend was characterized by angle of repose, untapped bulk density, tapped bulk density, Hausner’s ratio and compressibility index parameters.

2.3.1 Untapped bulk density

Untapped bulk density was analyzed by using volumeter by the method mentioned in United States Pharmacopoeia: General Chapter on bulk density <616> (10).

2.3.2 Tapped bulk density

Tapped bulk density was determined by the method mentioned in United States Pharmacopoeia: General Chapter on tapped density <616> (10), using density apparatus (Make: Electrolab, India Model: USP 1&2).

2.3.3 Hausner’s ratio

It is an indirect index of measuring powder flow by the method mentioned in United States Pharmacopoeia: General Chapter on powder flow <1174> (11), using a tap density apparatus (Make: Electrolab, India Model: USP 1&2).

2.3.4 Angle of Repose

It is an indirect index of measuring powder flow by the method mentioned in United States Pharmacopoeia: General Chapter on powder flow <1174> (11)

2.3.5 Compressibility index (Carr’s index)

It is an indirect index of measuring powder flow by the method mentioned in United States Pharmacopoeia: General Chapter on powder flow <1174> (11). Lower Carr’s index (between 15 and 20%) indicated fair compressibility property of the MCC.

2.3.6 Sieve analysis

Sieve analysis was performed by arranging different types of mesh sieves by the method mentioned in United States Pharmacopoeia: General Chapter on powder flow <786> (12).

2.4 Evaluation of tablet properties

2.4.1 Weight variation

Tablet weight variation was evaluated as per United States Pharmacopoeia: General Chapter on Uniformity of dosage units <905> (13).

2.4.2 Tablet Compaction

Compacts of 250 mg tablet in tablet compression machine 12 stations, with “D” tooling set (Make: Eliza Press, India, Model: EP-200). Machine operating pressure ranges 10 to 60 kN.

2.4.3 Tablet Hardness

Tablet hardness was determined using a calibrated hardness tester (Make: Labindia tablet hardness tester, India, Model No.-TH1050 M) as per the United States Pharmacopoeia: General Chapter <1217> (14).



2.4.4 Tablet Thickness

Thickness was measured by using a digital tablet thickness tester machine (Make: Labindia tablet hardness tester, India, Model No.-TH1050 M).

2.4.5 Friability

Tablet friability test was performed by using the friabilator (Make: Labindia India, Model: FT1020). The percentage friability was determined by method mentioned in United States Pharmacopoeia: general chapter on tablet friability <1216> (15).

2.4.6 Disintegration

Tablet Disintegration Tester machine (Make: Labindia, India, Model: DT1000) was used for evaluating disintegration time as per United States Pharmacopoeia: general chapter on disintegration time <701>, disintegration time of uncoated tablets should be NMT 15 min (16).

2.4.7 In-vitro dissolution test

The dissolution profile of diclofenac sodium immediate release tablet was performed using dissolution test apparatus (Make: Labindia India, Model: DS8000) by using the USP 44 compendial method, apparatus II (paddle), speed 50 rpm for 1 hr in 900 mL of phosphate buffer pH 7.5 at $37 \pm 0.5^\circ\text{C}$ medium temperature. Six tablets were placed in each dissolution vessel. Sample aliquots of 5 mL were withdrawn from each dissolution vessel at 5, 15, 30, 45 and 60 min. After withdrawal, samples were filtered through whatman filter paper (No. 45). 1 mL of filtrate from the beaker was taken and transferred into 10 mL of volumetric flask and diluted up to 10 mL with dissolution medium. The same procedure was repeated for all remaining 5 tablets. Standard and sample absorbances were recorded using a UV spectrophotometer (Make: Shimadzu Japan, Model: UV-1900) at $\lambda = 276$ nm wavelength. The diclofenac sodium released from tablet formulations was calculated using the below mentioned formula (17).

$$\text{Amount of drug released (mg)} = \text{Concentration of released drug} \times \text{Dilution factor} \times \text{Volume of dissolution medium} / 1000$$

$$\text{Drug dissolved (\%)} = \text{Amount of drug released (mg)} / \text{label claim (mg)} \times 100$$

2.4.7.1 Calibration curve of diclofenac sodium tablet

Phosphate buffer pH 7.5 filtered through whatman filter paper (No. 45) was used as diluent for preparing the standard solution of the drug. About 10 mg of diclofenac sodium was accurately weighed and transferred into 100 mL volumetric flask, the solution was sonicated and the resulting solution was diluted with the diluent to obtain a primary stock solution to obtain 100 $\mu\text{g/mL}$ diclofenac sodium. From this solution, suitable standard solutions of different concentrations were prepared. Linearity of the absorbance was determined by measuring standard dilution of diclofenac sodium in the range of 5 – 20 $\mu\text{g/mL}$. The absorbance of diclofenac sodium was monitored at 276 nm and the corresponding absorbance were obtained. From those absorbances, a graph of concentration and absorbance was plotted. The regression equation (Figure 1) obtained was used to estimate the amount of drugs present in tablet dosage formulations.

3. Results and discussion

3.1 Powder micromeritics

Diclofenac sodium formulations were prepared by using four grades of HiCel™ samples. These powder blends were evaluated by physical tests as in Table No. 2. Formulation F1, contained HiCel™ 25M, exhibited poor flowability, evidenced by an angle of repose of 52° and a bulk density of 0.35 g/ mL. This indicated a highly cohesive powder, posing potential challenges for uniform die filling during tablet compression (18). In contrast, formulations F2 and F3, containing HiCel™ 50M and HiCel™ 90M respectively showed improved flow characteristics. F2 presented an angle of repose of 50° and a bulk density of 0.37 g/ mL, while F3 displayed an angle of repose of 53° and a bulk density of 0.34 g/ mL. F3 shows higher angle of repose, both grades were generally recognized for their favorable flow properties, suggesting a balance of particle size and interparticulate forces conducive to more consistent powder handling. Formulation F4, which comprised the HiCel™ LP200 grade, exhibited superior flowability, characterized by a lower angle of repose of 46° . This indicated a highly free-flowing powder blend, attributable to the coarser particle size distribution typical of HiCel™ LP200.



3.2 Tableting properties

Physical properties of diclofenac sodium tablet containing varying grades of HiCel™ and obtained by direct compression technique is represented in Table No. 3. Formulation F1, contained HiCel™ 25M, exhibited good compressibility. This was primarily attributed to the fine particle size of HiCel™ 25M, which facilitated completely filling interparticulate void spaces, intimate particle contacts and enhanced interparticulate bonding upon compression. Furthermore, the inherent high surface area of these fine particles resulted into quick disintegration time, it enabled efficient water wicking properties and subsequent rapid tablet breakdown (19). Conversely, formulations F2 and F4, containing HiCel™ 50M and HiCel™ LP200, showed comparable hardness and disintegration time indicated that both grades provided a favorable balance between tablet mechanical strength and water adsorption. The coarser nature of HiCel™ LP200 (in F4) typically provided superior flow, which combined with its established binding properties, contributed to robust tablets (20). Formulation F3, featuring HiCel™ 90M, showed a relatively lower tablet hardness and a prolonged disintegration time of 418 sec. Also exhibiting higher friability than all other formulations. The overall performance of F3 in terms of hardness and disintegration was less favorable compared to F2 and F4. This suggests that while HiCel™ 90M offered adequate binding and higher friability, its particle size and characteristics may have resulted in a less efficient compaction profile compared to the other grades, thus influencing the critical quality attributes of the diclofenac sodium tablets.

3.3 *In-vitro* Dissolution study of diclofenac sodium immediate release tablet

At least 80% of the labeled amount of diclofenac sodium should be dissolved within 60 min (21). A comprehensive dissolution study was conducted on diclofenac sodium tablets, incorporating four distinct grades of HiCel™ Microcrystalline Cellulose (MCC) powder. As showed in Figure 2, F1 formulation which contained HiCel™ 25M that is finer grade of microcrystalline cellulose, exhibited an exceptionally rapid and complete drug dissolution. Drug release at the initial 5 min interval, followed by 111.84% at 15 min, 108.56%. This accelerated dissolution profile was attributed to the high surface area of fine particle of the HiCel™ 25M. This might have contributed to an increased surface area available for dissolution (22, 23). However improper filling of die cavity due to poor flowability of fine particles lead to fluctuation or unevenness in uniform distribution of powder blend resulting in uneven drug assay, disintegration and dissolution. Conversely, the remaining three formulations (F2, F3 and F4) demonstrated dissolution results well within acceptable compendial specifications. Notably, the F4 formulation, containing HiCel™ LP200, exhibited a superior drug dissolution profile as 90.78% drug dissolution were the other, F2 showed 91.84%, F3 showed 80.83% drug dissolution that closely aligned with the requirements stipulated in the United States Pharmacopeia (USP) monograph for diclofenac sodium tablets. All tested formulations successfully achieved more than 80% drug release within the 60 min time frame. This indicated their general suitability for formulating immediate-release solid oral formulations. The graph demonstrated in Figure 3 demonstrated a correlation between particle size distribution of different grades of HiCel™ microcrystalline cellulose and the tablet properties. F1 containing HiCel™ 25M with a D-90 of 55.6 µm, exhibits the fastest disintegration time of 10.33 sec. This rapid disintegration suggests a large surface area for water penetration and high porosity, lead to quick tablet breakdown. F2 containing HiCel™ 50M with a D-90 of 132 µm and average weight of 265 mg showed increased dissolution time of 358 sec. Also, the F3 containing HiCel™ 90M with a D-90 of 210 µm resulted into slower disintegration time of 418 sec. F4 containing HiCel™ LP200 with a D-90 of 444 µm showed a disintegration time of 372 sec. As the particle size of microcrystalline cellulose is increased it had resulted into longer disintegration time.

4. Conclusion

Evaluation of diclofenac sodium powder blends containing different HiCel™ Microcrystalline cellulose grades revealed significant correlations between particle size distribution and micromeritic properties, compressibility and dissolution profiles. Fine grade, HiCel™ 25M (F1) demonstrated poor flowability but excellent compressibility and rapid drug dissolution likely because of its fine particle size and high surface area. In contrast, coarser grade HiCel™ LP200 (F4) exhibited superior flowability and fair compressibility, leading to robust formulation with optimal dissolution characteristics. HiCel™ 50M (F2) also showed improved flow and favorable dissolution, similar to F4. While HiCel™ 90M (F3) demonstrated fair tablet strength and disintegration time. Overall, the study highlighted the critical role of microcrystalline cellulose particle size distribution in dictating the processability, quality and performance of diclofenac sodium tablets, with HiCel™ LP200 emerging as a promising excipient for achieving a balance of desirable micromeritics, manufacturing ease and formulation performance.

5. Acknowledgements

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6. Conflict of interest

The authors state and confirm no conflict of interest.



7. References

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Figure Legends

Figure 1. Standard calibration curve of diclofenac sodium.

Figure 2. *In-vitro* drug dissolution profile of diclofenac sodium tablet.

Figure 3. Effect of Particle size distribution (PSD) on disintegration time of diclofenac sodium tablet.

Tables

Table No.1 Diclofenac sodium tablet composition

| Sr. No. | Ingredients | Quantity of Ingredients (% w/w) | | | |
|---------|---------------------------|---------------------------------|-------|-------|-------|
| | | F1 | F2 | F3 | F4 |
| 1 | Diclofenac sodium | 10.00 | 20.00 | 20.00 | 20.00 |
| 2 | HiCel™ 25M | 83.75 | - | - | - |
| 3 | HiCel™ 50M | - | 73.75 | - | - |
| 4 | HiCel™ 90M | - | - | 73.75 | - |
| 5 | HiCel™ LP200 | - | - | - | 73.70 |
| 6 | Colloidal silicon dioxide | 1.15 | 1.15 | 1.15 | 1.15 |
| 7 | Croscarmellose sodium | 2.30 | 2.30 | 2.30 | 2.30 |
| 8 | Talcum powder | 2.00 | 2.00 | 2.00 | 2.00 |
| 9 | Magnesium stearate | 0.80 | 0.80 | 0.80 | 0.80 |
| | Total | 100 | 100 | 100 | 100 |

Table No. 2 Diclofenac sodium blend properties

| Sr. No. | Formulations | Particle size distribution (wet/dry) Sieve analysis | | Micromeritics | | | | |
|---------|--------------|---|----------------------|---------------------|-----------------|------------------|-------------------------------|----------------------------|
| | | +60 # mesh ASTM (%) | +200 # mesh ASTM (%) | Angle of repose (°) | Hausner's ratio | Carr's Index (%) | Untapped Bulk Density (g/ mL) | Tapped Bulk Density (g/mL) |
| 1 | F1 | 0.30 | 58.00 | 52 | 1.542 | 35.18 | 0.35 | 0.54 |
| 2 | F2 | 0.40 | 27.00 | 50 | 1.472 | 32.07 | 0.37 | 0.55 |
| 3 | F3 | 1.40 | 56.70 | 53 | 1.608 | 37.83 | 0.34 | 0.55 |
| 4 | F4 | 18.80 | 81.40 | 46 | 1.300 | 23.43 | 0.39 | 0.51 |

F1- Diclofenac powder blend containing HiCel™ 25M and other tablet excipients.

F2- Diclofenac powder blend containing HiCel™ 50M and other tablet excipients.

F3- Diclofenac powder blend containing HiCel™ 90M and other tablet excipients.

F4- Diclofenac powder blend containing HiCel™ LP200 and other tablet excipients.



Table No. 3 Diclofenac tablet physical properties

| Sr. No. | Formulations | Average Thickness (mm) | Average Hardness [Kp(kgf)] | Average Weight variation (mg) | Friability (%) | Average Disintegration Time (sec) |
|---------|--------------|------------------------|----------------------------|-------------------------------|----------------|-----------------------------------|
| 1 | F1 | 3.80 | 12.36 | 262.7 | 0.01 | 10.33 |
| 2 | F2 | 3.59 | 12.57 | 265.0 | 0.05 | 358.00 |
| 3 | F3 | 3.57 | 9.72 | 265.2 | 0.12 | 418.00 |
| 4 | F4 | 3.55 | 13.86 | 267.2 | 0.10 | 372.00 |

F1- Diclofenac tablets containing HiCel™ 25M and other tablet excipients.

F2- Diclofenac tablets containing HiCel™ 50M and other tablet excipients.

F3- Diclofenac tablets containing HiCel™ 90M and other tablet excipients.

F4- Diclofenac tablets containing HiCel™ LP200 and other tablet excipients.

Figures

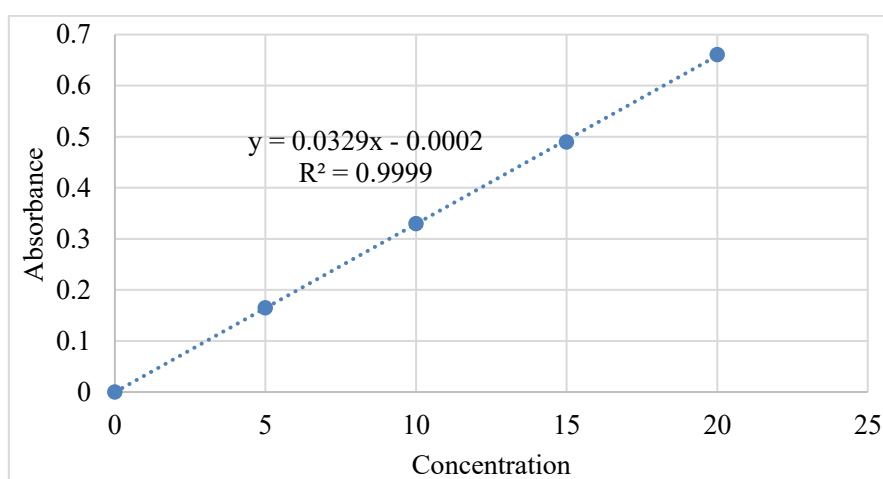


Figure 1. Standard calibration curve of diclofenac sodium.

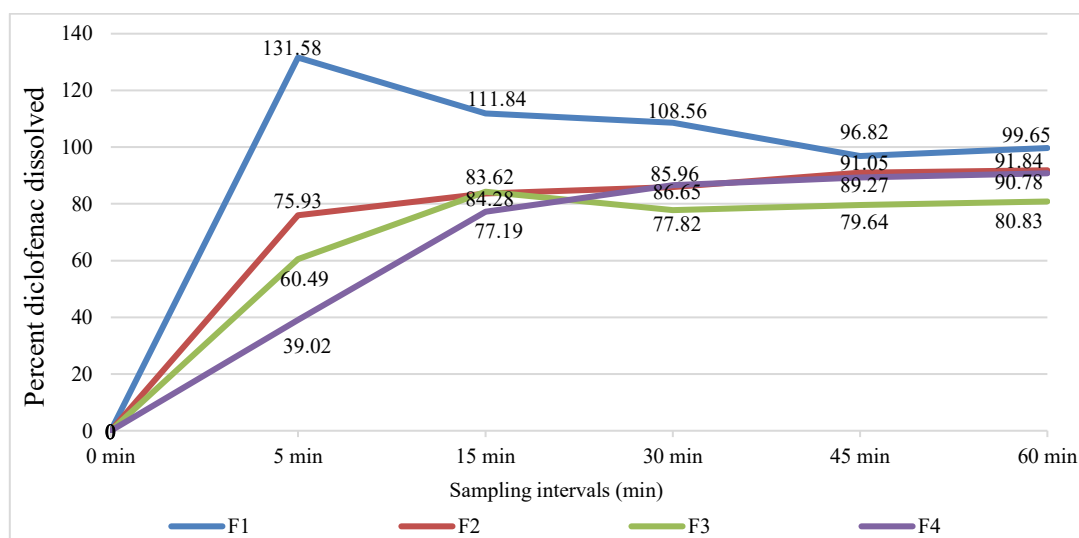


Figure 2. *In-vitro* drug dissolution profile of diclofenac sodium tablet.



F1- Diclofenac tablets containing HiCel™ 25M and other tablet excipients.

F2- Diclofenac tablets containing HiCel™ 50M and other tablet excipients.

F3- Diclofenac tablets containing HiCel™ 90M and other tablet excipients.

F4- Diclofenac tablets containing HiCel™ LP200 and other tablet excipients.

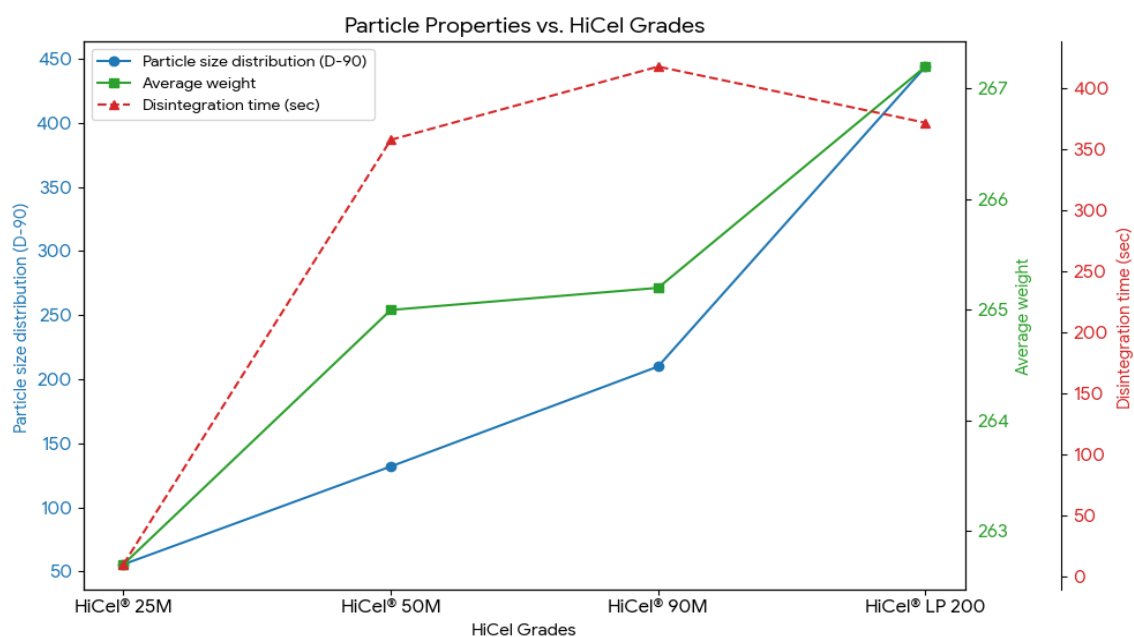


Figure 3. Effect of Particle size distribution (PSD) on disintegration time of diclofenac sodium tablet.

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