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# Paradoxical Effects of Superdisintegrants on Dissolution Performance in Ibuprofen Orodispersible Tablets

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## ABSTRACT

**Introduction:** Pharmacopoeial tests for the characterization of solid drug forms may not be sufficiently discriminatory when applied to orally dispersible tablets (ODTs), primarily due to the requirement for rapid disintegration. The aim was to examine the influence of mannitol and disintegrant content on the results of selected pharmacopoeial and non-pharmacopoeial methods for the characterization of ibuprofen ODTs. **Methods:** Eight different formulations of 100-mg ibuprofen ODTs were prepared with different proportions of mannitol in the filler (25% and 75%) and varying the type and concentration of superdisintegrant (SSG at 2% and 8% or CCS at 0.5% and 5%). The tablets were obtained by direct compression and had similar resistance to crushing ($p < 0.01$). The effects of the ODT composition on the results of disintegration, dissolution, wettability, medium absorption rate, and hygroscopicity were measured. **Results:** All eight formulations disintegrated in less than 3 minutes. Those with 5% CCS and 25% or 75% mannitol and the formulation with 0.5% CCS and 75% mannitol had disintegration times less than 30 seconds. With an increase in the proportion of CCS, the dissolution rate decreased in the formulations with a low proportion of mannitol. Increased disintegrant content enhanced medium absorption. The hygroscopicity test was most discriminatory, showing lower values in formulations with higher mannitol. **Conclusion:** The dissolution test is not discriminatory for formulations containing a high proportion of mannitol, if the first sampling is at 5 minutes. The disintegrant proportion must be considered to ensure proper disintegration times and achieve rapid dissolution rates.

**KEYWORDS:** sodium starch glycolate, croscarmellose sodium, dissolution, wettability, orally dispersible tablets

## INTRODUCTION

Ibuprofen (IBU) is a widely used active pharmaceutical ingredient (API) known for its anti-inflammatory, analgesic, and antipyretic effects. Due to its inherent properties, including low solubility and high permeability, IBU is classified in the second group of the Biopharmaceutical Classification System (BCS II) (*1*).

Solid dosage forms, such as orodispersible pharmaceutical formulations, are increasingly present in the pharmaceutical market due to their advantages, including easy administration without the need for additional water, rapid disintegration, and suitability for patients with swallowing difficulties (*2*). Although liquid forms of drugs are most suitable for children under 2 years of age, orodispersible tablets (ODTs) can be used from the second year of life. During the development of ODT formulation, the selection of excipients and disintegrants plays an important role. The desired properties of excipients are high physiological tolerability, non-toxicity, compatibility with other excipients and APIs, good taste and mouthfeel (which is especially important for ODT), good compressibility and flowability, and low hygroscopicity (*3*, *4*).

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Mannitol as an excipient stands out for its physicochemical characteristics such as low hygroscopicity and high inertness. These properties result in good compressibility, allowing for production of highly durable tablets. Furthermore, mannitol is well-suited for oral pharmaceutical dosage forms because of its excellent solubility and compatibility with individuals who have lactose or fructose intolerance (*4*).

Superdisintegrants, such as sodium starch glycolate (SSG) and croscarmellose sodium (CCS), are commonly used to increase the rapid dissolution of solid drug formulations. SSG is typically used at concentrations ranging from 2–8%, and CCS is utilized in concentrations between 0.5% and 5% in tablet formulations (*5*). The mechanism of action of both superdisintegrants is similar, as both promote swelling to facilitate tablet disintegration (*6*).

In this study, IBU ODTs were formulated and produced using the direct compression method, with a dose of 100 mg and varying concentrations of mannitol (25% and 75%) and superdisintegrants (SSG at 2% and 8% or CCS at 0.5% and 5%). The objective was to evaluate the effects of these modifications using both non-pharmacopoeial test methods, such as wettability, medium absorption rate, and hygroscopicity, as well as pharmacopoeial procedures, including disintegration and dissolution tests. Additionally, a comparison was made between the results of ODT testing using pharmacopoeial and non-pharmacopoeial methods.

## METHODS

### Materials

IBU, which complies with the *European Pharmacopoeia* 11 (EP) requirements, was sourced from Farmalabor (Italy). Spray-dried α-lactose monohydrate (LAC, Supertab 21AN, DFE Pharma, Germany) and mannitol (Farmalabor) were used as fillers. SSG (Primojel, DFE Pharma, Germany) and CCS (Galenika AD, Serbia) served as superdisintegrants. Colloidal silicon dioxide (Centrochem, Serbia) and magnesium stearate (Farmalabor) were employed as a glidant and lubricant, respectively.

For the content uniformity test, the tablets were dissolved in a sodium hydroxide solution (Lachner, Czech Republic) at a concentration of 4 g/L (*7*). A phosphate buffer with a pH of 7.2, prepared using potassium phosphate and potassium dihydrogen phosphate salts (Lachner, Czech Republic) according to United States Pharmacopeia (USP) recommendations, was used for the dissolution test (*8*).

Methylene blue (Fluka, Biochemika, Germany) at a concentration of 1 mg/mL and filter paper (ø 110 mm, Macherey-Nagel, Germany) were employed for the tablet wettability test.

### Preparation of Ibuprofen Orodisposable Tablets (ODTs)

The composition of the investigated formulations was characterized by a fixed proportion of IBU (20%), silicon dioxide (0.5%), and magnesium stearate (0.5%). The proportion of mannitol in the filler varied (25% or 75%), as did the proportions of the superdisintegrants used - SSG (2% or 8%) or CCS (0.5% or 5%) (Table 1). A total of 100 g of tablet blend was prepared. All components, except for magnesium stearate, were blended in a powder mixer (Farmalabor) for 25 minutes at a speed of 130 rpm (blending intensity 5/5) in a plastic box filled to approximately 50% of its volume. After the initial blending, magnesium stearate was added, and blending continued for an additional 2 minutes under the same conditions. The preparation of IBU ODTs (100 mg) was carried out using an eccentric tablet press (EK0, Korsch, Germany). The tablet blend contained 20% IBU, and the lower punch was adjusted to fill the tablet blend with a mass of 0.50 g, providing the desired dose. The position of the upper punch was adjusted to achieve satisfactory tablets with the lowest possible compression. After preparing, the tablets were stored in plastic boxes until testing.

*Table 1. Composition of Tested Formulations*

| Component | Formulation | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 |
| Ibuprofen | 20% | 20% | 20% | 20% | 20% | 20% | 20% | 20% |
| LAC:MAN (75:25) | 77% | 71% | 78.5% | 74% | – | – | – | – |
| LAC:MAN (25:75) | – | – | – | – | 77% | 71% | 78.5% | 74% |
| SSG | 2% | 8% | – | – | 2% | 8% | – | – |
| CCS | – | – | 0.5% | 5% | – | – | 0.5% | 5% |
| Silicon dioxide | 0.5% | 0.5% | 0.5% | 0.5% | 0.5% | 0.5% | 0.5% | 0.5% |
| Magnesium stearate | 0.5% | 0.5% | 0.5% | 0.5% | 0.5% | 0.5% | 0.5% | 0.5% |

*Dash (–) indicates not applicable.*
*LAC: lactose; MAN: mannitol; SSG: sodium starch glycolate; CCS: croscarmellose sodium.*

### *Experimental Design*

A $2^2$ factorial design (Design Expert 13, StatEase) was utilized to investigate the impact of formulation composition on the outcomes of selected tests. The independent variables were as follows: $X_1$, the proportion of mannitol in the filler, with levels set at –1 (25%) and +1 (75%), and $X_2$, the proportion of superdisintegrants, with levels at –1 (2% for SSG and 0.5% for CCS) and +1 (8% for SSG and 5% for CCS). The dependent variables analyzed included disintegration, IBU drug release at 5 minutes, wettability, medium absorption rate, and hygroscopicity.

### *Pre-Formulation Testing*

The solubility of IBU was determined in phosphate buffer (pH 7.2) and 0.1 M sodium hydroxide solution (pH 13). The test was conducted in a thermostatic water bath equipped with a shaker (Witeg, Germany). The temperature was maintained at 37 °C, and the shaking speed was set to 200 rpm. Sampling from the saturated solutions was carried out after 2 and 24 hours. The samples were then filtered through a 0.45-µm membrane filter (Sartorius Lab Instruments, Germany), diluted, and analyzed spectrophotometrically.

The bulk and tapped volumes of pure substances and prepared tablet blend were determined using a jolting volumeter (Stav II, J. Engelsmann AG, Germany). A 50-mL measuring cylinder was used, with a sample mass of approximately 30 g. Bulk volume and the volume after 10, 100, 500, 900, and 1250 impacts were recorded. All measurements were performed in triplicate, and the results are presented as mean values ± SD. The index of compressibility, Hausner ratio, and flow categorization were calculated according to EP guidelines (2.9.36.) (*9*).

The angle of repose was determined for pure substances and tablet blends. A glass funnel was positioned on a laboratory stand such that its outlet was 3 cm above the workbench and paper. The test powders were allowed to fall freely through the funnel in the amount required to form a cone 3 cm in height. The diameter of the cone's base was measured, and the angle of repose was calculated according to EP 2.9.36 (*9*). The test was performed in triplicate, and the results are presented as mean values ± SD.

### Physiochemical Assessment of IBU ODT Formulations

Disintegration (2.9.1), uniformity of mass (2.9.5) and content (2.9.6 Test A), friability (2.9.7), and hardness (2.9.8.) were evaluated in accordance with EP 11 (*9*). A disintegration (Erweka ZT54, Germany) and friability tester (Erweka TA) were used. Hardness was assessed using a durometer tester (Farmalabor). Additionally, the diameter and thickness of each tablet were measured with a Vernier caliper 24 hours after tablet preparation. The dissolution test was performed using a dissolution tester (Erweka DT800). Test conditions were set according to the United States Food and Drug Administration (FDA) recommendations for IBU chewable tablets (*10*). The test medium consisted of 0.05 M phosphate buffer with a pH of 7.2 (900 mL). The apparatus with paddles was operated at 50 rpm and 37 °C. Samples were withdrawn at 5, 15, 25, 35, 45, and 60 minutes. Prior to analysis, the samples were filtered using 0.45-µm membrane filters (Sartorius Lab Instruments).

The wettability and medium absorption rate were determined by placing one tablet in a prepared plastic Petri dish with a diameter of 3.5 cm. The preparation of the Petri dish involved placing three layers of filter paper, which were soaked with 550 µL of methylene blue solution (volume determined by pilot testing). The time required for the tablet to turn blue, indicating wetting of the surface, was recorded. The mass of the tablet before and after the wettability test was also measured, and the medium absorption rate was calculated. All tests were performed in triplicate.

The hygroscopicity of the tablets was evaluated under conditions of increased humidity (75% ± 2%) in a desiccator, using a saturated aqueous solution of sodium chloride. The weight of the tablets was measured before the test and after 2 and 7 days of exposure to increased humidity.

### UV/Vis Spectrophotometry

Spectrophotometric determination of IBU in the solubility, uniformity of content, and dissolution testing was performed by measuring the absorbance at 264 nm using the previously applied method (*11*). A UV-Vis spectrophotometer (8453, Agilent Technologies, USA) was used for the measurements. Linearity was confirmed within the concentration range of 3.90625–250 µg/mL ($R^2$ = 0.9989).

### Statistical Analysis

To examine the discriminative power of the methods, a one-factor analysis of variance (ANOVA) was performed. Pearson correlation coefficient was used to compare the results of the conducted tests. Preliminary analyses were conducted to assess normality, linearity, and homogeneity of variance. Statistical analysis was performed using IBM SPSS Statistics 26 software package.

## RESULTS AND DISCUSSION

The results of the IBU solubility test in two different media (phosphate buffer at pH 7.2 and 0.1 M sodium hydroxide solution at pH 13) at 37 °C were evaluated to determine the sink conditions for the dissolution test and to assess the suitability of each medium for the content determination test. After 24 hours at 37 °C, IBU solubility was 4.71 and 12.25 mg/mL at pH 7.2 and 13, respectively. IBU is a weak acid, with a pKa value in the range of 4.5–4.6 (*12*). Based on the obtained solubility values, it can be concluded that IBU solubility increases with increasing pH. The highest solubility is observed at pH 13, which can be explained by the increased dissociation of weak acids with rising pH, leading to IBU predominantly existing in its ionized, more soluble form. Similar results from an IBU solubility test were reported by Levis et al., i.e., solubility was similarly influenced by the pH of the tested media (at pH 6.8 and 7.4 at 37 °C) (*13*). The results confirm the presence of sink conditions when 900 mL of phosphate buffer at pH 7.2 (as per FDA recommendations) is used as the medium for testing the dissolution of 100-mg IBU ODTs.

Before tableting, the flowability of the IBU tablet blends was assessed, and it was found that the addition of a glidant improved the flowability compared to the filler (both individually and in blends) and pure IBU. However, the Hausner ratio, compressibility index, and angle of repose indicated better flowability for the formulations with 25% mannitol (F1–F4) compared to those with a 75% mannitol (F5–F8). Furthermore, the flowability results influenced the mass variation test, with formulations F1–F4 exhibiting less mass variation compared to formulations F5–F8. Formulations F5 and F7 contained 75% mannitol and did not meet EP 11 requirements for mass variation, but IBU content in individual tablets ranged from 91.11–111.93% (mean values) in all eight formulations.

Results of the tablet hardness test, tablet thickness measurements, friability, and disintegration times are shown in Figure 1. All measured tablet diameters were consistently 12.0 mm with no observed variation across all formulations (12.0 ± 0.0 mm). As shown in Figure 1A, the tablets were formulated to have similar hardness values ($p < 0.01$) to avoid biasing the test results. Low values were chosen to ensure rapid disintegration of the ODT. However, formulations with high mannitol content (F5–F8) had significantly higher friability values due to capping (Fig. 1B) compared formulations containing 25% mannitol. Therefore, future studies should focus on development and optimization of formulations with high mannitol content.

The longest disintegration time was required for formulations F1, F2, and F5 (Fig. 1C). Formulations F1 and F5 had 2% SSG. Having a higher proportion of SSG (8%) shortened the disintegration time in the formulation with 75% mannitol (F6) compared with the 25% mannitol formulation (F2). Formulations with CCS led to faster disintegration of the tested ODTs. Formulations F4, F8 (5% CCS) and F7 (0.5% CCS and 75% mannitol) had a disintegration time shorter than 30 seconds. Although USP and EP do not provide precise disintegration criteria specifically for ODTs, regulatory guidelines offer relevant recommendations. An in vitro disintegration time of approximately 30 seconds or less is generally considered appropriate for ODTs, as it supports administration without the need for water or chewing. Dosage forms with disintegration times exceeding 30 seconds are more suitably classified as chewable tablets or oral tablets (*14*). The results of similar studies suggest that mannitol is the recommended excipient for ODT, as is the superdisintegrant CCS, but it is necessary to optimize its proportion to avoid poor dissolution test results (*15*).

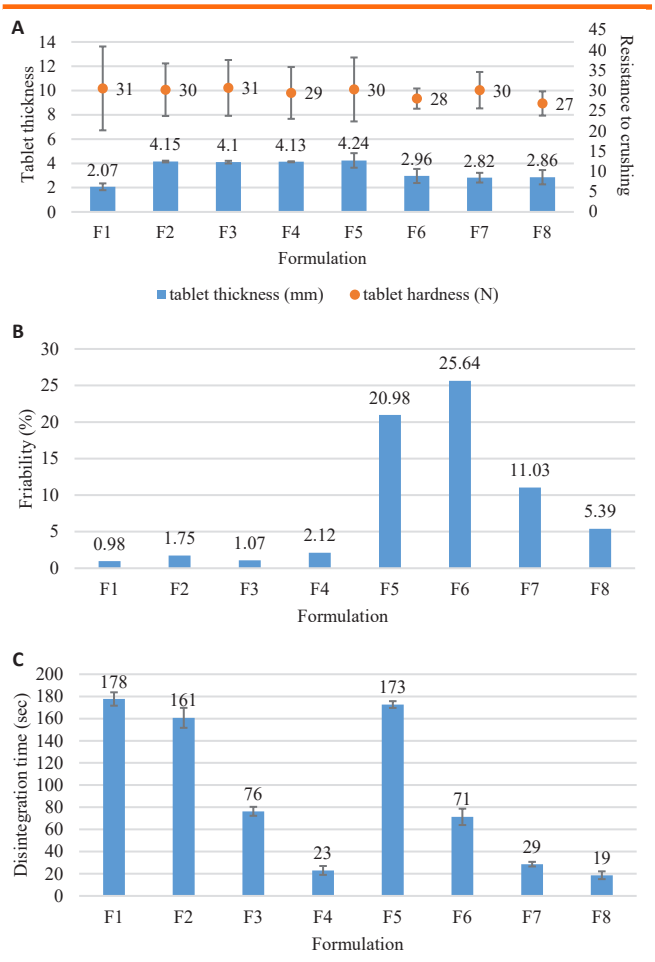


*Figure 1. Assessment of (**A**) tablet thickness and hardness, (**B**) friability, and (**C**) disintegration of the tested formulations.*

In this study, all formulations dominated by mannitol (F5–F8) released the entire content and were considered similar to each other, and the type and proportion of superdisintegrant had no significant effect on the dissolution test results (Fig. 2B). On the other hand, differences in the dissolution profiles for formulations with low mannitol content (F1–F4) were observed according to the type and amount of superdisintegrant present (Fig. 2A). An increase in the proportion of SSG from 2% to 8% resulted in faster dissolution content (F2 vs. F1). Paradoxically, an increase in CCS from 0.5% to 5%, resulted in a slower release of IBU (F4 vs. F3). The dissolution method used showed discriminative power in differentiating the dissolution profiles of formulations with low mannitol content (F1–F4). Previously published studies have identified a reduction in dissolution rate associated with higher concentrations of CCS. Partial gelation may occur, which can form a viscous barrier and limit the dissolution rate (*15*).

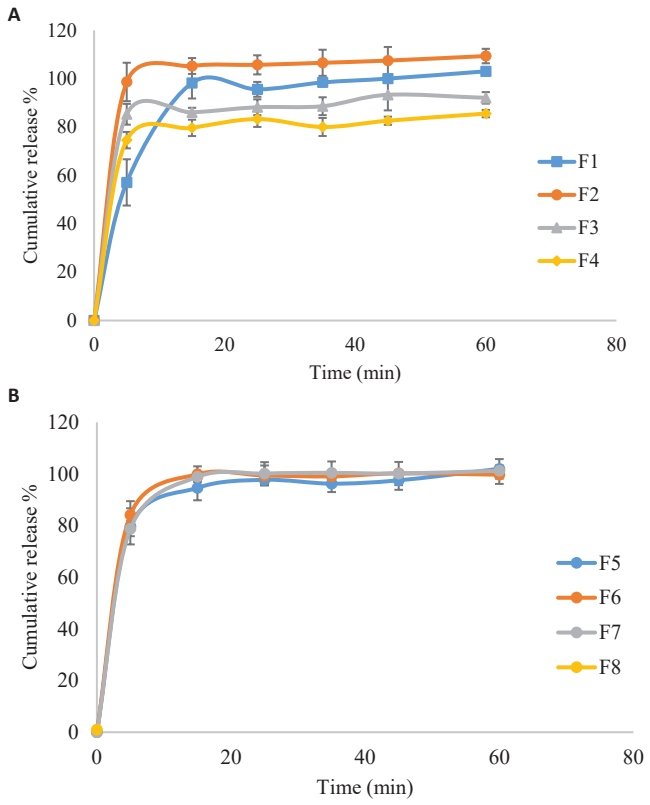


*Figure 2. Dissolution profiles of tested tablet formulations F1–F4 (**A**) and F5–F8 (**B**).*

Wettability measurement can be employed as an additional test for the characterization of ODT since disintegration and wettability have a positive linear correlation, as this study demonstrated (Fig. 3A). Wettability did not significantly change with 5% CCS compared with 0.5% CCS (F4 vs. F3 and F8 vs. F7). In any case, wettability of formulations with CCS (F3, F4, F7, and F8) was significantly faster than those with SSG (F1, F2, F5, and F6). Tsabita et al. reached the same conclusion. In their study of acetosal ODTs, the formulation containing CCS exhibited shorter wettability time compared to that with SSG (*16*).

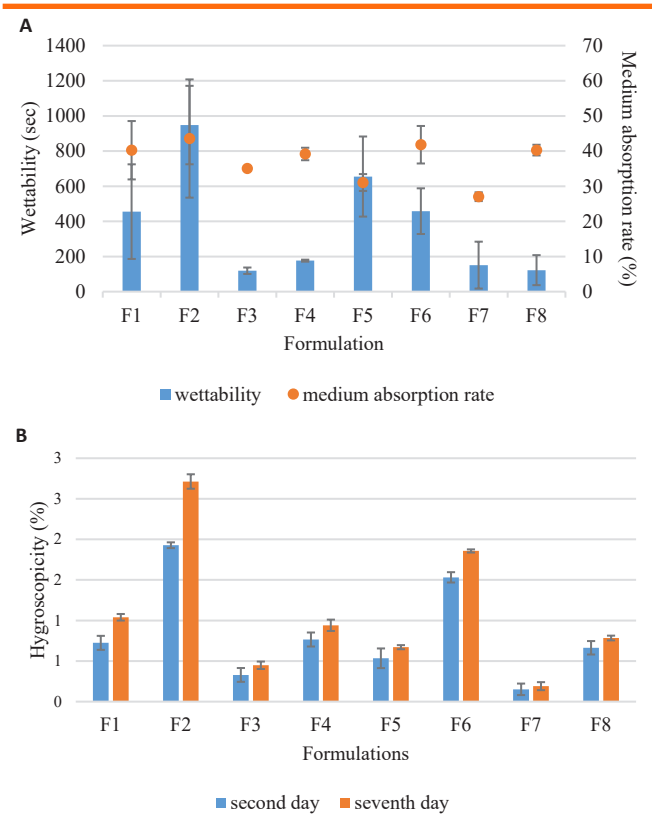


*Figure 3. Assessment of (**A**) wettability and medium absorption rate and (**B**) hygroscopicity of the tested formulations*

Medium absorption rate and wettability reflect the swelling capacity of superdisintegrants in the presence of a small amount of liquid (*17*). A higher medium absorption rate was observed for formulations with SSG, which also required a longer wettability compared to CCS (Fig. 3A). These results indicate a correlation between the medium absorption rate and hygroscopicity (Fig. 3B), i.e., a formulation that is more hygroscopic has a higher medium absorption rate. Data reported by Aglawe et al. suggest that SSG has a higher medium absorption rate than CCS (*18*).

Figures 4 and 5 illustrate the impact of mannitol and superdisintegrants on disintegration, cumulative release in 5 minutes, wettability, medium absorption rate, and hygroscopicity. Superdisintegrants have a dominant positive influence on hygroscopicity, which is reduced

by the negative influence of mannitol as a filler, and is further reduced by their interaction. The highest hygroscopicity level was observed in formulation F2 (Fig. 3B), which is characterized by 8% SSG. This outcome was expected based on the work of Faroongsarng et al., where higher hygroscopicity of SSG was observed compared with CCS under the same temperature and humidity conditions (*19*). According to the results of our study, the hygroscopicity test gave the most discriminatory results for the characterization of ODTs (Figs. 4 and 5) as well as a positive linear correlation with dissolution, wettability, and medium absorption rate.

## CONCLUSION

This study examined the influence of mannitol and superdisintegrants SSG and CCS on disintegration, dissolution, wettability, medium absorption rate, and hygroscopicity of IBU ODTs. All eight tested formulations disintegrated within 3 minutes. The strict regulatory requirement of disintegration within 30 seconds was met by formulations with 25% mannitol and 5% CCS (F4) as well as 75% mannitol with 0.5% and 5% CCS (F7 and F8). Friability testing highlighted the superiority of formulations with low mannitol (F1–F4), whereas those with high mannitol (F5–F8) require further optimization of process parameters. Paradoxically, in formulations with low mannitol content, increasing the proportion of superdisintegrant CCS (F4 vs. F3) led to slower dissolution of IBU. Among all evaluated tests, hygroscopicity proved to be the most discriminative, showing a positive linear correlation with dissolution, wettability, and medium absorption rate. The complex interplay of multiple factors affecting these results highlights the need for comprehensive consideration in future research focused on ODT development.

## DISCLOSURES

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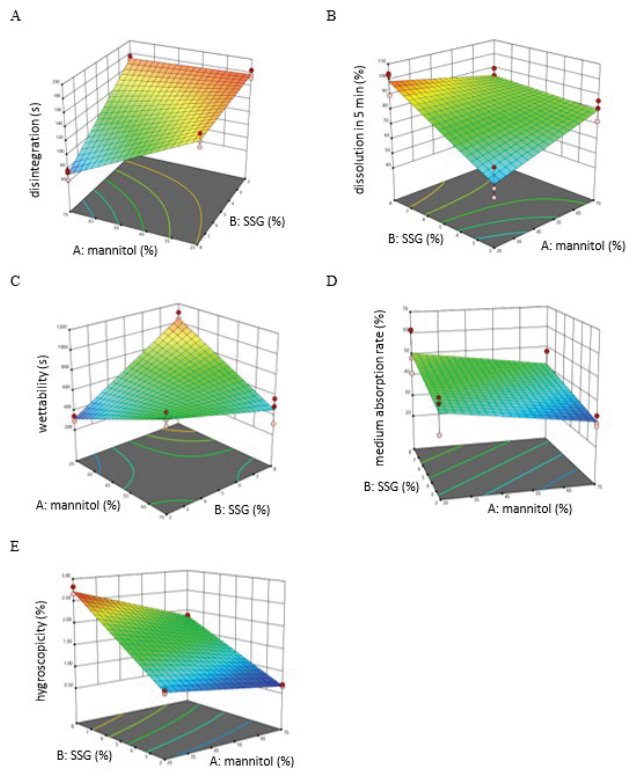


*Figure 4. Three-dimensional representation of the influence of formulation composition on (**A**) disintegration, (**B**) dissolution rate in 5 minutes, (**C**) wetting time, (**D**) degree of medium absorption, and (**E**) hygroscopicity of formulations F1–F4.*

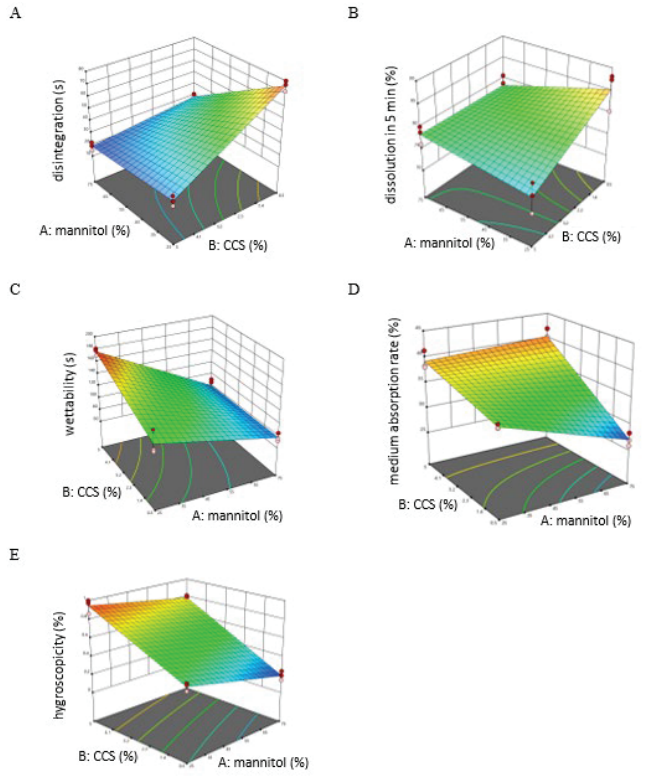


*Figure 5. Three-dimensional representation of the influence of formulation composition on (**A**) disintegration, (**B**) dissolution rate in 5 minutes, (**C**) wetting time, (**D**) degree of medium absorption, and (**E**) hygroscopicity of formulations F5–F8.*

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