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# Binder and Disintegrant Properties of Sweet Potato Starch from Côte D'ivoire on Tablet Formulation: Effect of Granulation Method.

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**Abstract**

This study demonstrates the differences obtained when using different methods of granulation to evaluate binder and disintegrant activities on sweet potato starch in pharmaceutical tablets.

Formulation made with starch paste, sweet potato starch and arabic gum were compared. In addition, cellulose was used in this study in dry granulation as disintegrant component whose properties are well understood.

Four tests formulation containing Amoxicillin were prepared by wet and dry granulation. In wet granulation, the starch paste was prepared using sweet potato starch comparing to arabic gum and in dry granulation sweet potato starch comparing to cellulose (Avicel pH 101).

The two methods of granulation were found to have similar traits when evaluated based on particle size distribution, powder rheology aspect. Tablets prepared from these granulations methods were shown to be similar when evaluated for degree of friability, weight uniformity. All starch formulation disintegrated within 5 minutes and produced a different dissolution profile.

The result of this study give an indication as to binding activity of sweet potato starch produce in Côte d'Ivoire but by wet granulation.

Key words**:** granules, Sweet potato starch, binder, disintegrant.

## 1. Introduction

Since the introduction of tablets into the pharmaceutical industry, corn starch has been recognized as the one of the most commonly used excipient in the manufacture of tablets **[1]**.In order to improve sweet potato starch which always used in Cote d'Ivoire, a west African country for its nutritive value , we found through some studies that Sweet potato starch can be use as binder.The evaluation of starch's binder and disintegrant activities has been the subject of numerous research publication **[2]** but it is interesting to note that however that while studies comparing different types of starches have been conducted **[3,4],** no one as yet evaluated the possible binder activity of sweet potato from Cote d'Ivoire and rases up the best method of granulation that improve best characteristics to tablets.Thus, the purpose of this study is to evaluate the difference in granule and tablets properties that may be obtained when using differents methods of granulation as both binder and disintegrant in the preparation of pharmaceutical tablets.

## 2. Materials and Methods

2.1. Materials.

Sweet potato starch (Ipomea batatas) from Cote d'Ivoire, microcristallin cellulose (Avicel pH101), tricalcium phosphate n° 016062, arabic gum and sweet potato starch paste as 15%, talcum n°223249 and magnesium stearate were the other excipients used in this study and were recieved from French Pharmaceutical Cooperation.

The test drug, Amoxicillin trihydrate (p 990251), was obtained from CIPHARM (Compagnie Ivoirienne Pharmaceutique).

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2.2. Preparation of tablets.
Four tests formulas containing Amoxicillin were prepared by wet and dry granulation (See Table 1).

Table 1: Composition of tablets formulation

| | Wet Granulation | | Dry Granulation | |
|---|---|---|---|---|
| | Formula I | Formula II | Formula III | Formula IV |
| **Amoxicillin trihydrate (mg)** | 250 | 250 | 250 | 250 |
| **Tricalcium phosphate (mg)** | 186,5 | 186,5 | - | - |
| **Sweet potato starch (mg)** | - | - | 186,5 | - |
| **Avicel pH101 (mg)** | - | s q f | - | 186,5 |
| **Starch paste as 15 %** | sqf | - | - | - |
| **Arabic gum as 15 %** | - | s q f | - | - |
| **Magnesium stearate (mg)** | 4 ,5 | 4,5 | 4,5 | 4,5 |
| **Talcum (mg)** | 9 | 9 | 9 | 9 |
| **Total** | 450 mg | 450 mg | 450 mg | 450 mg |

S q f 500 tablets

- **Wet granulation**

Amoxicillin, tricalcium phosphate were first blended in a instrumented mortar for 5 minutes. The dry blend was granulated whith the apropriate granulating fluid (starch paste as 15%) for the first formula and arabic gum as 15% for the second.
The granulations were sieved through a 1mm screen and dried in a bed fluid air (RETSCH G100, Germany). The dried granulations were then sieved and blended with magnesium stearate in a TURBULA mixer at 90 rpm for 20 minutes.

- **Dry granulation**

Amoxicillin, avicel pH101 and sweet potato starch were also blended in the same conditions but without granulating fluid.
Final blends were compressed on an instrument from FORGERAIS OA type (France) equipped with a motor faced punches to a weight around 450 mg and hardness of 6-10 kg.

2.3. Granules Evaluation.
Each granulation was evaluated for powder flow, bulk, and particle size distribution.

2.4. Tablet evaluation.
Tablets disintegration was evaluated in 37°± 0, 5 C distilled water (disintegration apparatus ERWEKA ZT3 type -Germany).The weight, hardness and friability of tablets were also evaluated.
Dissolution profiles. Dissolution profiles of tablets were obtained on 900ml of 0,1 N Hcl using a dissolution apparatus (Pharmatest PTW II- Germany). The amount of drug released into the dissolution media was measured via UV spectrophotometry at 229 nm wavelength.

## 3. Results and Discussion

3.1. Granules evaluation

a. Sieve analysis

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Figure 1: Particle size distribution

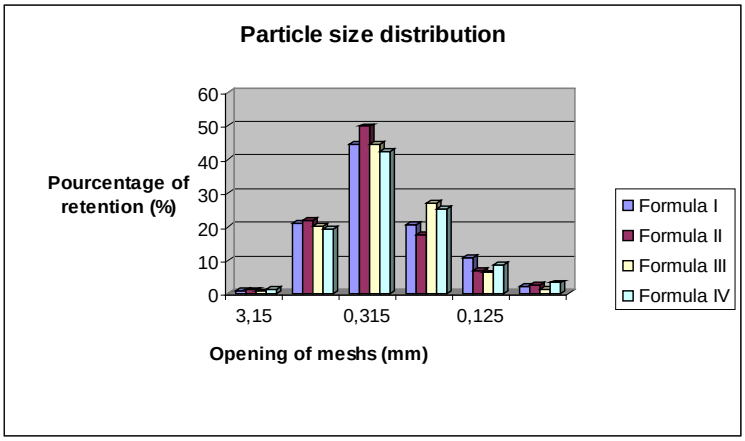


Figure 1 illustrate the results obtained from sieve analysis of the four granulations.The particle size distribution do not appear to differ significantly from one granulation to other. 80% of the particle of grains prepared by the two methods ranged between 0, 8 – 0, 2 mm.
Although, this same trend is noted, the range in particle size does not appear to have been affected by the method of granulation.

b. Powder flow

Powder flow through a 1, 25 cm orifice was monitored for each granulation obtained by the two methods of granulation.Triplicate measurement reveled that all the results are inferior to the standard value of Eur. Pharm **[5]**.
These results have revelled also no difference between granulation obtained by wet and dry granulation upon the flowability.Same to bulk density but with best characteristcs for granulations obtained by wet granulation.

c. Granulation density

Table 2: Powder flow of formulas (n = 3)

| | Wet Granulation | | Dry Granulation | |
|---|---|---|---|---|
| | Formula I | Formula II | Formula III | Formula IV |
| Flowability before lubrification | 6,4 ± 0,12 | 8,51 ± 0,17 | 11,93 ± 0.21 | 11,8 ± 0,19 |
| Angle of repose before lubrification | 28°± 1,8 | 29° ± 1,7 | 45,13° ± 2,1 | 45,21° ± 1,8 |
| Compressibility Index (%) | 40 | 50 | 50 | 50 |
| Flowability after lubrification | 4,69 ± 1,2 | 6,41 ± 1,5 | 8,89 ± 1,4 | 8,91 ± 1,9 |
| Angle of repose after lubrification | 27° ± 1,4 | 28° ± 1,6 | 39,23° ± 1,8 | 39,26° ± 2,1 |

Table 2 lists the properties of the four formulas including properties already done and compressibility index. Compressibility index is an indicator of the granulations flowability and is calculated as follows:

CI = 1- (Vtap / Vbulk)

Where CI = Compressibility Index

V tap = Volume of Tapped powder

V bulk = Volume of bulk powder

Granulations having CI's less than 15% usually exhibit good flow tendancies while those with CI value grater than 25 % most likely have poor flowability **[6]**. The results obtained from the powder flow analysis indicate that the granulations prepared with the two methods of granulation did not produce at least favorable results that are why we added in the formulation talcum to lubricate the tablets powder.

3.2. Tablets evaluation

a. Disintegration time

Table III is a summary of the tablet properties of each of the formulas.

Table III: Tablets properties

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| | Wet Granulation | | Dry Granulation | |
|---|---|---|---|---|
| Tablets evaluation | Formula I | Formula II | Formula III | Formula IV |
| Weight variation (average) | 450,25 ± 4,04 | 450,15 ± 4,03 | 459,45 ± 4,91 | 460,20 ± 2,42 |
| Disintegration time (minutes) | 7min ± 1,3 | 10 min ± 1,5 | 5min ± 1,4 | 6 min ± 1,3 |
| Friability (%) | 0,84 ± 0,01 | 0,75 ± 0,04 | 0,97 ± 0,02 | 0,95 ± 0,03 |
| a)Compression forces (KN) | 9,00 ± 1 | 9,00 ± 1 | 15,00 ± 1 | 15,00 ± 1 |
| b)Hardness (KP) | 8,64 ± 1,34 | 8,07 ± 1,74 | 8,36 ± 2,44 | 8,86 ± 2,38 |

All formulations obtained with the two methods of granulation produced tablets which disintegrated within 5minutes in 37° ± 0, 5° C in distilled water.
Although the arabic gum granulation produced tablet whose disintegration were longer than those tablets prepared with starch paste as 15 % sweet potato starch and Avicel pH 101, these differences were not significant because French pharmacopoeia revele that the standard norm must be less than 15 minutes.

b. Friability
All granulations produced tablets by wet granulation method having acceptable levels of friability which were below the industry standard of 0,8 % **[7]** than the other produced by dry granulation where the level of friability is over the standard.Thus, the value obtained with starch paste as 15 % gives a best result.

c. Weight variation
All formulation produced tablet that fell within the French pharmacopoeia specification for weight uniformity for wet granulation method when the other method produce tablets for which one of them is beside of the confidence interval at the risk 0, 05
This is in good agreement with the result obtained from powder analysis of formulation obtained by wet granulation.

d. Hardness

Table 3: Tablets properties (n = 3)

| | Wet Granulation | | Dry Granulation | |
|---|---|---|---|---|
| Tablets evaluation | Formula I | Formula II | Formula III | Formula IV |
| Weight variation (average) | 450,25 ± 4,04 | 450,15 ± 4,03 | 459,45 ± 4,91 | 460,20 ± 2,42 |
| Disintegration time (minutes) | 7min ± 1,3 | 10 min ± 1,5 | 5min ± 1,4 | 6 min ± 1,3 |
| Friability (%) | 0,84 ± 0,01 | 0,75 ± 0,04 | 0,97 ± 0,02 | 0,95 ± 0,03 |
| a)Compression forces (KN) | 9,00 ± 1 | 9,00 ± 1 | 15,00 ± 1 | 15,00 ± 1 |
| b)Hardness (KP) | 8,64 ± 1,34 | 8,07 ± 1,74 | 8,36 ± 2,44 | 8,86 ± 2,38 |

Table 3 lists the mean compression forces required to produce tablets of the same degree of hardness is not the same according to the method of granulation.This compression force is less for wet granulation than the dry granulation even if they produce an acceptable level beyong the French pharmacopoeia standard.

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e. Dissolution profile

Figure 2: Dissolution profile of tablets

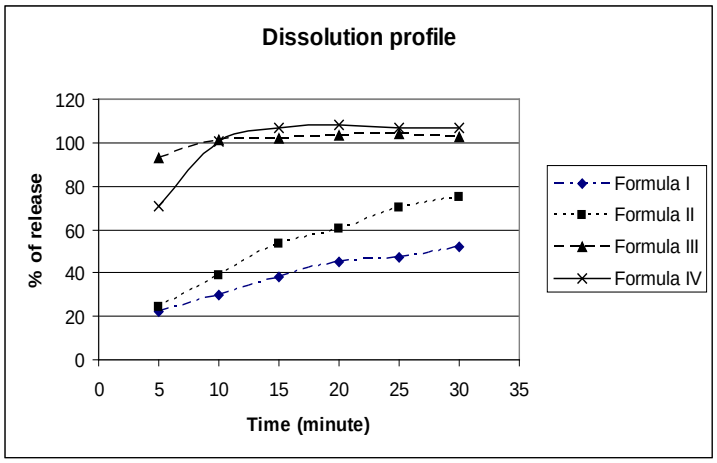


Figure 2 shows the dissolution profile obtained from tablets produced by each of the four formulations.Tablets produced from starch paste as 15 % and arabic gum were found to have lower amount of Amoxicillin released in five minutes time point compared to tablets produced from sweet potato starch and Avicel pH 101 formulation (dry granulation).This result was expected, as these tablets were found also to have longer disintegration time.
No significant differences in dissolution profiles were found between tablets produced from these formulas among the same method.

## 4. Conclusion

This study demonstrate the binder and disintegration properties of sweet potato starch in tablet formulation by two methods of manufacturing tablets.The results obtained shown as that:

- Starch paste as 15 % made with sweet potato starch has the same behaviour to arabic gum as 15 % in tablets formulation.
- The properties of tablets obtained by wet granulation demonstrate best characteristics than those obtained by dry granulation.
- The two methods are convenient to be use to prepare tablets but the process of wet granulation produce tablets with best characteristics.
- Sweet potato starch from Cote d'Ivoire can be considered as excipient in tablets formulation and an alternative to traditional binder agent.

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