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## Research Article

### POWDER AND TABLET PROFILE OF MICROCRYSTALLINE CELLULOSE (MCC) OF DIFFERENT WITH DEGREES OF POLYMERIZATION

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Hydrolysis of wood pulp, Microcrystalline Cellulose (MCC), Degree of polymerization (DOP), Tablet compression, Tablet Hardness.

#### ABSTRACT

In pharmaceutical industries microcrystalline cellulose (MCC) is used as bulking agent. MCC is multifunctional excipient, thus when microcrystalline cellulose is used in formulation and other additional excipient quantities become less. It provides sufficient tensile strength and fast disintegration of the tablets. Tensile strength of tablets containing MCC depends on Degree of polymerization of MCC. Degree of polymerization of microcrystalline cellulose powder is directly related to hydrolysis reaction of wood pulp. We have prepared different grades of MCC, in which temperature, pressure and acid concentration are the same, only hydrolysis time has been changed. All four grades of HiCel™ microcrystalline cellulose had different DOP, these all four samples were used for makes the tablets. All tablets were manufactured by direct compression process and without mixing any pharmaceutical Active ingredient. Thereafter the tensile strength and thickness of tablets were evaluated. In this study, we find the correlation between hydrolysis reaction time and degree of polymerization of MCC powder, and second correlation is between degree of polymerization and tensile strength of tablet.

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#### INTRODUCTION

Microcrystalline cellulose (MCC) is most common excipient used for tableting in pharmaceutical industries. Microcrystalline cellulose is purified depolymerised cellulose, Obtained as pulp from plants. Dissolving wood pulp is the most common source of microcrystalline cellulose [1]. In wood, cellulose chains are packed in layers held together by a cross-linkage polymer and strong hydrogen bond. Cellulose consists of linear chains of β-1,4-D anhydroglucopyranosyl units. Softwood, hard wood and dissolving wood pulp can be used, these wood pulp differ considerably of alpha cellulose content, chemical and structural structure i.e. region which are relatively more crystalline or amorphous. The amorphous regions are more prone to hydrolysis so partial depolymerization by acid hydrolysis results in shorter and more crystalline fragments like as microcrystalline cellulose [2],[3].

Microcrystalline cellulose is prepared by hydrolysis of wood pulp with dilute mineral acid, washed up to neutralized condition with water, filtered and dried with spray dryer[4],[5]. The properties of MCC include DOP depends on the different grade of wood pulp and hydrolysis condition temperature, pressure, time and acid concentration. DOP is the number of glucose units present in the cellulose chain. As per pharmacopeia DOP should be below 350[2],[6]. It plays a very importance role in tensile strength of tablets. Microcrystalline

cellulose is considered as diluent having self binding properties and it is predictable as one of the preferred direct compressible binder to its dry binding properties in comparison to other excipients. It is considered as self disintegrating with low lubricant requirements due to its extremely low coefficient of friction. However these properties do not replace the need for true disintegrants and lubricants when MCC is used in the formulation. In fact when MCC and superdisintegrants both are mixed together it may be complementary to promote fast disintegration [7].

In this study we investigate the correlation between hydrolysis time, degree of polymerization, and tensile strength by using four different DOP of microcrystalline cellulose having trade mark is HiCel™. All four grades of microcrystalline cellulose samples of different degree of polymerization were made at some pressure, temperature, and acid concentration, only time of reaction was varying. After physical analysis evaluate DOP of all four grades of HiCel™ Microcrystalline cellulose for different degree of polymerization samples. All HiCel™ Microcrystalline cellulose grades of different degree of polymerization of used for making the tablets without added the pharmaceutical active ingredient used by direct compression process. Evaluate the tensile strength and tablet thickness of the tablets.

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## MATERIAL AND METHOD

### Material

Dissolving wood pulp, Hydrochloric acid, Ammonia solution, Reactor and Spray dryer were used for manufacturing of the HiCel™ MCC. 1 M Cupriethylenediamine hydroxide solution of Aldrich make, U tube Canon-Flaske direct flow viscometer (Serial no- 1333 and 5659) were used for check the DOP of MCC powder. Hot air oven (Model no. PNX-14) used for testing moisture content. Class A graduated measuring cylinder (Electro lab instrument, Model No. ETD1020) used for check bulk density of powder. Digital weight balance (Mettler Toledo, Model no. ML802/A01) used for weight the samples. Tablet Compression machine 10 station, D tooling of Proton make and hardness tester machine (TH1050M) of Labindia make were used for the tests in application lab. Vernier caliper (M&W Precision tools serial no-11071909) was used for thickness test.

### Method

#### Hydrolysis of Wood Pulp [8]

Fibrous wood pulp cut into the pieces and charged in reactor with mineral acid and water and hydrolyzed V/V at specific temperature, pressure, acid concentration and time. After hydrolysis wood pulp breaks down into slurry. Thereafter it is washed and filtered with ammonia with the help of filter press for getting the conductivity below 100µs/cm, pH is neutral.

#### Degree of Polymerization [8],[6]

Degree of polymerization of HiCel™ MCC, Weight accurately 1.3 mg microcrystalline cellulose in a 125 ml conical flask, Add 25 ml of water and 25 ml of 1 M Cupriethylenediamine hydroxide solution, dissolved properly with the help of glass rod. When dissolved properly, transfer an appropriate volume of the solution into a calibrate number 150 Cannon-Fenske. Allow the solution to equilibrate at 25±0.1 for not less than 5 minutes. Time the flow between the two marks on the viscometer, and record the flow time, t<sub>1</sub> in seconds and Calculate the kinematic viscosity viscosity (KV)<sub>1</sub> of MCC taken by the formula: t<sub>1</sub>(K<sub>1</sub>)

In which k<sub>1</sub> is the viscosity meter constant (See viscosity 911 in USP). Obtain the flow time t<sub>2</sub> for a 0.5 M cupriethylene diamine hydroxide solution using a number 100 Cannon-Fenske or equivalent viscosity meter. Calculate the kinematic viscosity (kv)<sub>2</sub> of the solvent by the formula, t<sub>2</sub> (k<sub>2</sub>). In which k<sub>2</sub> is the viscosity, (η<sub>rel</sub>) of MCC specimen taken by the formula: (KV)<sub>1</sub> / (KV)<sub>2</sub>

$$\eta_1 = \frac{(KV)_1}{(KV)_2} \quad (1)$$

Determine the intrinsic viscosity, (η) c by interpolation, using the intrinsic viscosity table in reference table section. Calculate the DOP, it is denoted by “P”.

$$P = \frac{(95)(\eta)C}{WS \left\{ \frac{100 - \%LOD}{100} \right\}} \quad (2)$$

Where

WS= weight of sample (MCC)

%LOD= Loss on drying of sample (MCC)

#### Angle of Repose [8]

Pour 30gm of dry MCC through pour on powder flow tester (#10 mesh size), powder comes on the S.S cylinder surface until a pile build on the top of S.S cylinder. Measure the total height (S.S cylinder & pile) by scales. Using following formula find the calculated value this value check natural tangents chart for angle of repose and reported.

$$\text{Angle of Repose} = \frac{2h}{d} \quad (3)$$

Where

h = height of S.S cylinder

d = diameter of S.S cylinder

#### Untapped Density [8]

Untapped density is analyzed through graduated measuring cylinder class A. Take 20 gm of dry MCC powder pours into a graduated A grade 100 ml capacity cylinder slowly from the sidewall. Level the surface of sample in cylinder by slow movement and note down the occupied volume and calculate the untapped density of Hicel™ MCC by using following formula.

$$\text{Untapped density (BD)} = \frac{\text{Weight of powder in gram}}{\text{Occupied volume in mL}} \quad (4)$$

#### Tablet Compaction [9]

Compacts of 500 mg tablet in tablet compression machine 10 stations, D tolling (Model no-MINI PRESSSS 10 “D”). Machine operating pressure ranges 10 to 60 KN.

#### Tensile Strength [9]

Random 10 tablets were taken from each sample. Electronic digital hardness test machine (Labindia tablet hardness tester, Model No.-TH1050 M) was used for tensile strength test. Individually, a tablet was placed between two anvils, force was applied to the anvils, and the crushing strength that just caused the tablet to break was recorded. Finally the reading was recorded in kp[kgf] on display of hardness machine.

#### Tablet Thickness [9]

Random 10 tablets were taken from each sample. Vernier caliper (M&W Precision tools serial no-11071909) was used for thickness test. Individually, a tablet was placed between two external jaws and take reading in millimeter (mm).

## RESULT AND DISCUSSION

### Wood Pulp Hydrolysis

All four Hicel™ MCC samples of different DOP have been manufactured by at same acid concentration, temperature and pressure, only hydrolysis time of reaction has been changed. Resultant increase in the hydrolysis reaction time of dissolving wood pulp, the DOP of MCC was found decreasing, related data mentioned in fig. no.1.

### Degree of Polymerization

Degree of polymerization of wood pulp powder decrease when increases in the hydrolysis time of reaction. When DOP of powder increased, physical properties of HiCel™ powders change and all result are summarized and shown in table no.1 and fig.no.1.

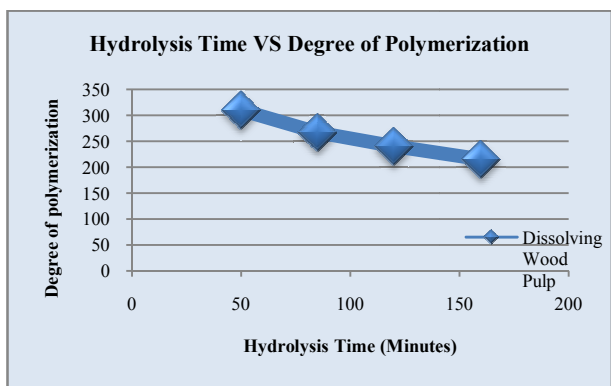


Fig.1 Hydrolysis reaction time and degree of polymerization of all HiCel™ MCC samples of different DOP

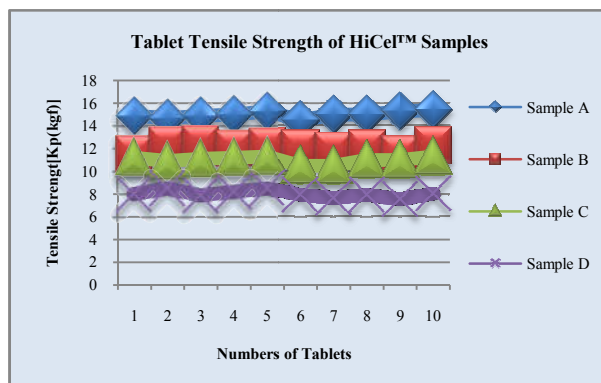


Fig.2 Tensile strength of individual tablets of all four grades of HiCel™ microcrystalline cellulose of different DOP sample, in red and green color(sample B&C) have no more difference in DOP, in blue color (sample A)have high DOP and in brinjal color(sample D) have low DOP.

**Physical Properties of Powder**

Physical properties of HiCel™ samples are changed with degree of polymerization. Where Sample A have high DOP and 0.14 g/cc untapped bulk density with 61 degree angle of repose, Sample B and C are HiCel™ regular batches sample it have excellent result untapped density 0.29 to 0.30, Angle of repose was 42 to 39 and sample C is low DOP it have 0.37 untapped density and 45 degree angle of repose, all details are mentioned in table no.1.

**Table no.1** Physical properties and Degree of polymerization of all four grades of HiCel™ MCC different DOP samples

HiCel™ Microcrystalline Cellulose				
Parameter	Results			
Sample Identification	A	B	C	D
Degree of Polymerization	310	267	240	215
Bulk Density (Untapped) g/cc	0.14	0.29	0.30	0.37
Angle of Repose (°)	61	40	39	45

**Tablet Compaction**

All tablets are manufactured 500 mg at 30-KN release pressure of proton mini press. All tablets are round shape with white color. Sample A (HiCel™ High DOP) due to poor flow, the filling in the die was not smooth.

**Tensile Strength of Tablet**

Tensile strength of sample A(High DOP) had 15 Kp(kgf), HiCel™ sample B and C had 12-11 Kp(kgf) and sample D (low DOP) had 8 Kp(kgf), related data mention in table 2 and fig no.2 and 3.

**Table no2** Tablet profile of all four grades of HiCel™ MCC different DOP samples

HiCel™ Microcrystalline Cellulose				
Parameters	Results			
Sample Identification	A	B	C	D
Degree of Polymerization	310	267	240	215
Tensile Strength [Kp(kgf)]	15	12	11	08
Thickness(mm)	6.5	5.5	5.5	5.00

**Thickness of Tablet**

Tablets of Sample A (high DOP) had 6.5mm thickness, HiCel™ sample B and C and Sample D had 5.5mm tablet thickness.

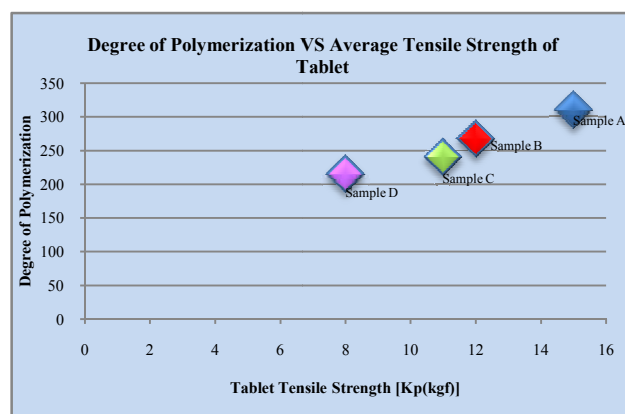


Fig.3 Average Tensile strength of individual tablets of all four grades of HiCel™ microcrystalline cellulose samples, in red and green color have similar tensile strength (sample B & C), in blue color(sample A) has high tensile strength and in brinjal color(sample D) has low tensile strength.

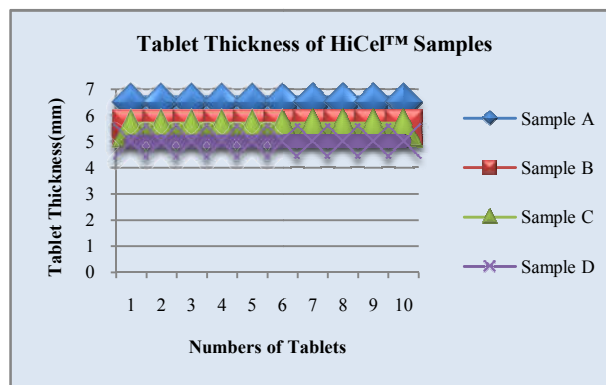


Fig.4 Thickness of individual tablets of all four grades of HiCel™ sample of different DOP, in blue color (sample A) has more thickness compare with the other three grades (Sample B,C and D)

**CONCLUSION**

The variation of the microcrystalline cellulose production parameter (hydrolysis time of reaction) has a significant influence on degree of polymerization and finally on the physical properties of the powder. The study found a correlation between hydrolysis time and Degree of polymerization and second correlation between degree of polymerization and tensile strength of tablet. Increase in hydrolysis time of reaction results in decrease of DOP and

increase in DOP results in increased tensile strength and tablet thickness. No significant difference were found between DOP of 267 and 240 keeping the angle of repose and untapped density same. In contrast to previous studies, this study found that the crystallinity does not have a primary influence on the mechanical properties of the product tablets.

#### Scope of Study

This study is helpful for select the excipients for manufacture the solid dosage form tablets and it helps for improve the yield also. HiCel™ Microcrystalline Cellulose having 240 to 267 degree of polymerization is good excipient for direct compression process.

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