IJPSR (2018), Volume 9, Issue 4 (Research Article)

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 15 July, 2017; received in revised form, 25 September, 2017; accepted, 27 January, 2018; published 01 April, 2018

TYPICAL PHYSICAL ATTRIBUTES OF MICROCRYSTALLINE CELLULOSE DRIED BY SPRAY, SPIN FLASH AND BULK DRIER AND THEIR RESULTANT EFFECTS ON TABLET PROPERTIES

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Keywords:

Excipient, Microcrystalline cellulose, SEM analysis, Crystallinity, Flow property, Direct compressible tablets

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ABSTRACT: The solid dosage form is the easiest method of administering drugs for systemic effect. All dosages forms are made by two main components one is API and second is excipient. Excipient is present in bulk quantity and is required for binding the API. There are mainly two techniques uses for manufacturing the tablets (i) wet granulation (ii) direct compression. Wet granulation is a time consuming process, and direct compression technique is time saving, cheap and convenient for pharmaceutical industries. In direct Compression technique, microcrystalline cellulose powder properties are very versatile. There are many processes used for drying of MCC. Out of these, we evaluated MCC with three different type of drying process *i.e.* Spray dried (SPD), spin flash dried (SFD) and bulk dried. Different drying methods do not change the chemical parameters of microcrystalline cellulose, only difference being the physical attributes of the MCC powder, it's morphology and it's consequents flow properties which directly effect the tablet properties *i.e.* compaction, hardness and *in-vitro* disintegration among others.

INTRODUCTION: Any pharmaceutical product or formulation is fundamentally composed of two parts: Active Pharmaceutical Ingredient (API) and excipient. API is the substance that has direct effect on the ailment, while excipient is the inert substance that provides stability, bulk, protection to the API, and also improves the bioavailability and helps in increasing the shelf-life of the drug [1]. A number of excipients are used in pharmaceutical industries in the manufacturing of medicament to enhance stability, absorption, flowability. Excipients are inert material and can be natural, semi-synthetic and synthetic in nature [2].

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.9(4).1545-54

Article can be accessed online on: www.ijpsr.com

DOI link: http://dx.doi.org/10.13040/IJPSR.0975-8232.9(4).1545-54

In case of natural excipient they are obtained from different biological resources, for example (i) zoological (lactose, gelatin, stearic acid, honey, lanolin *etc.*), (ii) botanical and earth element (minerals) (microcrystalline cellulose, starch, mint, glycoproteins, saccharides, silicon dioxide *etc.*) Semisynthetic excipients are chemically altered from natural excipients, for example hydropropyl methylcellulose (HPMC), eudragit and carboxy methyl ethyl cellulose (CMEC) *etc*. Synthetic are those excipients which are chemically synthesized from organic compounds, for example boric acid, saccharin, lactic acid, polyethylene glycols *etc.*[3, 4]

Among aforementioned groups, natural excipients are widely used because they have limited traces, ease of availability, and are economically cheap as compared to their synthetic counterparts. Micro-crystalline Cellulose (MCC) is one of the most commonly used natural excipient that is obtained from wood pulp [5].

Basically MCC is a polysaccharide biomolecule made up of glucose subunit. Microcrystalline cellulose is one of them. It is used in bulk in pharmaceutical, cosmetic, food and other industries [5]. It is considered as an ideal excipient due to its multiple uses, in pharma industries used as a binder, as filler, as disintegrant, as lubricant, as glident as adsorbent and as anti-adherent, in food industries used as stabilizer, anti-caking agent, emulsifier, stabilizer, texture modifier, suspending and fat substitute agent and in cosmetic industries used as thickener agent, binder fat substitute, stabilize, suspending and anti caking agent [6].

MCC is prepared by hydrolyzing wood pulp with dilute mineral acid. During hydrolysis, the accessible amorphous regions are hydrolyzed and a higher degree of polymerization of wood pulp to lower degree of polymerization microcrystalline cellulose is obtained [7]. It is fine, white color crystalline, granular and free flowing powder. MCC exhibits a high dilution potential thus broadly used in direct compression formulation [8]. In pharmaceutical industries direct compression has progressively gained ground because of being economically advantageous. Direct compression (DC) is only two step process such as mixing and compressing [9]. In DC process, with high production with low cost, the qualities of tablets are outstanding on all parameters. In direct compression technique excipient plays a very important role, it fulfills certain requirements which includes good binding and flow properties, compatibility with API and other additional excipients [10, 11]. Microcrystalline cellulose is used in direct compression due to the extremely good bonding properties as a dry binder [12].

In the present study, microcrystalline cellulose was dried by different methods and evaluated for its physical parameters. Scanning electron microscope was used for studying their morphology. Percentage crystallinity and flowability were tested by using X-ray diffraction and rheometer. Other parameters like hardness, friability, thickness, weight variation and *in-vitro* disintegration time were also evaluated. The present study is aimed towards comparing morphology, flow properties of microcrystalline cellulose dried by spray, bulk and flash drier and their resultant effects on tablet properties.

MATERIAL AND METHODS:

Material: All three samples manufactured at Sigachi Industries Pvt. Ltd., Spray drier (SPD) HiCel™ MCC is manufactured in Dahej, Gujarat. Bulk drier AceCel™ MCC manufactured in Jhagadia, Gujarat. Spin flash drier (SFD) AceCel™ MCC sample manufactured in Hyderabad

Method:

Microcrystalline Cellulose Sample Preparation:

Spry Drier (SPD) HiCel™ Microcrystalline Cellulose: [13] Dissolving grade wood pulp was cut into small pieces and charged into glass line reactor. Mineral acid, temperature, pressure, and time are used as catalyst in reaction. In this reaction, cellulose polymer chain breaks down in presence of water and mineral acid at specific temperature and pressure in required time. This reaction is known as hydrolysis. After hydrolysis, wood pulp breaks down into slurry. Neutralized pH by washing with water and ammonia. Then make suspension by addition of water in wet MCC and dried with the help of spray drier.

Spin Flash Drier (SFD) AceCel™ Micro-crystalline Cellulose: Hydrolysis, washing and filtration are same as spray dried MCC, only drying procedure is different. MCC wet cake breaks down into small pieces with mixer and material is dried with spin flash drier.

Bulk Drier AceCel™ Microcrystalline Cellulose: Hydrolysis, washing and filtration are same as spray dried MCC, only drying procedure is different. In this process MCC wet cake is crushed with the help of mixer and dried with bulk drier.

Physical Analysis of Different Dried Micro-crystalline Cellulose:

Moisture Content: [14] Heat the shallow bottle in a hot air oven (Model no. PNX-14) at 105 °C for 30 minutes after that cool it in desiccator at room temperature. Tare weight the Shallow bottle (W_1) and take about 1 gm of MCC sample (W_S) in shallow bottle, set oven at 105 °C and kept for 3 hours. After 3 hours take out the shallow bottle allow to cool in desiccator at room temperature. When the shallow bottle is cool take weight (W_2) again, Calculate moisture content (M.C.) by using the following formula.

$$\text{Moisture content (M.C.)} = \frac{W_2 - W_1}{W_S} \times 100 \quad \text{...(i)}$$

Bulk Density: [15] Bulk density (BD) of powder is two types- (i) Untapped density (ii) Tapped density.

Untapped Density: Untapped density is known as loose bulk density (LBD), it is analyzed through graduated measuring cylinder class A. Take 20 gm of MCC sample (WS) using weight balance (Toledo, Model No.-ML 802 /A01) and poured 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 (SV) and calculate the untapped density of MCC by using following formula.

$$\text{LBD} = \frac{W_S \text{ (gram)}}{S_V \text{ (ml)}} \quad \text{.....(ii)}$$

Tapped Density: Tapped bulk density (TBD) was anlaysed by using (Electro lab instrument, Model No. ETD1020), measuring cylinder placed in tapped density machine and fixed required taps. After taps measured the volume (S_V) of measuring cylinder and calculate the tapped density by using following formula.

$$\text{TBD} = \frac{W_S \text{ (gram)}}{S_V \text{ (ml)}} \quad \text{.....(iii)}$$

Hausner Ratio: Hausner ratio is another method to check flow of powder. The flow of powder was measured by "Hausner ratio". Tapped bulk density (TBD) is divided by loose bulk density (LBD). Formula is mention below.

$$\text{H. Ratio} = \frac{\text{TBD}}{\text{LBD}} \quad \text{.....(iv)}$$

Average Particle Size Distribution Analysis [16]: Average particle size was analyzed by Sieve shaker, PSD software (Retch-Japanese instrument). PSD software operate through computer. Take cleaned mesh sieve with bottom pan and top cover. Check sieve shaker and set mesh sieve with sample being analyzed on sieve jet. Take weight of all required mesh sieve with bottom. Arrange the sieve mesh sequence from top mesh +60, mesh +200 and bottom. Weight accurately 10 gm of MCC powder with the help of weight balance (Mettler Toledo, Model no. ML802/A01) and put into top of sieve. Fill the initial weight of mesh sieve and bottom into PSD table and start. After 5 minutes take out the sieves and again take weight with retain sample. Fill into the PSD software table, and note down D10, D50 and D90 values.

Compressibility Index: [17] Compressibility index is known as Carr's index, it indicates compressibility of powder. It is calculated by following formula.

$$\text{Compressibility Index} = 100 \times \frac{\text{(TBD-LBD)}}{\text{TBD}} \quad \text{.....(v)}$$

Flowability Analysis: [17] Particle size, Shape, surface characteristic will greatly influence the flow of powder. Flowability analysis of HiCel™ 90M and both AceCel™102 samples were done using FT4 Powder rheometer (Freeman technology). All samples were tested at 6 kpa shear and preshear, 23.5 mm blade and 25 mm ×10 ml split vessel were used. Sample vessel made by Kulfimix Carragenan material.

The rotational Shear Cell module consists of a vessel containing sample (powder) and Shear head to induce both vertical and rotational stresses. The Shear head moves downwards inserting the blades into the powder and induces a normal stress as the shear head face contacts the top of the powder. The Shear head continues to move downward until the required normal stress (σ) is stable. Slow rotation of the shear head then begins, inducing a Shear stress (τ). A Shear plane is established below the ends of blades. When the powder bed resists the rotation of the Shear head, the Shear stress increases until the bed fails of Shears, at this time maximum Shear stress is observed and the normal Stress is maintained constant throughout the Shear step.

Generally cohesive powder will have higher Cohesion values and unconfined yield strength (σ_c) consequently a low flow fraction (ff_c), a high value of ffc indicates that the powder flow is free flowing. ffc calculated by below equation-

$$ff_c = \sigma_1/\sigma_c \quad \text{.....(vi)}$$

σ_1 = major principal strees (MPS);
σ_c = Unconfined yield strength (UYS)

We can define flow behaviour parameter mention in below **Table 1**.

TABLE 1: FLOW BEHAVIOR ON BEHALF OF ffc VALUE [15]

S. no.	ff_C Value	Flow character
1.	Below 1	Not flowing
2.	Between 1-2	Very Cohesive
3.	Between 2-4	Cohesive
4.	Between 4-10	Easily flowing
5.	Above 10	Free flowing

XRD Analysis [16]: Crystallinity of spray dried MCC (HiCel^{TM}90M), spin flash dried MCC (AceCel^{TM}102) and Bulk dried MCC (AceCel^{TM} 102) analysis using XRD. XRD patterns were recorded in the 10 - 85° 2θ range at steps of 0.05 and a counting time of 0.5 s / step on a Bruker AXS (D8 advance) diffractometer, equipped with a Cu tube (source: Cu K-alpha having wavelength 1.54056). The X-ray Source is a 2.2 kW Cu anode long fine focus ceramic X-ray tube. Scintillation detector is used in XRD.

A computer controlled absorber is mounted directly in front of the detector and is used to attenuate the beam by about 2 orders of magnitude. Dried microcrystalline cellulose approximately 1g sample is used for this analysis. Scan was obtained from 10 - 85 degree 2 theta at steps of 0.05 and a counting time of 0.5 s/step. Calculate the percentage crystallinity of microcrystalline cellulose using below formula.

Percentage crystallinity = 100 × Total area of crystalline peaks / Total area of all peaks .....(vii)

Scanning Electron Microscope Analysis: [17] Take approximate 1 to 2 milligram MCC sample from each batch. Microcrystalline cellulose sample were mounted on double sided taped on aluminium stabs and sputter coated with platinum with the help of auto fine coater JEOL (JFC. 1600). Micrographs were taken at appropriate magnification and particles surface visualization detailed analyzed by scanning electron microscope JEOL (JSM. 76000 F).

Manufacturing Tablets: [18] Compacts of~500 mg tablet were made on 10 station proton mini press (Model no. MINI PRESS 10 "D") using D tooling dies and punches.

Evaluation of Tableting: [19]

Weight Variation: Random 10 tablets were taken from each batch and each tablet was weighted individually using electronic digital balance (Mettler Toledo, Model No.-MS204S /A01). The average weight of all tablets was calculated by following formula.

Average weight of tablet = total weight of tablet / total number of tablets .....(viii)

Hardness: Random 10 tablets were taken from each batch. Electronic digital hardness test machine (Labindia tablet hardness tester, Model No.-TH1050 M) was used for hardness 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 taken in kp [kgf] on display of hardness machine.

Friability: At first 10 tablets were taken. The tablets were carefully dusted prior to testing, then the 10 tablets were weighted electronic digital balance (Mettler Toledo, Model no. MS303/A01). This was considered as the initial reading. After weight the tablets, all the tablets were placed in the drum of friability tester and rotate 100 times at 25 rpm. After 100 revolutions the 10 tablets were removed and re-weighted. This was the final reading.

The percentage was calculated by following formula. According to USP the tablets should not lose more than 1% of their total weight.

% Friability = (Tablet weight before friability – Tablet weight after friability) × 100 / Tablet weight before friability .....(ix)

Disintegration Time: This test was carried out at 37 ± 2 °C in 600 ml of dematerialized water. Six tablets were taken and one tablets was introduce in each tube disk was placed and basket was positioned in 1 liter beaker containing 37 ± 2 °C temperature of water. Note down tablet disintegration time

RESULT AND DISCUSSION:

Moisture Content: Moisture content of all samples mentioned in **Table 2**.

Bulk Density: Untapped density and tapped density both are mentioned in **Table 2**. Untapped density of all samples were mentioned in **Table 2**.

Hausner Ratio: Hausner ratio of both samples are mentioned in the **Table 2**. Bulk dried MCC (AceCel^{TM}102) has higher hausner ratio.

Average Particle Size Distribution: Average particle size of all samples is mentioned in **Table 2**.

Compressibility Index: Compressibility index of all MCC samples are mentioned in **Table 2**. Spray dried MCC (HiCel^{TM}90M) has excellent compressibility index.

TABLE 2: PHYSICAL PARAMETER OF SPRAY DRIED, SPIN FLASH DRIED AND BULK DRIED MICROCRYSTALLINE CELLULOSE

S. no.	Name of Test	Spray dried MCC (HiCel^{TM}90M)	Spin flash dried MCC (AceCel^{TM}102)	Bulk dried MCC (AceCel^{TM}102)
1.	Moisture content (%)	4.50	4.50	4.48
2.	Untapped density (g/CC)	0.31	0.31	0.30
3.	Tapped density (g/CC)	0.44	0.46	0.46
4.	Hausner ratio	1.42	1.48	1.53
5.	PSD (µm) (D_{50})	98	98	98
6.	Compressibility Index (%)	29.55	32.61	36.73

Flowability Analysis: Spray dried microcrystalline cellulose (HiCel^{TM}90M) have high ffc value than Spin flash and Bulk dried microcrystalline cellulose (AceCel^{TM}102). Spin flash dried MCC has greater cohesion.

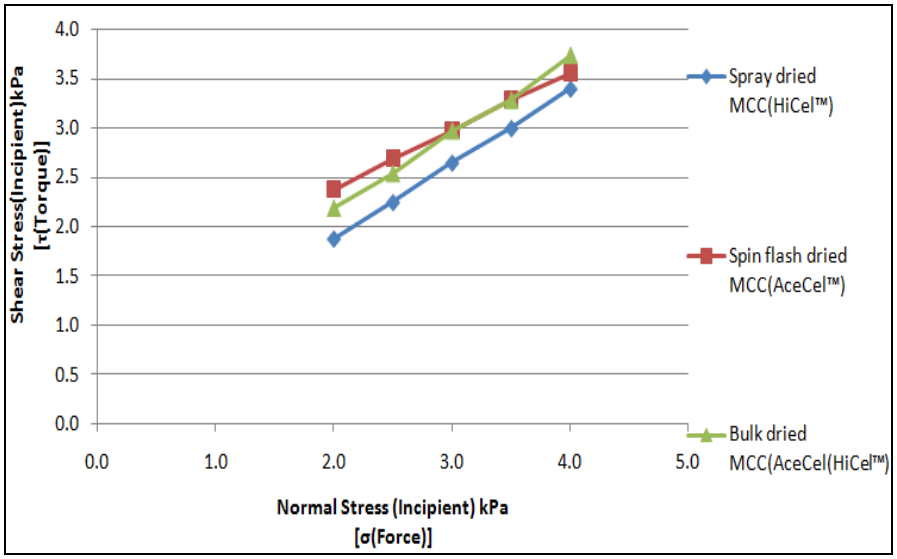


FIG. 1: GRAPH EXPLAINS CO-RELATION BETWEEN SHEAR STRESS AND NORMAL STRESS FOR VARIOUS GRADES OF MICROCRYSTALLINE CELLULOSE

TABLE 3: SUMMARY OF RESULT OBTAINED BY SHEAR AND WALL FRACTION TEST AT 6kPa USING FT4 POWDER RHEOMETER AND THEIR PARAMETER MEASURED DURING THE SHEAR TEST

Name of Sample	Cohesion (kPa)	σc (kPa)	$\sigma 1$(kPa)	ffc	$\varphi e(^{\circ})$	$\varphi s(^{\circ})$	$\varphi(^{\circ})$
Spray dried MCC(HiCel^{TM}90M)	0.37	1.47	12.09	8.22	49.02	36.96	40.11
Spin flash dried MCC(AceCel^{TM}102)	1.22	4.25	10.72	2.52	41.94	33.37	30.30
Bulk dried MCC(AcelCel^{TM}102)	0.65	2.64	9.91	3.75	44.07	35.02	37.36

XRD Analysis: Spray dried MCC (HiCel^{TM}90M) found three crystalline peaks at different 2 theta 15.484, 22.92 and 28.547 at two theta angle, height of peaks is 1263.2, 3620.5 and 90.3 Lin (counts). Spin flash dried (AceCel^{TM}102) MCC crystalline peaks found same as spray dried MCC, peaks two theta angles are 15.578, 23.11, 28.46, height of crystalline peaks are 1216.3,3617.4 and 152 Lin (counts) and bulk dried (AceCel^{TM}102) MCC crystalline peaks are also same as spray dried MCC but height is different. 2 Theta of bulk dried MCC are 15.578, 23.011 and 29.105, height of crystalline peaks are 597.1, 2122.2 and 87 Lin (counts).

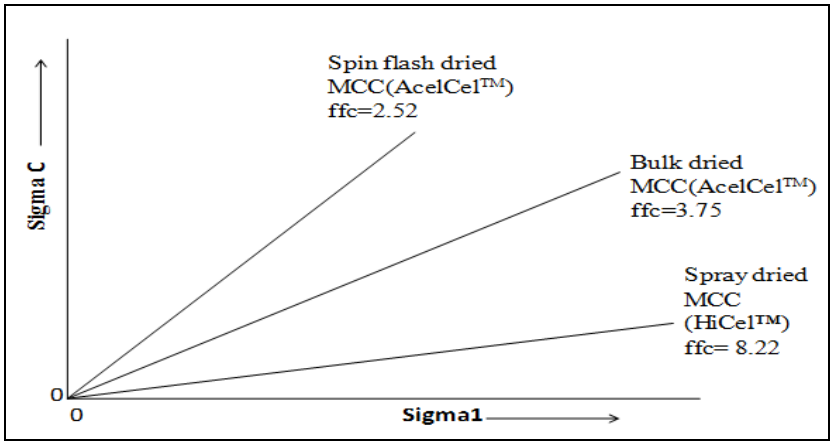


FIG. 2: INSTANTANEOUS FLOW FUNCTION

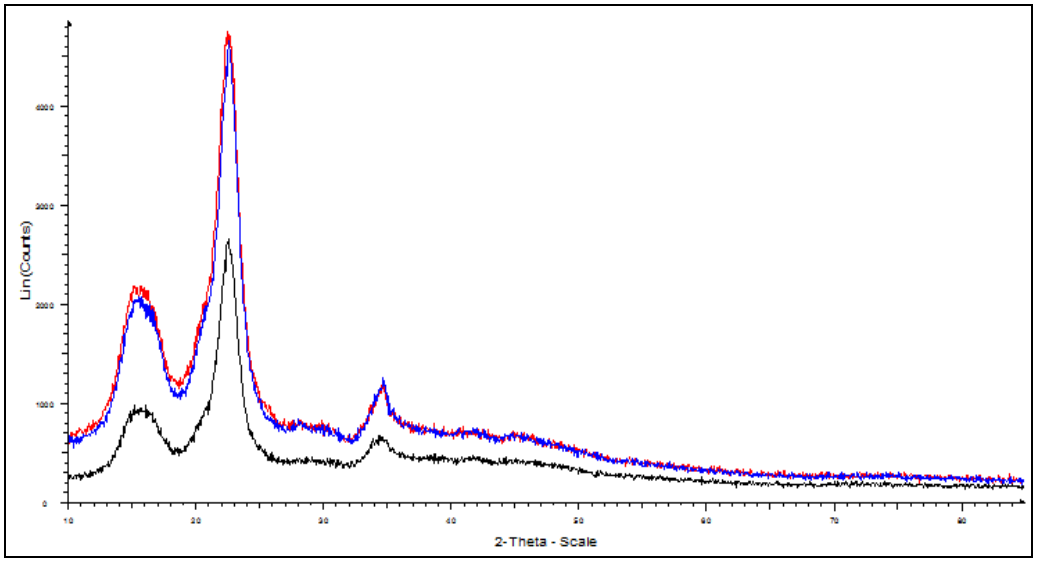
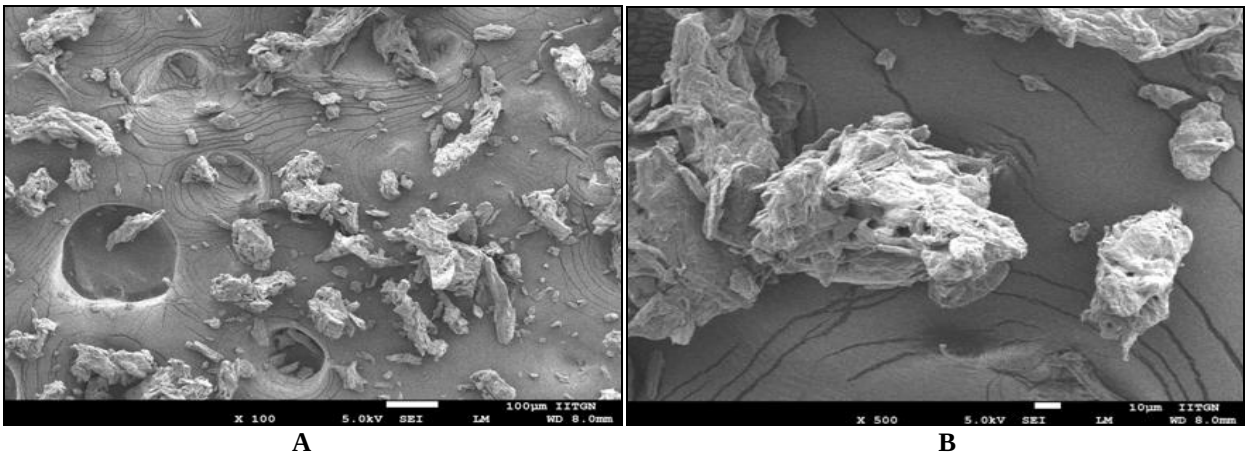


FIG. 3: XRD GRAPH OF MICROCRYSTALLINE CELLULOSE (BLACK COLOR SHOWS BULK DRIED MCC (ACECEL™102), BLUE COLOR SHOWS SPRAY DRIED MCC (HICEL™90M) AND RED COLOR SHOWS SPIN FLASH DRIED MCC (ACECEL™102)

TABLE 4: PERCENTAGE CRYSTALLINITY OF SPRAY DRIED, SPIN FLASH DRIED AND BULK DRIED MICROCRYSTALLINE CELLULOSE [18]

S. no.	Peak description	Percentage crystallinity (%)		
		Spray dried (HiCel™90M)	Spin flash dried (AceCel™102)	Bulk dried (AceCel™102)
1.	Consider First and second peaks	89.16	86.73	86.63



A **B**

FIG. 4: SPRAY DRIED MICROCRYSTALLINE CELLULOSE (HICEL™90M)

Scanning Electron Microscope Analysis: Spin flash dried (HiCel™90M) and spray dried (AceCel™102) microcrystalline cellulose particles were about to same in structure, but bulk dried (AceCel™102) microcrystalline cellulose particles were small and flat at X500 magnification. Spray dried and Spin flash drier microcrystalline cellulose particles were uniform particle distribution than and bulk dried microcrystalline cellulose. Bulk dried MCC forms complex shown in **Fig. 6 (e)**, **(f)**. All three MCC samples particles were found rod shape.

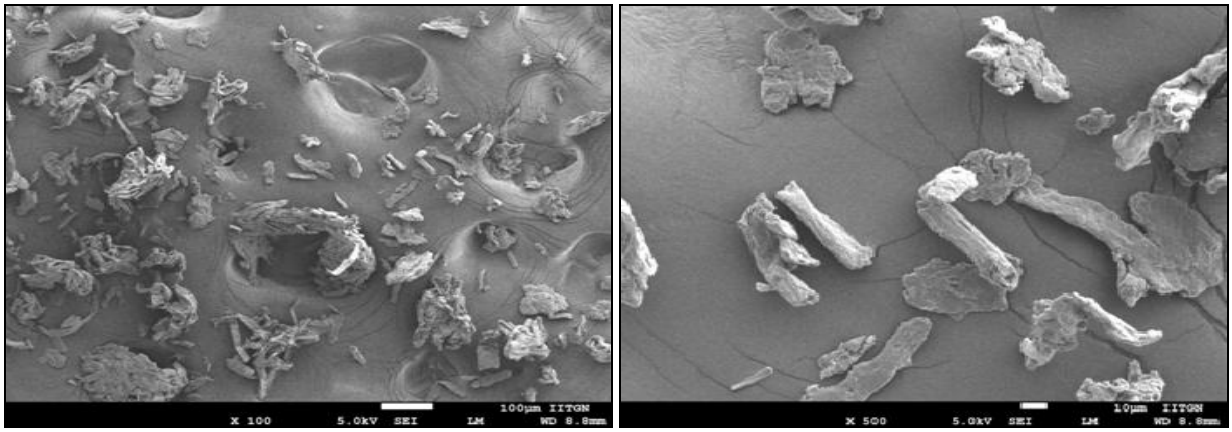


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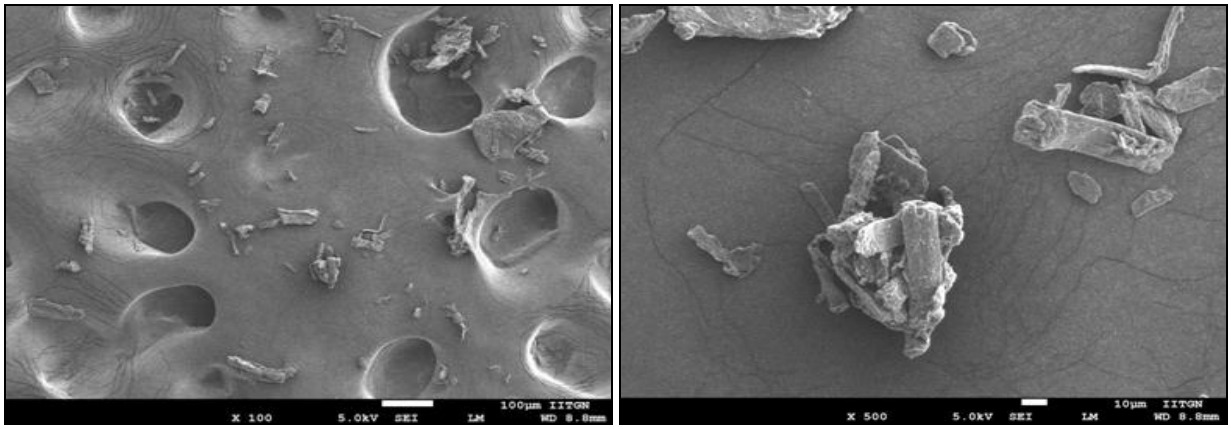
FIG. 5: SPIN FLASH DRIED MICROCRYSTALLINE CELLULOSE (ACECEL™102)



E F

FIG. 6: BULK DRIED MICROCRYSTALLINE CELLULOSE (ACECEL™102)

Weight Variation: Tablet weight variation shown in **Fig. 7** and average tablet weight is mentioned in **Table 5**.

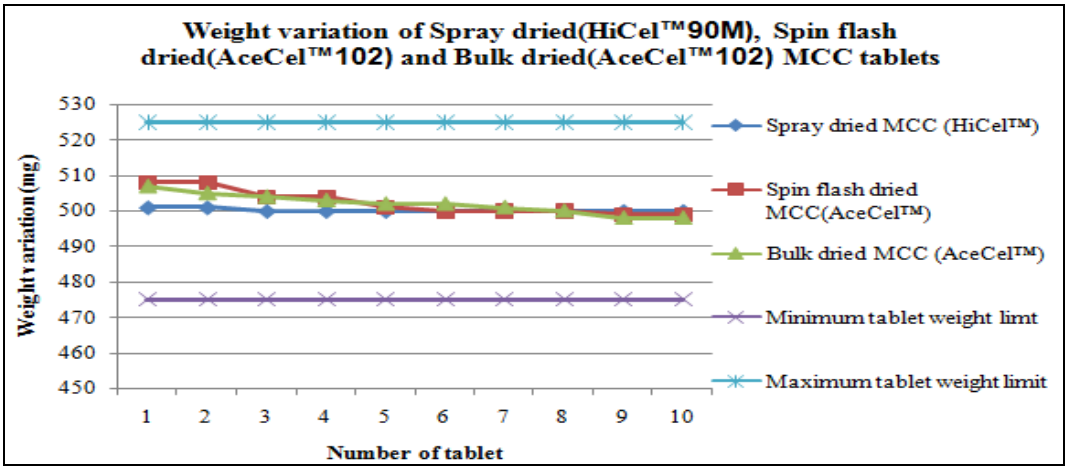


FIG. 7: TABLET WEIGHT VARIATION OF DIFFERENT SOURCE OF DRYING CONTAINING MICROCRYSTALLINE CELLULOSE

Hardness: Individual tablet hardness variation is mentioned in **Fig. 8** and average hardness of MCC tablets are mentioned in **Table 5**.

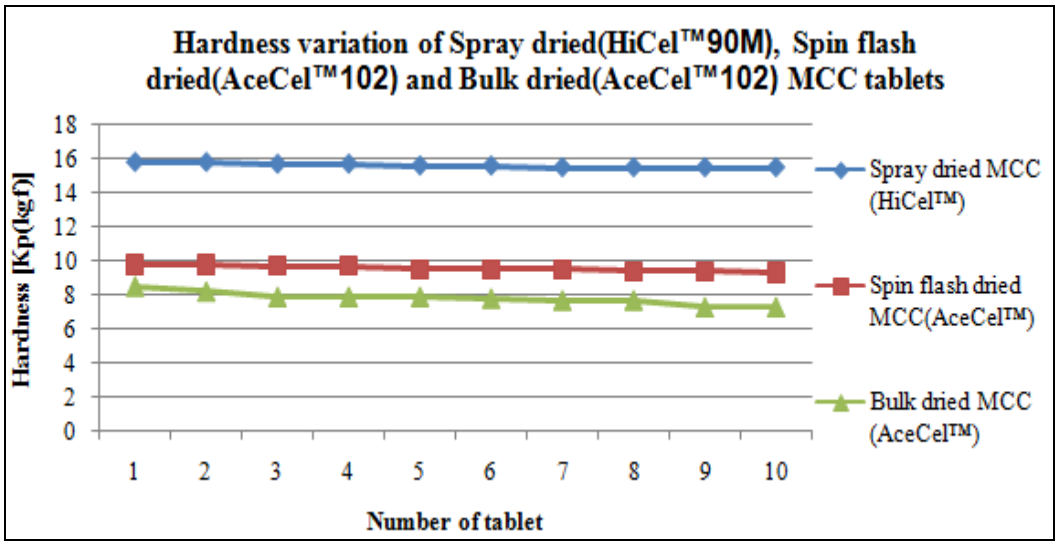


FIG. 8: TABLET HARDNESS OF DIFFERENT SOURCE OF DRYING CONTAINING MICROCRYSTALLINE CELLULOSE

Friability: Percentage friability of MCC tablets are mentioned in **Table 5** and **Fig. 9**.

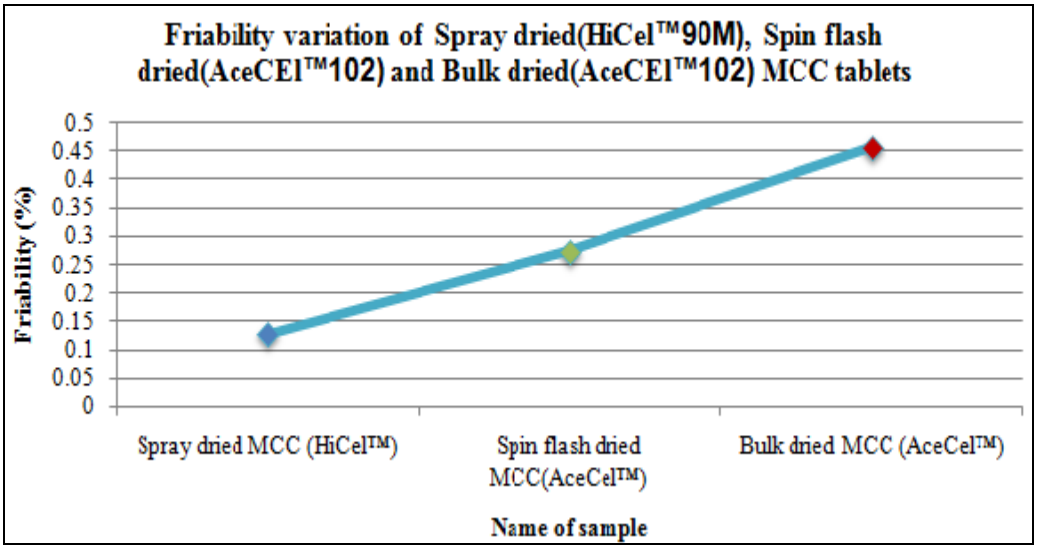


FIG. 9: TABLET FRIABILITY OF DIFFERENT SOURCE OF DRYING CONTAINING MICROCRYSTALLINE CELLULOSE

***In vitro* Disintegration Time:** Disintegration time (DT) of individual tablet mentioned in **Fig. 10**, and average DT of MCC tablets are mentioned in **Table 5**.

TABLE 5: TABLET EVALUATION PARAMETERS OF SPRAY DRIED SPIN FLASH DRIED AND BULK DRIED MICROCRYSTALLINE CELLULOSE

S. no.	Name of Test	Spray dried MCC (HiCel™90M)	Spin flash dried MCC (ACeCel™102)	Bulk dried MCC (ACeCel™102)
1.	Average Weight (mg)	500.2	502.3	502.0
2.	Average Hardness [kp(kgf)]	15.62	9.56	7.82
3.	Average Friability (%)	0.127	0.275	0.458
4.	Average disintegration Time (Seconds)	17.67	21.17	196.50

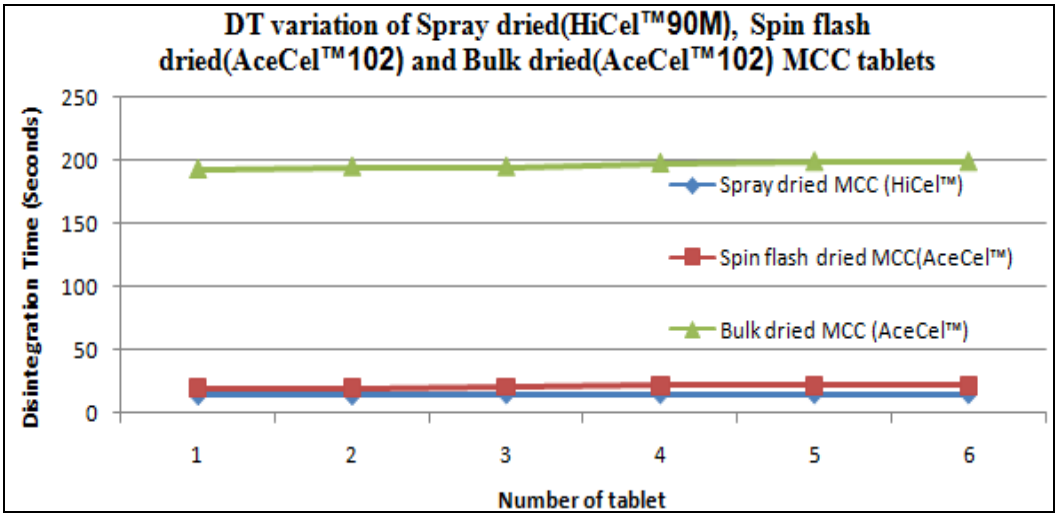


FIG. 10: TABLET DISINTEGRATION TIME OF DIFFERENT SOURCE OF DRYING CONTAINING MICROCRYSTALLINE CELLULOSE

CONCLUSION: Spray dried (SPD) microcrystalline cellulose (HiCel^{TM}90M) has higher crystallinity at 89.16%. We have found rod shape and big particles and equal particle distribution in SEM analysis. It has higher ffc value and less cohesive that represents its free flowing behaviour. It has excellent tablet profile too in terms of weight uniformity, hardness, friability and disintegration time. Though Spin flash dried (SFD) microcrystalline cellulose (AceCel^{TM}102) has found almost same crystallinity and Similar SEM analysis, but other parameters like flowability, hardness, friability, disintegration time are different than SPD MCC. It is cohesive in nature and has poor flowability than SPD MCC. In tablet profile, hardness is less and friability and disintegration time is more through it passes under pharmacopoieal limits. In SEM analysis we have found that bulk dried MCC particles form clusters and these clusters represent its unequal particle distribution. Its tabletting profile has found poor results.

ACKNOWLEDGEMENT: The authors are very thankful to Chinmay Ghoroi Assistant Professor from IIT Gandhinagar for providing Flow and SEM testing facility.

CONFLICT OF INTEREST: The authors state and confirm no conflict of interests. No direct funding was received for this study.

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How to cite this article:
Tomar M, Sinha AR and Singh AK: Typical physical attributes of microcrystalline cellulose dried by spray, spin flash and bulk drier and their resultant effects on tablet properties. Int J Pharm Sci Res 2018; 9(4): 1545-54.doi: 10.13040/IJPSR.0975-8232.9(4).1545-54.