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Characterization of Cellulose Derivatives as Pharmaceutical Excipient

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Abstract: The aim of this study was characterization and evaluation of the various pharmaceutical excipients. Cellulose derivatives like Methyl cellulose, Hydroxy propyl methyl cellulose (HPMC) and Micro crystalline cellulose (MCC) were evaluated. The characterization parameters such as bulk density, tapped density, Hausner's ratio, Carr's index and angle of repose were evaluated. Results revealed that Methyl cellulose showed maximum bulk density of 0.39±0.02 g/ml while MCC showed minimum bulk density of 0.36 ±0.02 g/ml. All the polymers were found to possess a good flow property.

Key words: Pharmaceutical Excipients · Polymer · Binder · Disintegrant · Lubricant · Active Pharmaceutical Ingredient.

INTRODUCTION

Dosage forms are the complexes which comprises of active pharmaceutical ingredient (API) along with many other components. These are added with the API to protect and enhance the stability of the formulation as well as to improve the bioavailability of the drug [1]. Excipients are defined as the substances other than the pharmacologically active drug and inert in nature included in the manufacturing process [1, 2]. Excipient is derived from the Latin word "excipere" which means 'To except' or 'other than' [3, 4].

Excipients are present in higher proportion as compared to active pharmaceutical ingredient forming the bulk of the formulation. Selection of excipients is based on the characteristics such as availability, source, functionality, acceptance, cost etc. Formulation development is also dependant on chemical, mechanical, rheological, thermal and micromeritic properties of the excipients [1].

Classification of Excipients: Excipients are classified on the basis of their function which depends on the role they play for the development of the formulation.

Diluents: These are also called as fillers. These agents form the bulk of solid unit dosage forms as the drug itself is inadequate to produce the bulk [1, 4]. By increasing the bulk volume by fillers it is possible to handle the final formulation easily [2]. Ideal filler should be inert, compatible, non-hygroscopic, soluble and cheap. Examples of diluents are lactose, starch, dextrin, glucose, MCC and inorganic compounds such as silicates, calcium and magnesium salts etc [2, 4].

Binders and Adhesives: These agents provide cohesive properties to the powdered material forming granules of desired hardness and size. An improved flow quality is provided to the formulation by the use of binders. Also required mechanical strength to the solid dosage form is also provided by the binders. Acacia, Gelatin, Starch paste, Polyvinyl pyrrolidone, Glucose, Carboxymethyl cellulose, Sugar alcohols and Cellulose derivatives are commonly used binders. [1,2, 4].

Disintegrants: Disintegrants are the agents added to the formulation to enhance the breakup or disintegration of the tablets into smaller particles [5]. On exposure to moisture, tablet breaks in the digestive tract in presence of disintegrants to release the API for absorption. Compounds such as which swell or dissolve in water such as starch, clays, alginates (Sodium alginate), cellulose derivatives (MCC), cross povidone etc. are used as disintegrants [1,4,6].

Lubricants: They reduce the inter-particular friction and prevent adhesion of tablet material to the surface of dies and punches. Use of lubricants assists in ease of ejection

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of tablet from die cavity [1]. Lubricants prevent clumping of ingredients and sticking them to the punches or capsule filling machine [2]. Talc silica, stearic acid, Magnesium stearate, Polyethylene glycol etc are the most frequently used lubricants [1,2,4,5].

Glidants: Glidents reduce the interparticle friction and cohesion force thus improves the powder flow. These are added in dry state before the compression step in combination with the lubricants [1,2,4]. These are also used as anti-caking agents [4]. Examples of glidants are Colloidal Silicone dioxide (Carbosil), talc, Asbestos free starch, Corn starch etc [1,2,4,5].

Anti-adherents: These are the agents which reduce adhesion between the powder (Granules) and the punch surfaces and thus prevent powder from sticking to the tablet punches [2,5].

Colours, Flavors and Sweeteners: Colours impart an aesthetic appearance to dosage form by disguising off color drugs and allows easy product identification. FD and C, D and C dyes and lakes are commonly used colours.

Flavors: These are mainly used in chewable tablets or tablets intended to dissolve in mouth to mask the unpleasant and bitter taste. In paediatrics formulation these are widely used. Examples are Spray dried and other flavours.

Sweeteners: They provide sweet taste to the formulation and their use is limited to chewable tablets, antacid or liquids like cough syrup. Examples are Mannitol, Saccharin etc [1,5].

Coating Materials: These materials protect the tablet from deterioration by moisture in the air and are also used to mask the unpleasant taste of the tablets thus an easy swallowing of the tablet is possible. Examples include synthetic polymers, HPMC, shellac, zein, Povidone, Ethyl cellulose etc [1,4,5].

MATERIAL AND METHODS

Methyl cellulose (MC), Hydroxy propyl methyl cellulose (HPMC) and Micro crystalline cellulose (MCC) were purchased from Central Drug House (P) Ltd. New Delhi. Polymers were supplied as "required no purification before use".

Characterization of Polymers

Polymers Were Characterized for Following Parameters

Bulk Density and Bulkiness: Bulk density is the density of the bulk mass and bulkiness is the inverse of bulk density. For determination of bulk density accurately weighed quantity of 5 g was introduced into a graduated measuring cylinder and the cylinder was fixed on the bulk density apparatus. The volume occupied by the powder was noted down [5,7,8,9]. Bulk density and bulkiness was calculated using equations 1and 2 given below:

$$\text{Bulk density} = \frac{\text{weight of powder blend}}{\text{bulk volume}} \quad (1)$$

$$\text{Bulkiness} = \frac{1}{\text{bulk density}} \quad (2)$$

Tapped Density: Tapped density is the density of the tapped mass after tapping 50 times from a fixed height. It was calculated by tapping powder in a bulk density apparatus until constant volume was obtained. The final volume was noted [5,7,8,9]. Tapped density was calculated using equation 3 given below:

$$\text{Tapped density} = \frac{\text{weight of powder blend}}{\text{tapped volume}} \quad (3)$$

Powder Flow Property: Flow property of powder was calculated by measuring angle of repose. Using the formula, angle of repose was calculated thrice [5,7,8,9]. Angle of repose was calculated using equation 4 given below:

$$\text{Tan}(\theta) = \frac{h}{r} \quad (4)$$

Powder Compressibility: Compressibility of powder is determined by Carr's Index. For this finely powdered gum (5g) was transferred into a measuring cylinder and using the bulk density apparatus calculations were done [5, 7, 8, 9]. Compressibility Index and Hausner's ratio was calculated using equation 5 and 6 given below:

$$\%\ \text{Carr's Index} = \frac{\text{tapped density} - \text{bulk density}}{\text{tapped density}} * 100 \quad (5)$$

$$\text{Hausner's ratio} = \frac{\text{tapped density}}{\text{bulk density}} \quad (6)$$

RESULTS AND DISCUSSION

Results obtained after physical characterization of polymers are described here. Methyl cellulose showed

Table1: Physical characterization of polymers

S. No.	Polymers	Bulk Density (gm/ml)	Bulkiness (ml/ gm)	Tapped Density (gm/ml)	Hausner's Ratio	Carr's Index (%)	Angle of Repose (°)
1.	Methyl cellulose (MC)	0.39 ±0.02	2.72 ±0.03	0.39 ±0.03	1.02 ±0.01	15.65 ±0.48	24.91 ±0.34
2.	Hydroxy propyl methyl cellulose (HPMC)	0.38 ±0.03	2.71 ±0.02	0.40 ±0.02	1.05 ±0.02	4.13 ±0.50	24.24 ±0.40
3.	Micro crystalline cellulose (MCC)	0.36 ±0.02	2.76 ±0.03	0.42 ±0.01	1.16 ±0.01	19.00 ±0.33	29.00 ±0.22

maximum bulk density of 0.39±0.02 g/ml while MCC showed minimum bulk density of 0.36 ± 0.02 g/ml. This implies that MCC exhibits the largest bulk in the formulation and Methyl cellulose the lowest bulk. Maximum tapped density was found of MCC (2.76 ±0.03 g/ml) as it exhibits the maximum reduction in volume due to packing and methyl cellulose possess minimum tapped density of 0.39 ±0.03 g/ml. Table 1 illustrates the physical characterization of cellulose derivatives.

Thus it is concluded that after the applied tapping pressure methyl cellulose promoted closer packing of particles. Powder flow properties of the polymers were observed. It showed the results that MCC possess highest Hausner's ratio (1.16 ±0.01), Carr's index (19.00 ±0.33) and angle of repose (29.00° ±0.22) which confirms that MCC has poor flow amongst all the other polymers.

CONFLICT OF INTEREST: Authors have no conflict of interest.

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