WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.074
Volume 7, Issue 7, 1790-1821. Research Article ISSN 2277– 7105

ESTABLISHMENT OF RICE HUSK BY-PRODUCT AS PHARMACEUTICAL EXCIPIENTS

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Article Received on
14 Feb. 2018,
Revised on 06 March 2018,
Accepted on 27 March 2018,
DOI: 10.20959/wjpr20187-11722

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ABSTRACT

Rice husk is a value added material for pharmaceuticals because rice husk produce significant role as producing cellulose, which used as an excipients in pharmaceuticals. Rice husk has such compatible properties, which can enhance the disintegration process with optimum required at reach to that of standard level of pharmaceutical disintegrating agents. Rice husk extracted celluloses are previously used as disintegrating agents in pharmaceuticals. To utilized rice husk as disintegrating agents to promote its activities in different parameters. Because 1000gm of rice husk considered only 20% weight of cellulose, on that of 50% is pure cellulose and rest of 25 to 30% is lignin and 15 to 20% is silica as well. So that would be costly to perform extraction process to separate out these components from rice husk, as per guidance of teachers , constriction of modules to enhance these activities to perform disintegration evaluation with directly using rice husk tablet in disintegration medium, and other evaluation parameters to be done thoroughly. Most of the husk from the milling is either burnt or dumped as waste in open fields and a small amount is used as fuel for boilers, electricity generation, bulking agents for composting of animal manure, etc The exterior of rice husk are composed of dentate rectangular elements, which themselves are composed mostly of silica coated with a thick cuticle and surface hairs. The mid region and inner epidermis contain little silica confirmed that the presence of amorphous silica is concentrated at the surfaces of the rice husk and not within the husk itself. The chemical composition of rice husk is similar to that of many common organic fibres and it contains of cellulose 40-50 percent, lignin 25-30 percent, ash 15-20 percent and moisture 8-

15 percent. The typical properties of rice husk are indicated in Table 03. The particle size and the specific surface area can provide desirable flow characteristics, which are exploited to improve the properties of dry powder in various processes, such as tablet. It is also used to stabilize emulsions and as a thyrotrophic agent, thickening and suspending gels and for semisolid preparation. In aerosols is used to promote the suspension of particles and minimize the clogging of spray nozzles. In addition, it can be used as a disintegrating agent in tablets and as a dispersant for powders or suppositories. It is known that the rice husk is an important silicon dioxide source. Silicon dioxide (SiO2) is a composite of a remarkable structural complexity, presenting 12 different crystal forms. As well as different brands of rice husk producing differ disintegration, which of comparative studies are indulge. Those evaluation parameters where these different brands of rice husk producing variation in evaluation can reach us to desire rice husk could be uses betterment for enhancement in disintegration process.

KEYWORD: Dissolution rates, Absorption Enhancement, Rise husk, Pharmaceutical Excipients, Celluloses.

INTRODUCTION

Rice is the seeds of the grass species Oriza Sative; it is the most widely consumed food for a large part of the world's human population. Rice husk is the outermost layer of the paddy grain that is separated from the rice grain during the milling process. Rice husk produce cellulose which is used as pharmaceutical excipients. Excipients are the non-therapeutic but vital components of drug delivery systems. They influence drug delivery through increased/decreased solubility, modified dissolution rates, absorption enhancement, ultimately leading to improved therapeutic activity and even a decrease of unwanted side effects.

The cost of drug development drives the quest to search for low-cost ingredients and enabling companies to enhance their existing products as well as to develop new drug delivery systems in order to cope with the global challenges and competition. Novel excipients enable pharmaceutical companies to develop new drug delivery systems, improve efficiency, enhance functionality and reduce the cost of drugs, Furthermore, with more drug patents set to expire in the next three to four years, novel excipients offer patent holders opportunities to upgrade their products and thereby extend their patent lives.

Development of excipients from natural sources which are known to be utilized for food consumption may reduce the regulatory requirements for approval. Excipients from plant sources would be cost and environmentally friendly due to the availability of plants, low or no toxicity and biodegradability. Even agricultural wastes such as corn stalk and rice hulls has been recycled and microcrystalline cellulose produced from them, Excipients from plant sources are appealing because plant resources are renewable and if maintained and harvested in a sustainable manner, they can be constant sources of raw materials.

Pharmaceutical excipients are generally obtained from natural sources or prepared synthetically or manufactured semi synthetically from plant based substances. Pharmaceutical excipients are classified depending on their physicochemical characteristics or their role in the formulation of pharmaceutical dosage forms. It is also used to increase the bulk of the formulations, it also help to administer the accurate and desired quantity of the dosage form conveniently. A large number of excipients are available and it is used in formulation of different dosage forms based on the nature of the active ingredient and Pharmaceutical excipients are generally obtained from natural sources or prepared synthetically or manufactured semi synthetically from plant based substances.

Pharmaceutical excipients are classified depending on their physicochemical characteristics or their role in the formulation of pharmaceutical dosage forms. It intended route of active ingredient administration. Cellulose probably is the most abundant organic compound in the world which mostly produced by plants. It is the most structural component in herbal cells and tissues. Cellulose is a natural long chain polymer that plays an important role in human food cycle indirectly. This polymer has versatile uses in many industries such as veterinary foods, wood and paper, fibres' and clothes, cosmetic and pharmaceutical industries as excipient. Cellulose has very semi-synthetic derivatives which are extensively used in pharmaceutical and cosmetic industries. Cellulose ethers and cellulose esters are two main groups of cellulose derivatives with different physicochemical and mechanical properties. Cellulose and its derivatives (ether and ester) are among the excipients frequently used in pharmaceutical compounded and industrialized products with various purposes. Among their uses, the most frequently reported are as suspending agents in oral liquid extemporaneous preparation and as viscosity increasing agents in topical formulations, particularly, in oral solid dosage forms, cellulose and its derivatives (also known as cellulosic) can render distinct drug delivery property patterns: immediate, controlled/sustained or delayed release. In

Cellulose probably is the most abundant organic compound in the world which mostly produced by plants. It is the most structural component in herbal cells and tissues. Cellulose is a natural long chain polymer that plays an important role in human food cycle indirectly. This polymer has versatile uses in many industries such as veterinary foods, wood and paper, fibres and clothes, cosmetic and pharmaceutical industries as excipient. Cellulose has very semi-synthetic derivatives which are extensively used in pharmaceutical and cosmetic industries. Cellulose ethers and cellulose esters are two main groups of cellulose derivatives with different physicochemical and mechanical properties.

Cellulose and its derivatives (ether and ester) are among the excipients frequently used in pharmaceutical compounded and industrialized products with various purposes. Among their uses, the most frequently reported are as suspending agents in oral liquid extemporaneous preparation and as viscosity increasing agents in topical formulations, Particularly, in oral solid dosage forms, cellulose and its derivatives (also known as cellulosic) can render distinct drug delivery property patterns: immediate, controlled/sustained or delayed release. Addition, cellulosics show several interesting characteristics such as low cost, reproducibility, biocompatibility, and recyclability. The latter is currently an important aspect considering the need for green technology. These polymers are broadly used in the formulation of dosage forms and healthcare products. These compounds are playing important roles in different types of pharmaceuticals such as extended and delayed release coated dosage forms, extended and controlled release matrices, osmotic drug delivery systems, bioadhesives and mucoadhesives, compression tablets as compressibility enhancers, liquid dosage forms as thickening agents and stabilizers, granules and tablets as binders, semisolid preparations as gelling agents and many other applications.

Now a day's cellulose and cellulose based polymers have gained a great popularity in pharmaceutical industries and become more and more important in this field owing to production of the new derivatives and finding new applications for existed compounds by pharmaceutical researchers. Cellulose is the most abundant naturally occurring biopolymer. Various natural fibres such as cotton and higher plants have cellulose as their main constituent. It consists of long chains of anhydrous-D-glucopyranose units (AGU) with each cellulose molecule having three hydroxyl groups per AGU, with the exception of the terminal ends. Cellulose is insoluble in water and most common solvents; the poor solubility is attributed primarily to the strong intra molecular and intermolecular hydrogen bonding

between the individual chains. In spite of its poor solubility characteristics, cellulose is used in a wide range of applications including composites, netting, upholstery, coatings, packing, paper, etc. Chemical modification of cellulose is performed to improve process ability and to produce cellulose derivatives (cellulosic's) which can be tailored for specific industrial applications.

1. Importance of cellulose in pharmaceuticals

Cellulose such as methyl, ethyl, hydroxyethyl, hydroxyethylmethyl, hydroxypropyl (HP), hydroxypropyl methyl (HPM, also denominated hypromellose) and carboxymethyl ethers cellulose. The practice of compounding requires not only the drugs (active pharmaceutical ingredient, API), but also, the excipients (pharmacological inert component) in order to obtain the final medicine. The excipients are chosen according to the characteristics of the required dosage form. Each excipient exerts specific functions in the formulation, as, for instance, a diluents for hard capsules or powders, a coating agent for solid oral dosage forms, a suspending, thickening or stabilizing agent for oral liquids, etc. The excipient function depends on the concentration in a particular pharmaceutical formulation.

Cellulose and its derivatives (ether and ester) are among the excipients frequently used in pharmaceutical compounded and industrialized products with various purposes. Among their uses, the most frequently reported are as suspending agents in oral liquid extemporaneous preparation and as viscosity increasing agents in topical formulations. Particularly, in oral solid dosage forms, cellulose and its derivatives (also known as cellulosic's) can render distinct drug delivery property patterns: immediate, controlled/sustained or delayed release. In addition, cellulosic's show several interesting characteristics such as low cost, reproducibility, biocompatibility, and recyclability. The latter is currently an important aspect considering the need for green technology. Polymeric delivery systems are mainly intended to achieve controlled or sustained drug delivery. Polysaccharides fabricated into hydrophilic matrices remain popular biomaterials for controlled-release dosage forms and the most abundant naturally occurring biopolymer is cellulose; so hdroxypropylmethyl cellulose, hydroxypropylcellulose, microcrystalline cellulose and hydroxyethyl cellulose can be used for production of time. Controlled delivery systems. Additionally microcrystalline cellulose, sodium carboxymethylcellulose, hydroxyl propyl methyl cellulose, hydroxyl ethyl cellulose as well as hydroxyl propyl cellulose is used to coat tablets. Cellulose acetate phthalate and hydroxyl methyl cellulose phthalate are also used for enteric coating of tablets. Targeting of

drugs to the colon following oral administration has also been accomplished by using polysaccharides such as Hydroxyl propyl methyl cellulose and hydroxyl propyl cellulose in hydrated form; also they act as binders that swell when hydrated by gastric media and delay absorption. Polymers are classified in several ways; the simplest classification used for pharmaceutical purposes is into natural and synthetic polymers. Polysaccharides, natural polymers, fabricated into hydrophilic matrices remain popular biomaterials, for controlled-release dosage forms and uses of a hydrophilic polymer matrix is one of the most popular approaches in formulating an extended-release dosage forms. This is due to the fact that these formulations are relatively flexible and a well designed system usually gives reproducible release profiles. Since drug release is the process by which a drug leaves a drug product and is subjected to absorption, distribution, metabolism, and excretion (ADME), eventually becoming available for pharmacologic action, hence drug release is described in several ways as follows:

a) Immediate release refers to the instantaneous availability of drug for absorption Or pharmacologic action in which drug products allow drugs to dissolve with no intention of delaying or prolonging dissolution or absorption of the drug.

b) Modified-release dosage forms include both delayed and extended-release drug products. Delayed release is defined as the release of a drug at a time other than immediately following administration, while extended release products are formulated to make the drug available over an extended period after administration.

c) Controlled release includes extended-release and pulsatile-release products. Pulsatile release involves the release of finite amounts (or pulses)of drug at distinct intervals that are programmed into the drug product. One of the most commonly used methods of modulating tablet drug release is to include it in a matrix system. The classification of matrix systems is based on matrix structure, release kinetics, controlled release properties (diffusion, erosion, swelling), and the chemical nature and properties of employed materials. Matrix systems are usually classified in three main groups: hydrophilic, inert, and lipid. In addition, the drug release is a function of many factors, including the chemical nature of the membrane, geometry and its thickness, and the particle surface area of the drug device, the physicochemical nature of the active substance and the interaction between the membrane and the permeating fluids are also important. In fact, the mechanism probably varies from membrane to membrane, depending on the membrane structure as well as on the nature of the permeating solution. It is believed that

several different mechanisms are involved in the drug release through a non-disintegrating polymer coat.

d) ermeation through water-filled pores; in this mechanistic model, the release of the drug involves transfer of the dissolved molecule through water-filled pores. The coating membrane is not homogeneous. The pores can be created by the incorporation of leachable components, such as sugars or incompatible water soluble polymers into the original coating material or can be produced by an appropriate production process.

e) Permeation through membrane material; in this mechanism, the release process involves the consecutive process of drug partition between the core formulation and the membrane. The drug molecules are dissolved in the membrane at the inner face of the coat, representing equilibrium between a saturated drug solution and the membrane material. The transport of drug across the coat is then driven by the concentration gradient in the membrane. Outside them embrane, the drug is dissolved in an aqueous environment.

f) Osmotic pumping; this release mechanism is driven by a difference in osmotic pressure between the drug solution and the environment outside the formulation. In addition to the above, controlled release of drug from the matrix is dependent on particle size and type of the polymer wetting, polymer hydration, polymer dissolution, and drug: polymer ratio. The hydration rate depends on the nature of the constituents, such as the molecular structure and the degree of substitution. The viscosity of the aqueous solution can be increased by increasing the average molecular weight of the polymer, the concentration of the polymer or decreasing the temperature of the solution So, the factors associated with polymers, such as molecular weight type (nominal viscosity), concentration, degree of substitution, and particle sizes have been shown to have a significant influence on drug release. For example, in tablet formulations containing hydrophilic polymers like HPMC, their lease of active drug is controlled by the rate of formation of a partially hydrated gel layer of the tablet surface formed upon contact with aqueous gastric media following ingestion and the continuous formation of additional gel layers. In addition to this, process variables like method of granulation, amount of binder added during granulation, use of high or low shear mixer, granule size distribution, compression force during tablet, etc., are also important for extended-release.

2. Pharmaceutical uses of cellulose and cellulose derivatives

Cellulose ethers are widely used as important excipients for designing matrix tablets. On contact with water, the cellulose ethers start to swell and hydro gel layer starts to grow around the dry core of the tablet. The hydro gel presents a diffusion barrier for water molecules penetrating into the polymer matrix and the drug molecules bringer leased.

2.1. Oxycellulose

Oxidized cellulose (oxycellulose) is cellulose in which some of the terminal primary alcohol groups of the glucose residues have been converted to car-boxy groups. Therefore, the product is possibly a Synthetic poly anhydrocello biuronide and that contain25% carboxyl groups are too brittle (friable) and too readily soluble to be of use. Those products that have lower carboxyl contents are the most desirable. The oxidized cellulose fabric, such as gauze or cotton, resembles the parent substance; it is insoluble in water and acids but soluble in dilute alkalis. In weakly alkaline solutions, it swells and becomes translucent and gelatinous. When wet with blood, it becomes slightly sticky and swells, forming a dark brown gelatinous mass. So, it is used in various surgical procedures, by direct application to the oozing surface except when used for homeostasis, it is not recommended as a surface dressing for open wounds. The oxidized cellulose product readily disperses in water and forms thyrotrophic dispersions. Such suspensions/dispersions, which may be optionally combined with other pharmaceutical and cosmetic adjutants, can be used for producing novel film forming systems. A wide variety of solid (crystalline or amorphous) and liquid (volatile or non-volatile) acidic, neutral, and basic bioactive compounds can be entrapped/loaded in such systems, thereby producing substantive controlled and/or sustained release formulations, having unique applications in the development of variety of cosmetic, pharmaceutical, agricultural, and consumer products. Topical formulations (cream, lotion, or spray) prepared using the oxidized cellulose material, are bio adhesive, can be applied on the human skin or hair, can be included in cosmetics. Oxidized cellulose dispersion uses in anti acne cream, anti-acne lotion, sunscreen spray, anti-fungal cream also. For using oxidized cellulose as a direct compression excipient Banker and Kumar grounded it and prepared tablets by mixing the ingredients by ratio of 20, 79 and 1% for oxidized cellulose, lactose NF(Fast-Flo), magnesium stearate respectively, each tablet weighed 500 ± 10 mg. The hardness, the disintegration times and water penetration rate were 5.17 kg, 30 sec and 10.49 mg/sec respectively.

2.2. Microcrystalline Cellulose

Since its introduction in the 1960s, MCC has offered great advantages in the formulation of solid Dosage forms, but some characteristics have limited its application, such as relatively low bulk density, moderate flow ability, loss of compatibility after wet granulation, and sensitivity to lubricants. Solidification of MCC improves the functionality of MCC with such properties as enhanced density, low moisture content, flow ability, lubricity, larger particle size, compatibility and compressibility. Silicified MCC (SMCC) is manufactured by drying a suspension of MCC particles and colloidal silicon dioxide such that the dried finished product contains 2% colloidal silicon dioxide. Silicon dioxide simply adheres to the surface of MCC and occurs mainly on the surface of MCC particles; only a small amount was detected in the internal regions of the particles. So, SMCC shows higher bulk density than the common types of MCC also, tensile strength of compacts of SMCC is greater than that of the respective MCC and it is most probably a consequence of inter surface interactions of silicon dioxide and MCC. Tablet studies have suggested that SMCC has enhanced compatibility, even after wet granulation, and reduced lubricant sensitivity, compared to the regular grade of MCC. For example, Sherwood and Becker have compared the direct-compression tablet performance of SMCC 90 with a regular grade of MCC (Avicel PH102) that has similar particle size and density. They found that, SMCC 90 was 10–40% more compactable than regular MCC in the absence of drug. The SMCC 90 also showed a lower lubricant sensitivity and retained, two to three times the compatibility in tablet of the comparable MCC grade in a blending time study. Also, Guo and Augsburger compared SMCC's performance to that of other excipients commonly used in hard gelatine capsule direct-fill formulations such as anhydrous lactose (direct tableting grade), pregelatinized starch (PGS), and MCC. The study revealed that SMCC exhibited relatively higher compactibility under the low compression force of a donator capsule filling than either PGS or lactose. Products formulated with the SMCC materials exhibited faster dissolution rates than those formulated with PGS and anhydrous lactose when loaded with 5% piroxicam, 30 and 50% acetaminophen. Suchhigher compactibility and fast dissolution rates suggest that SMCC could be a suitable alternative excipient for direct- fill formulations for hard shell capsules. In another study, comparison of the compaction force versus tablet tensile strength showed that SMCC was approximately 20% more compatible than regular MCC. Stronger tablets manufactured from SMCC were easier to coat further also, the size and weight of individual tablets were decreased, which increases patients' compliance. SMCC possesses further advantages, decreasing the hygroscopicity of the active ingredient (increased stability of tablets). Due to a decreased

size, higher compressibility, and better flow properties (lower sensitivity to the rate of tableting); a larger number of tablets in one batch can be achieved, which makes their manufacture substantially cheaper.

2.3. Methylcellulose (MC)

In this cellulose ether derivative approximately 27–32% of hydroxyl groups are changed to the methyl ether (CH3O) form. MC is practically insoluble in most organic solvents. Various grades of MC can be found with degrees of polymerization in the range of 50 to 1000 and molecular weights (number average) in the range 10 000 to 220 000 Da. In compounded medicines, MCs function as emulsifying agents (1-5%), suspending agents (1-2%), capsule disintegrants and viscosity increasing agents. In compounding pharmacies, MCs of different viscosity grades, low and high, have been applied in oral liquid (oil emulsions, suspensions, solutions) and topical (creams, gels) formulations respectively. MC is often used instead of sugar-based syrups and other suspension bases. MC delays the settling of suspensions and increases the contact time of drugs in the stomach.

2.4. Ethyl cellulose (EC)

This cellulose derivative is partially or completely ethoxylated, yielding 44-51% of ethoxyl groups (OCH_2CH_3). EC is a long-chain polymer of ethyl-substituted □-glucan units joined together by glycoside linkages. In compounded medicines, EC functions as flavouring and as a viscosity increasing agent. In compounding pharmacies, EC finds applications in oral and topical (creams, lotions, gels) formulations. For oral use, it works as an active delivering agent and for topical dosage forms as a thickening agent. It has been evaluated as a stabilizer for emulsions.

2.5. Hydroxyethylcellulose (HEC)

This cellulose derivative is partially substituted hydroxyethyl (CH_2CH_2OH) ether of cellulose. It is found in various viscosity grades, with respect to the DS and molecular weight. Some grades are modified so as to improve aqueous dispersion. HEC is in soluble in most organic solvents. In compounded medicines, HEC has the following functions a suspending, a thickening and a viscosity-increasing agent. It is widely employed in topical formulations (gel) and cosmetics due to its non-ionic and water-soluble polymer characteristics. The main use is as a thickening agent.

It is the non-ionic, pH insensitive cellulose ether and insoluble in water but soluble in many polar organic solvents. It is used as;

- A non-sellable, insoluble component in matrix or coating systems.
- When water-soluble binders cannot be used in dosage processing because of water sensitivity of the active ingredient, EC is often chosen.
- It can be used to coat one or more active ingredients of a tablet to prevent them from reacting with other materials or with one another.
- It can prevent discoloration of easily oxidizable substances such as ascorbic acid.
- Allowing granulations for easily compressed tablets and other dosage forms.
- It can also be used on its own or in combination with water-soluble polymers to prepare sustained release film coatings that are frequently used for the coating of micro-particles, pellets and tablets. In addition to EC, HEC is also non-ionic water-soluble cellulose ether, easily dispersed in cold or hot water to give solutions of varying viscosities and desired properties, yet it is insoluble in organic solvents. It is used as a modified release tablet matrix, a film former and a thickener, stabilizer and suspending agent for oral and topical applications when a non-ionic material is desired.

2.6. Hydroxypropylcellulose (HPC)

This cellulose derivative is partially hydroxypropyl, yielding 53.4–80.5% of hydroxyl propyl groups [OCH_2CH (OH) CH3]. Because the added hydroxyl propyl contains a hydroxyl group which can also be etherified during the preparation, the degree of substitution of hydroxypropyl groups can be higher than three. HPC is found in different grades that provide solutions with various viscosities. Its molecular weight has a range of 50,000 to 1 250 000. HPC with a value of moles of substitution of approximately four is necessary in order to have good water solubility. In compounded medicines, HPC is used as an emulsifying, a stabilizing, a suspending, a thickening or a viscosity-increasing agent. In compounding pharmacies, HPC is also employed in topical formulations (gel) and especially in cosmetics, as an emulsifier and a stabilizer.

2.7. Hydroxypropylmethylcellulose (HPMC)

This cellulose derivative, also called hypromellose, is a partly O-methylated and O-(2-hydroxypropylated) cellulose. HPMC is found in various grades with different viscosities and extents of substitution. The content of methoxyl (OCH_3) and hydroxypropyl groups [OCH_2CH (OH) CH3] affects the HPMC molecular weight, which ranges from 10,000 to1

500 000. HPMC has many different functions in compounded medicines as a dispersing, an emulsifying, a foaming, a solubilising, a stabilizing, a suspending (0.25-5%) and a thickening (0.25-5%) agent. In addition, HPMC can be applied as a controlled-release and sustained release agent. In compounding pharmacies, HPMC has found application for nasal (liquid) and topical (gel, ointment) formulations as a thickening, a suspending, an emulsifying and a stabilizing agent. The aqueous solution produced with HPMC presents greater clarity and fewer not dissolved fibres compared with MC. HPMC can prevent droplets and particles from coalescing or agglomerating, thus inhibiting the formation of sediment. In addition, it is also widely used in cosmetics.

2.8. Carboxymethylcellulose (CMC)

It is available as calcium and sodium salt forms of a polycarboxymethyl (CH2COOX, n X=Ca or Na) ether of cellulose. Only sodium CMC is commonly used in compound preparations. The degree of substitution can be estimated by a sodium assay, which must be between 6.5-9.5%. CMC-Na acts as a capsule disintegrant and a stabilizing, a suspending, an emulsifying (0.25-1%), a gel-forming (3-6%) and a viscosity-increasing (0.1-1%) agent in compounded medicines.In compounding pharmacies, CMC-Na has applications in oral (liquid, solid) and topical (liquid, gel, emulsion) formulations, primarily for its viscosity-increasing properties. Viscous aqueous solutions are used to suspend powders intended for either topical or oral use. In emulsions, CMC may be used as stabilizer. At higher concentrations, a CMC of intermediate-viscosity grade forms gels that are employed as a base for cosmetics or other drug formulations. Similarly to microcrystalline cellulose, CMC-Na is also described as a constituent of vehicles used for oral suspension. More recently used cellulose ethers in bio adhesives include non-ionic cellulose ethers such as ethyl cellulose (EC), hydroxyethyl cellulose, hydoxypropyl cellulose (HPC), methyl cellulose (MC), carboxymethyl cellulose (CMC) or hydroxylpropylmethyl cellulose (HPMC) and anionic ether derivatives like sodium carboxylmethyl cellulose (NaCMC).

Table No. 01: Applications for Sodium Carboxymethylcellulose.

Specific applications	Properties utilized
Ointments, creams, lotions	emulsion, stabilizer, thickener, film-former
Jellies, salves	thickener, gelling agent, protective colloid, film-former
Tablet binder, granulation aid	high-strength binder
Sustained release	thickener, diffusion barrier
Tablet coating	film-former
Bulk laxatives	physiologically inert, high water-binding capacity
Syrups, suspensions	thickener, suspending aid
Toothpaste, foamed products suspending aid, thickener	thickener, flavour stabilizer, suspending aid, binder
Shampoos	foamed products suspending aid, thickener,
Denture adhesives	foam stabilizer, high water-binding capacity

3. Source of rice husk cellulose

Agriculture produces significant amounts of wastes which contain high quantities of cellulose a linear polysaccharide constituting the major component of rigid cell wall of plants, the rice husk cellulose is an alternative exicipent as a pharmaceutical exicipents. These plants are almost exclusively grown as fibre crops and there is a growing concern on the future availability and price of the fibres' from these crops due to the limitations of land, water, and energy needed to grow these crops. Therefore, attempts are being made to develop alternative sources for natural cellulose fibres. By products of agricultural crops are being considered as inexpensive, abundant, annually renewable, and sustainable sources for natural cellulose fibres. The by-products of major food crops including cornhusks, cornstalks, rice and wheat straw and sorghum stalk and leaves, pineapple leaves and sugarcane stalks have all been studied as potential fibres sources. It has been shown that fibres obtained from these alternative sources have properties similar to or better than the properties of cotton and linen. Rice husk (RH) is one of the by-products obtained during milling of rice. This surrounds the paddy grain. It is reported that approximately 0.23 tons of rice husk (rice hull) is formed from every ton of rice produced. World rice production is approximately 645 million tons. Asian farmers produce rice about 90% of total production of 100,000 tons or more, with two countries, China and India, growing more than half of the total crop. In certain countries, it is sometimes used as a fuel for parboiling paddy in the rice mills and to power steam engines. The partially burnt rice husk in turn contributes to environmental pollution. It would be beneficial to the environment to recycle the waste to produce eco-material having high end value. End use of any material including wastes depends on its structure, properties and

mainly on chemical composition. Chemical compositions of rice husk vary from sample to sample. This variation is due to differences in climatic and geographical conditions, type of paddy etc.

1. Source of cellulose

These plants are almost exclusively grown as fibre crops and there is a growing concern on the future availability and price of the fibres from these crops due to the limitations of land, water, and energy needed to grow these crops. Therefore, attempts are being made to develop alternative sources for natural cellulose fibres. By products of agricultural crops are being considered as inexpensive, abundant, annually renewable, and sustainable sources for natural cellulose fibres. The by-products of major food crops including cornhusks, cornstalks, rice and wheat straw and sorghum stalk and leaves, pineapple leaves and sugarcane stalks have all been studied as potential fibre sources. It has been shown that fibres obtained from these alternative sources have properties similar to or better than the properties of cotton and linen. As well as such maize, cellulose sweet corns cellulose, so many fibres containing celluloses are available in our environments. The sources of those produce the extent variety of cellulose.*(Kumar & Patel,2015).*

2. Uses of Rice Husk

A number of rice-producing countries including India are currently conducting research on industrial uses of rice husk. Some of the current and potential applications in various fields are listed below:

- Non energy applications
- Incorporation in soil for composting
- Bio-fertilizer additive
- Animal husbandry low quality feed
- Sorbent material in environmental remediation
- Building material with good thermal insulation
- Pest control agent
- Board manufacturing
- Composted manure

a. Application of rice husk

Rice husk are widely applicable for several industries now a days, because it has appropriate composition to be utilised in the field of several industries as well pharmaceutical area. Commonly applied at cement factories for pozzolan and such applications have been maintained below in table no 02. Accelerating the part of its value in economical price today. While enhancing those industries its significant role in their field. Now a day's industries are using such a material which is easily available and economically consumed without harming any of the unwanted environmental hazards.

Rice husk parts which are likely to considered rice hull, rice straws, rice herbs etc. Ash which gain after the burnet of rice herbs or rice straw or rice hull, these ash are used in dusting materials in the several area of factories to make bricks and building concrete.

Table No. 02: Application of rice husk.

Feature	Application
Absorbent	For oils and chemicals
Insulator	As insulation powder in steel mills • In homes and refiner-ants • In the manufacture of refractory bricks
Release agent	As a release agent in the ceramics industry
Pozzolan	Cement industry • Concrete industry
Repellents	As repellents in the form of "vinegar-tar"
Binding agents	As binder for tablets, granules,

PROFILE OF RICE HUSK

Rice husk is a value added material for pharmaceuticals because rice husk produce significant role as producing cellulose, which used as an excipients in pharmaceuticals. Rice husk has such compatible properties, which can enhance the disintegration process with optimum required at reach to that of standard level of pharmaceutical disintegrating agents. It is known that the rice husk is an important silicon dioxide source. Silicon dioxide (SiO_2) is a composite of a remarkable structural complexity, presenting 12 different crystal forms.

The colloidal silicon dioxide is largely used in pharmaceutical, beauty and food products. A lot of effort had been devoted to the development of pharmaceutical tablet excipients from locally available materials, among which are; microcrystalline cellulose from rice husk.

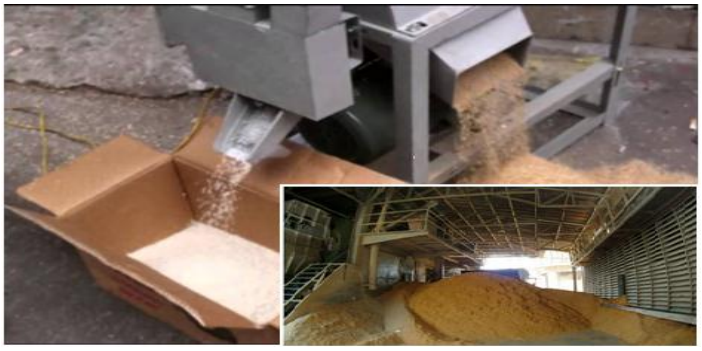


Figure No. 01.

Table No. 03: Typical analysis properties of Husk.

S.no	Property	Range
1.	Bulk density (kg/m^3)	96- 160
2.	Length of husk	2-5
3.	Hardness (Mohr scale)	5-6
4.	Ash (%)	22-29
5.	Carbon (%)	≈ 35.0
6.	Hydrogen (%)	4-5
7.	Oxygen (%)	31.0-37.0
8.	Sulphur (%)	0.04-0.08
9.	Nitrogen (%)	0.23-0.32
10.	Moisture content (%)	8.0-9.0

Cellulose from many sources have long been used in tablet formulations as a diluents, binder, and disintegrant depending on the method of incorporation and the quantity used. The starch, United States Pharmacopeia (USP) grade, may be obtained from either the grain of corn, rice, or wheat, or from tubers of tapioca or potato Cellulose is a natural, cheap, available, renewable, and biodegradable polymer produced by many plants as a source of stored energy. It is the second most abundant biomass material in nature. It is found in plant leaves, stems, roots, bulbs, nuts, stalks, crop seeds, and staple crops such as rice, corn, wheat, cassava, and potato. It has found wide use in the food, textiles, cosmetics, plastics, adhesives, paper and pharmaceutical industries. Recently modified rice starch, starch acetate and acid hydrolyzed dioscorea starch were established as multifunctional excipients in the pharmaceutical industry.*(Ram Prasad et al,2012).*

Components and Structure of Rice Husk

It is generally reported that in rice husk, silica is predominantly in inorganic linkages, but some of the silica is also bonded covalently to the organic compounds. This portion of the silica is un-dissolved in alkali and can withstand very high temperatures. It has been cleared

that once the organic part of RH is extracted, the inorganic residue may be relatively pure, forming a better source for silica. Characterizations by Scanning electron microscopy (SEM), energy-dispersive X-ray analysis (EDX) etc., suggest that silica is present all over, but is concentrated on protuberances and hairs (trichomes) on the outer epidermis, adjacent to the rice kernel.

Table No. 04: Chemical analysis of raw rice husk.

Constituent	Content (wt %)
Organic material and moisture	73.87
Al2O3	1.23
Fe2O3	1.28
CaO	1.24
MgO	0.21
SiO2	22.12
MnO2	0.074

MATERIAL AND METHODS

1. Materials

Different brand of rice husk like HMT rice husk, Mahamaya rice husk, Sorna rice husk and Safari rice husk was collected from Ambika Rice mill, Durg (C.G). And mucilage was collected from village of Chhattisgarh. And other material like chemicals was prepared in our institute.

2. Preparation of Rice Husk powder

The different brand of rice husk was collected from local rice mill. About 40 gm of the husk was taken and check the absence of foreign matter. Then it was crushed and sieved through 80# sieve. The sieved powder was collected and stored into air tight container.

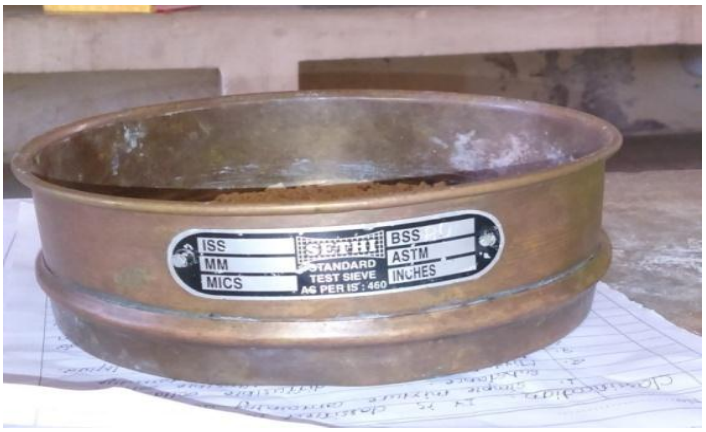


Figure No. 02: Sieve 80# size.

3. Characterization of Rice Husk Powder

The collected husk samples was evaluating for swelling factor, ash value and foreign particle according to standard.

3.1. Physicochemical properties

The Organoleptic characteristic (Taste, odour and colour) of different brand of rice husk.

3.2. Particle size analysis by Sieve method

A sieve-shaker was used for this assessment. Test sieves were arranged in a descending order after recording individual weight of the empty sieves and the pan. A 100 g quantity of rice husk samples powder was placed on the top sieve and the set-up was shaken for 5 min. The weight of material retained on each sieve was determined. Particle size of retained husk was then determined.

3.3. Flow property by Angle of Repose

The static angle of repose, a, was measured according to the fixed funnel and free standing cone method. A funnel was clamped with its tip 2 cm above a graph paper placed on a flat horizontal surface. The powders were carefully poured through the funnel until the apex of the cone thus formed just reached the tip of the funnel. The mean diameters of the base of the powder cones were determined and the tangent of the angle of repose calculated using the equation:

$Ø = \tan^{-1} (h/r)$

Where h is the height of the heap of powder and r is the radius of the base of the heap of powder

3.4. Bulk and Tapped densities

Exactly 20 g of starch was weighed on chemical balance and transferred into a 100 ml measuring cylinder. The volume occupied by the starch recorded as the bulk volume. The cylinder was dropped on a wooden platform from a height of 2.5 cm three times at 2 seconds intervals until the volume occupied by the starch remained constant. This was repeated five times for the pregelatinized starch and average bulk and tapped volumes recorded. The data generated were used in computing the Carr's index and Hausner's ratio of different brand of husk.

3.5. Melting point range by capillary

Melting point of different rice husk samples was determined by Using melting point apparatus. And observed the point where sample is melt.

3.6. Foreign particles

The powders are visually inspected for any foreign Particles.

4. Swelling study

The prepared films were peeled out and cut into 1 x 1 cm2 samples, then dried at 100 °C for a period of 6 h to remove the moisture content. The dry weight of each sample was noted initially and immersed in 0.1 M solutions of NaOH. After a fixed time interval (5 min), the samples were taken out, wiped carefully with filter paper. Then thickness and mass were measured by screw guage and digital electronic balance. The weights and thickness were measured in triplicate and their mean was reported. Further, the percentage weight gains were calculated by equation (1) and welling by difference in thickness.

SR= (Wg – Wo) / Wo,

Where, Wg is final weight, Wo is initial weight of formulation.

4.1. Preparation of rice husk granules

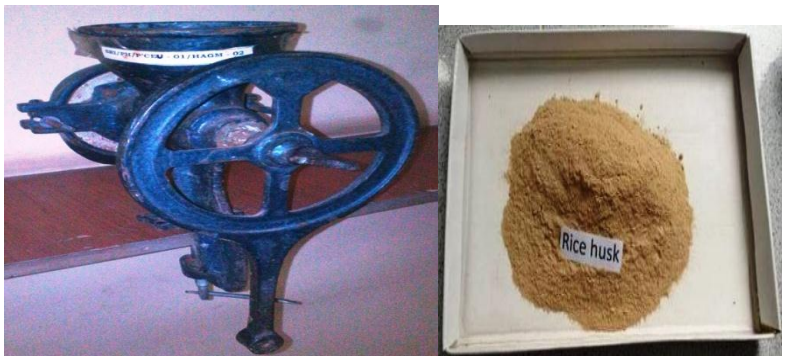
Preparation of rice husk tablet was prepared by tablet making machine. Accurately weighed 180 mg different brand of rice husk and weighed 10mg microcrystalline cellulose, magnesium stearate 4 mg and Talc 2mg.All ingredients are mix well in motar pestle with sufficient quantity of distil water. Then prepare small balls of material and dried in hot air oven 30-40 ° C. then small balls passed through from 44# mesh sieve, and again dried in hot air oven at same temperature.

Table No. 05: Formulation of different brand of rice husk.

Ingredients	Formulation F1	Formulation F2	Formulation F3	Formulation F4
Rice husk	180	180	180	180
Microcrystallinecellulose	10	10	10	10
Magnesium st.	4	4	4	4
Talc	2	2	2	2
Water	q.s.	q.s	q.s	q.s

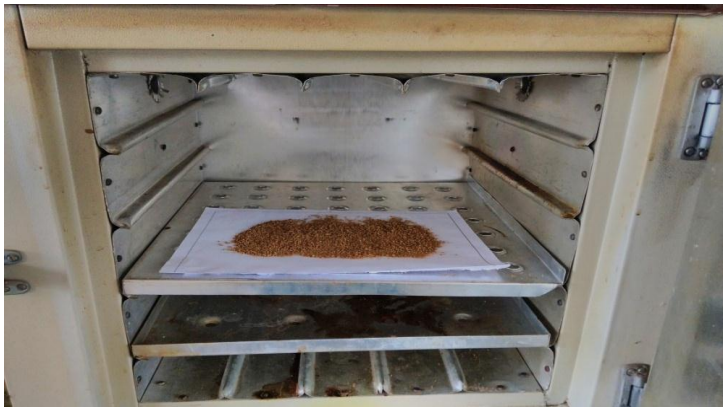
4.2. Steps of preparation of granules of rice husk.

COLLECTED RICE HUSK

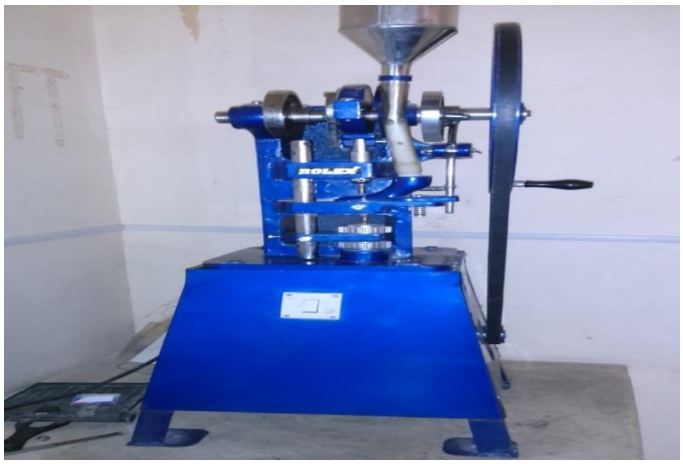


PREPARED RICE HUSK POWDER

PREPARATION OF GRANULES



DRIED GRANULES IN HOT AIR OVEN



PREPARATION OF TABLETS

TABLETS PREPARED

Figure No. 03 Tablet formulations.

4.3. Evaluation of Tablet

1. Disintegration Testing Method

(1) Place 1 dosage unit in each of six tubes of basket and if prescribed add a disk operate the apparatus using water or specified medium as (NaOH, 0.1 N Hcl, 0.5 N Hcl)

(2) Maintain the temperature at 37 C At the End of the time limit specified lift the basket from the fluid and observe the tablet.

(3) All the tablets have disintegrated completely. if 1 or 2 tablets fail to disintegrate completely repeat the test on 12 additional tablets. The requirement is met if not less than 16 of the total of 18 tablets tested are Disintegrated.

3. Hardness Testing Method

Determine hardness of the tablet by using Fisher Hardness Testing Apparatus. That of process of assaying of hardness of any tablets would be in order, firstly taken 20 tablets and then measured each tablets separately through fisher hardness test apparatus, that variation of all tablets could weighted again. And then finally observed that of loss of weight, either acceptable or not.

4. Friability Test Method

To determine friability of rice husk tablets, weighted 4 tablets individually and together, as well as adjusted 25 rpm to that of apparatus for 4 minutes in 100 revolutions, and again weighted all tablets, their loss of weight will express the evaluation of rice husk tablets.

Formula:- $\frac{intial\ weight - final\ weight}{intial\ weight} x\ 100$

RESULT AND DISCUSSION

The comparative study of the physiochemical characteristics of different rice husk powder samples was carried out and result show in table no.3. The analysis of particle size by sieving method it shows the particle size of rice husk samples, in (table no. 4) sieve no 60 # most of particle was remaining it shows that the particle size of different rice of husk was 250 micrometer. The angle of repose of powders insight in to the magnitude of the cohesiveness of the powders and hence its flow ability. Mildly cohesive powders have angle of repose between 40-60º when measured by any standard method shown in table no. 04. Compare then all rice husk safari was show more density as compare to other shows in table no. 05. But comparison with Carr's index Mahamaya was shows excellent flow property as compare to

other shows in table no. 06. And also study about melting point all different rice husk powder a sample was found different melting point shows in table no.07.

1. Physiochemical properties of Rice husk powder samples

Physicochemical properties of different rice husk samples HMT rice husk (A), Mahamaya rice husk (B),Sarona rice husk (C) and Safari rice husk (D) are following as:

Table No. 06: Physiochemical properties of rice husk powders.

Parameter	Inference (A)	Inference (B)	Inference (C)	Inference (D)
State	Solid	Solid	Solid	Solid
Colour	Golden brown	Yellowish brown	Yellowish brown	Golden and yellowish brown
Odour	Odourless	Odourless	Odourless	Odourless
Taste	Tasteless	Tasteless	Tasteless	Tasteless

2. Particle size analysis by Sieve method

By this method we are analysis of the particle size by sieve method, data showed in table no.4.

Table No. 07: Particle size analysis by Sieve method.

Samples of rice husk powder	Sieve no 60# in gm	Sieve no.80 # in gm	Sieve no.100 # in gm	Sieve no.120 # in gm
HMT	79.32	1.35	0.25	0.10
Mahamaya	91.03	4.55	0.61	0.12
Sarona	84.62	1.42	1.22	1.20
Safari	92.05	0.86	1.20	1.47

3. Flow property by Angle of Repose

Angle of repose showed the flow property of different rice husk are shown in following table no.

Table No. 08: Flow property by Angle of Repose.

Samples of rice husk powder	Angle of repose	Flow property
HMT	43.44	Very poor
Mahamaya	41.79	Very poor
Sarona	44.18	Very poor
Safari	45.96	Very poor

4. Bulk and tapped Density

Bulk densities of different rice husk was shown in table no.09.

Table No. 09: Bulk densities and tapped densities of rice husks.

Samples of rice husk powder	Bulk Density (kg/m^3)	Tapped Density (g/cc)
HMT	0.4	0.41
Mahamaya	0.5	0.50
Sarona	0.19	0.19
Safari	0.21	0.21

5. Carr's consolidation Index of different rice husk

Table No. 10: flow property of different rice husk according to Carr's index.

Samples of rice husk powder	Carr's %	Flow
HMT	25	Poor
Mahamaya	6	Excellent
Sarona	15.78	Good
Safari	19.04	Fair to passable

6. Melting point range

By Capillary method it was observed that, shown in table no. 7.

Table No. 11: Melting point of different rice husk.

Samples of rice husk powder	Melting point
HMT	220
Mahamaya	219
Sarona	227
Safari	234

7. Particle size analysis by Sieve method

By this method we are analysis of the particle size by sieve method, data showed in table no.3.

Table No. 12: Particle size analysis by Sieve method.

Samples of rice husk powder	Sieve no 60# in gm	Sieve no.80 # in gm	Sieve no.100 # in gm	Sieve no.120 # in gm
HMT	79.32	1.35	0.25	0.10
Mahamaya	91.03	4.55	0.61	0.12
Sarona	84.62	1.42	1.22	1.20
Safari	92.05	0.86	1.20	1.47

9. Flow property by Angle of Repose

Angle of repose showed the flow properties of different rice husk are shown in following table no5.

10. Swelling study

The thickness was calculated by difference of dry and soaked film. The observed percentage weight gain and swelling were found to be 118.27% and 21.2%, respectively.

11. Preparation of rice husk powder

Rice husk powder was prepared by using mixer. Then powder passed through sieve no. 80# and then packed in closed tight container.

Figure: 04: Rice husk powder of sample 1.

Figure 05: Rice husk of sample 2.

12. Preparation of rice husk granules

All ingredients mix well and prepared granules by using sieving method through sieve 10# mesh size.

Figure 06: granules of sample 1.

Figure 07: Granules of sample 2.

13. Preparation of rice husk tablets

Weighed accurately 500 mg amount of granules and compressed in punching machine through tablet punching machine. And granules were dried in hot air oven at 30-40°C temperature.

Figure 08: Tablets of rice husk.

14. Evaluation of Rice Husk Tablets

Disintegration time of Rice Husk and Straw tablets.

Table No. 13: Disintegration Time Observation Table.

Sample of Rice Husk Tablets	Media	pH	Vol. of H_2O	Temperature	Disintegration Time (per/min)
HMT	NaOH	9	900 ml	37°C	15.5 min.
Mahamaya	H_2O	7	900 ml	37°C	11.32 min.
Sarona	0.1 N HCL	0.18	900 ml	37°C	6.2 min.
Safari	0.5 N HCL	1	900 ml	37°C	8.5 min.

The NaOH Sample was disintegrated by disintegration method and disintegration time was found to be 15.5 min.

15. Hardness of Rice Husk and Straw Tablet

Table No. 14: Hardness Observation Table.

Sample of Rice Husk and Straw Tablet	*Hardness (per/kg)*
HMT	3
Mahamaya	3.5
Sarona	4
Safari	4.5

Observation has been determined above in tables, which explore the hardness of different brands of rice husks.

CONCLUSION

Rice husk is a value added material for pharmaceuticals because rice husk produce significant role as producing cellulose which used as an excipients in pharmaceuticals. Rice husk has such compatible properties, which can enhance the disintegration process with optimum required pharmaceutical disintegrating agents. Rice husk for pharmaceutical applications is attractive because they are economical, readily available, non-toxic, capable of chemical modifications, potentially. Natural cellulose can also be modified to have tailor-made products for drug delivery systems and thus can complete with the synthetic controlled release excipients available in the market. Mainly used as binder for preparation of tablet, it conclude that the waste of rice, now rice husk used as excipients, because it doesn't have any toxicities.

Rice husk extracted celluloses are previously used as disintegrating agents in pharmaceuticals. On my research, I aimed to utilized rice husk as disintegrating agents to promote its activities in different parameters. Because 1000gm of rice husk considered only 20% weight of cellulose, on that of 50% is pure cellulose and rest of 25 to 30% is lignin and 15 to 20% is silica as well. So that would be costly to perform extraction process to separate out these components from rice husk.

As per guidance of my supervision, constriction of modules to enhance these activities to perform disintegration evaluation with directly using rice husk tablet in disintegration medium, and other evaluation parameters to be done thoroughly.

As well as different brands of rice husk producing differ disintegration, which of comparative studies are indulge. Those evaluation parameters where these different brands of rice husk producing variation in evaluation can reach us to desire rice husk could be uses betterment for enhancement in disintegration process.

The comparative study of the physiochemical characteristics of different rice husk powder samples was carried out and results. The analysis of particle size by sieving method it shows the particle size of rice husk samples, in sieve no 60 # most of particle was remaining it shows that the particle size of different rice of husk was 250 micrometer. The angle of repose of powders insight in to the magnitude of the cohesiveness of the powders and hence its flow ability. Mildly cohesive powders have angle of repose between 40-60º when measured by any standard method. Compare then all rice husk safari was show more density as compare to other. But comparison with Carr's index Mahamaya was shows excellent flow property as compare to other, And also study about melting point all different rice husk powder samples was found different melting point.

Preparation of rice husk granules have been optimized with the standard of pharmaceutical ethic and guidance, on the bases of that order all process of formulation took place. Gradually promoting their efficacy to get enormous feature of these rice husk brand.

A pharmaceutical purpose is into natural and synthetic polymers. Polysaccharides, natural polymers, fabricated into hydrophilic matrices remain popular biomaterials, for controlled-release dosage forms and uses of a hydrophilic polymer matrix is one of the most popular approaches in formulating an extended-release dosage forms. This is due to the fact that these formulations are relatively flexible and a well designed system usually gives reproducible release profiles. Since drug release is the process by which a drug leaves a drug product and is subjected to absorption, distribution, metabolism, and excretion (ADME), eventually becoming available for pharmacologic action.

Pharmaceutical compounded and industrialized products with various purposes. Among their uses, the most frequently reported are as suspending agents in oral liquid extemporaneous preparation and as viscosity increasing agents in topical formulations, Particularly, in oral solid dosage forms, cellulose and its derivatives (also known as cellulosic) can render distinct drug delivery property patterns: immediate, controlled/sustained or delayed release. Addition, cellulosics show several interesting characteristics such as low cost, reproducibility,

biocompatibility, and recyclability. The latter is currently an important aspect considering the need for green technology. These polymers are broadly used in the formulation of dosage forms and healthcare products. These compounds are playing important roles in different types of pharmaceuticals such as extended and delayed release coated dosage forms, extended and controlled release matrices, osmotic drug delivery systems, bioadhesives and mucoadhesives, compression tablets as compressibility enhancers, liquid dosage forms as thickening agents and stabilizers, granules and tablets as binders, semisolid preparations as gelling agents and many other applications.

The characterisation of these starches shows rice starch with the lowest cohesiveness would be the starch of choice when good flow ability is desirable. It also shows that rice starch could be a better tablet disintegrant. These findings would be useful in the handling of these starches and in their use as pharmaceutical excipients in the production of powders, tablets and other relevant drug delivery systems.

The concept to explore different brand of rice husk like HMT rice husk, Mahamaya rice husk Sorna rice husk and Safari rice husk was collected from Chhattisgarh, among which one have the best evaluation characteristics that could help to understand usability in pharmaceutical as an excipients. Or having disintegration assessment for such formulation, where comparative studies determined that which brand of rice husk could produce the best disintegration properties which are available in Chhattisgarh state.

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