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Review Article

A STUDY ON RICE BRAN WAX- A NOVEL EXCIPIENT FOR PHARMACEUTICAL TOPICAL DOSAGE

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ABSTRACT

Rice bran wax, derived from the outer layer of rice grains, has emerged as a novel excipient for pharmaceutical topical dosage forms. This study explores the unique physicochemical properties of rice bran wax, such as its excellent emulsifying, thickening, and stabilizing capabilities, which make it an ideal ingredient for topical formulations. Through a series of formulation experiments, rice bran wax demonstrated its potential to enhance the consistency, stability, and bioavailability of active pharmaceutical ingredients (APIs) in creams, ointments, and lotions. Furthermore, its natural origin and biocompatibility offer significant advantages over synthetic excipients. This research underscores the versatility and efficacy of rice bran wax, paving the way for its broader application in the pharmaceutical industry.

Keywords: Rice Bran Wax**,** Pharmaceutical Excipients**,** Topical Dosage Forms**,** Emulsifying Agent**,** Bioavailability

INTRODUCTION

Many waxes such as white wax, carnauba wax, etc have been tried for cosmetic formulations and have been used as pharmaceutical aids. Compared to these waxes rice bran wax is cheap and obtained from natural source (*Oryza sativa*, Family Graminae) and is abundantly available. It is an important byproduct of rice bran oil industry (Sabale *et al*., 2009).

Most of these topical dosage forms contain waxes and oils are the major ingredients. Many fats and oils contain a number of minor components, which are referred as “nonglycerides” or “waxes”. Some of these nonglycerides play an important role in providing pharmaceutical and industrial benefits. Infact, the recent trends are directed to explore and establish proper usage of nonglycerides occurring in the natural lipid materials like oils and fats. Such trends are considered extremely important to improve the economy of the lipids and to meet also the newer possibilities of utilization of the nonglycerides and derivatives of oils and fats. Many investigations around the world have already shown newer pathways for utilizing the nonglycerides in some specific fields. R and D efforts are still pursued to find out newer technologies for utilizing the nonglycerides in a diversified manner. Although waxes are abundant in nature, a limited numbers only are commercially used (Basarkar and Basarkar, 2011).

Rice is Asia's most significant cereal, and it is a staple diet for the vast majority of the region's people. Rice bran wax is an important by product of Rice bran oil industry and belongs to (Oryza sativa) Family Graminae and is abundantly available (Rajeev *et al*.,

2017). Rice bran Wax (RBW) hard yellowish to brownish wax from leaves of the carnauba palm used especially in floor waxes and polishes is a good substitute carnauba wax. It can also be used as component in formulations like stencils, candles,carbon paper base etc (Abhirami and Venkatachalapathy, 2019). Rice bran wax is waste material of dewaxing process in oil refining. Dewaxing is accomplished by mean cooling and filtrating for separating wax from the oil to avoid turbidity in the final product. The dewaxing residue may have 20 up to 80 wt% of oil, followed by a main fraction of waxes, free fatty alcohols, free fatty acids and hydrocarbons. Rice Bran Wax has broad application in a wide variety of foods as a thickener, binding agent, plasticizer, cosmetics, coating and gelling agent. RBW primarily consists of high molecular weight monoesters ranging from C-46 to C-66. Our domestically refined Rice Bran Wax is not solvent extracted, and is rendered of its color using natural carbons and clays (Sanghi and Tiwle, 2015).

Source of Rice Bran Wax

Rice bran wax is a hard, crystalline, high melting vegetable wax obtained from husks of rice *O. sativa* (Tinto *et al*., 2017).

Composition of Rice Bran Wax

Rice bran wax consists of high molecular weight monoesters. These are very long-chain saturated $C_{46}C_{62}$ esters from $C_{20}C_{36}$ fatty alcohols and $C_{20}C_{26}$ fatty acids. The major components of rice bran wax are aliphatic acids (wax acids) and higher alcohol esters. The aliphatic acids consist of palmitic acid (C_{16}), behenic acid (C_{22}), lignoceric acid (C_{24}), and other higher wax acids. The higher alcohol esters consist mainly of ceryl alcohol (C_{26}) and melissyl alcohol (C_{30}). Rice bran wax also contains constituents such as free fatty acids (palmitic acid), squalene, and phospholipids. Rice bran wax is compatible with most vegetable and mineral waxes, as well as vegetable oils, mineral oils, and petrolatum (Ito *et al*., 1981; Aminu *et al*., 2014).

Preparations of Rice Bran Wax

Rice bran wax is obtained through the cold press dewaxing of rice oil and this yields a yellow, hard natural wax with a high melt point, which is often compared to carnauba wax. However, there are functional differences between the two. Rice bran wax is a superior binder of oils and has been useful in combining with and stabilizing oils in both anhydrous and emulsion systems. Rice bran wax is usually refined through batch chromatography technology and is not solvent extracted. This method of refinement retains low concentrations of policosanols, phospholipids, phytosterols, and squalene. The resulting rice bran wax is of superior quality (Feuge and Cousins, 1957).

Uses of Rice Bran Wax

Rice bran wax has been historically used in a wide variety of cosmetics, replacing carnauba wax in some applications. It is used in paper coatings, textiles, explosives, fruit and vegetable coatings, confectionery, pharmaceuticals, candles, molded novelties, electric insulation, textile and leather sizing, waterproofing, carbon paper, typewriter ribbons, printing inks, lubricants, crayons, adhesives, chewing gum, and cosmetics (Creams, Glamour Products, Lotions, Sun Care, Mascara, Lip Balms) (American Oil Chemists, 2004). Rice bran wax can be used as a thickener and has emollience properties.

Rice bran wax also works well as a binding, coating, or gelling agent. It has exceptional oil gelling properties in relatively small concentrations. It is an interesting wax to use in emulsions, creating new textures. It is seen as particularly effective in reducing syneresis in lipstick and other oil-based systems (Sabale *et al*., 2009).

Characterization of rice bran wax (RBW)

Melting Point: Finely powdered RBW at a temperature considerably below its melting point. Transferred a portion to a dry capillary tube and packed the powder by tapping on a hard surface so as to form a tightly packed column 4 to 8 mm in height.Attached one of the tubes to a thermometer graduated in 0.5°C so that the substance is close to the bulb of the thermometer.Introduced the thermometer with the attached tube into a beaker so that the distance between the bottom of the beaker and the lower part of the bulb of the thermometer is 1 cm. fill the beaker with water to a depth of 5cm.Increased the temperature of the water gradually at a rate of 1 c/min (Hartman and Lago, 1973).

Specific Gravity: Dry the pycnometer that previously has been calibrated by determining its weight and the weight of recently boiled water contained in it at 25°C. Melted the substance and filled the pycnometer with it. Adjusted the temperature of filled pycnometer to 25°C and weighed. The specific gravity is the quotient obtained by dividing the weight of sample contained in the pycnometer by the weight of water contained in it, both determined at 25°C (Maihara *et al*., 2001).

Moisture Content

Standardization of the reagent: Placed about 34 ml of dehydrated methanol in the titration vessel and added sufficient KF reagent to give the characteristic end-point. Added quickly 150 to 350 mg of sodium tartrate accurately weight by difference and titrated to end-point (Warth, 1991).The water equivalence factor F in mg of water per ml of reagent is given by the formula.

$$\text{Factor} = \frac{\text{Wt of D. s. T} \times 0.1566}{\text{B. R}}$$

Procedure: After determination of factor added 0.5 g RBW accurately to the titration vessel. Stirred for 1 minute and titrated against the electrometric end-point using KF reagent (Pharmacopoeia, 2007).

$$\text{Moisture content} = \frac{\text{B. R} \times \text{Factor} \times 100}{\text{Wt of sample}}$$

Saponification Value: Weighed 2 g of the RBW into a 200 ml flask, added 40.0 ml of the ethanolic solution of potassium hydroxide and boiled under a reflux condenser for 2 hour, rotating the contents frequently. While the solution was hot, titrated the excess of alkali with 0.5 M Hydrochloric acid using phenolphthalein solution as indicator. Repeated the operation without RBW (British Pharmacopoeia, 2008). Calculated the Saponification Value from the expression 28.05 v/w where v is the difference, in ml, between the titrations and w is the weight, in g, of substance taken.

$$\text{Sap value} = \frac{28.05 \times \text{Diff}}{\text{Wt. of sample}}$$

Acid Value: Dissolved 10.00 g of RBW in 50 ml a mixture of equal volumes of ethanol (96 %) and light petroleum, previously neutralized with 0.1 M sodium hydroxide, using 0.5 ml of phenolphthalein solution as indicator. Heated to about 90°C to dissolved the RBW. When the substance has dissolved, titrated with 0.1 M sodium hydroxide until the pink color persists for at least 15s (n ml of

titrant). When heating has been applied to aid dissolution, maintained the temperature at about 90°C during the titration (Rukmini and Raghuram, 1991).

$$\text{Acid value} = \frac{5.610 \times \text{n}}{\text{Wt of sample}}$$

Ester Value: The ester value calculated by following formula;

Ester value = Sap value – Acid value

Hydroxyl Value: 2.0 gm of RBW into a 150 ml acetylating flask fitted with an air condenser. Add 5 ml of acetic anhydride solution and attached the air condenser. Heated the flask in a water- bath for 1 h keeping the level of the water about 2.5 cm above the level of the liquid in the flask (Sunitha *et al*., 1997). Withdrawn the flask and allowed it to cool. Add 5 ml of water trough the upper end of the condenser. Added sufficient pyridine to clear cloudiness and the volume added was noted. Shaken the flask and replaced it in the water-bath for 10 min. Withdrawn the flask again and allowed to cool. Rinsed the condenser and the walls of the flask with 5 ml of alcohol, previously neutralized to phenolphthalein solution. Titrated with 0.5 M alcoholic potassium hydroxide using 0.2 ml of phenolphthalein solution as indicator (n2 ml of 0.5 M alcoholic potassium hydroxide). Carried out a blank test under the same conditions (n2 ml of 0.5 M alcoholic potassium hydroxide)

$$\text{Hydroxyl value} = \frac{28.05 \times (\text{n2} - \text{n1})}{\text{Wt of sample}} + \text{Acid value}$$

Unsaponifiable Matter: To 2.0 to 2.5 g of RBW contained in a 250 ml flask, added 25 ml of 0.5 M ethanolic potassium hydroxide and boiled under a reflux condenser in a water bath for 1 hour, swirling the contents frequently. Washed the contents of the flask into a separating funnel with the aid of 50 ml of water and while the liquid was slightly warm, extracted by shaking vigorously with three 50 ml quantities of peroxide free ether, rinsing the flask with the first quantity of ether. Mixed the ether solutions in a separating funnel containing 20 ml of water. Gently rotated separating funnel for a few minutes without violent shaking, allowed the liquids to separate and discarded the aqueous layer (Qureshi *et al*., 2002). Washed the ether solution by shaking vigorously with two 20 ml quantities of water and then treated with three 20 ml quantities of 0.5 M potassium hydroxide, shaking vigorously on each occasion, each treatment was followed by washing with 20 ml of water.Finally washed with successive 20 ml quantities of water until the aqueous layer was no longer alkaline to phenolphthalein solution. Transferred the ether extract to a weighed flask rinsing the separating funnel with peroxide free ether, distilled the ether and added 3 ml of acetone to the flask. With the aid of a gentle current of a air removed the solvent completely from the flask which was almost immersed in boiling water and hold obliquely and rotated. Dried to constant weight at a temperature not exceeding 80° C and dissolved the content of the flask in 10 ml of freshly boiled ethanol (96 %) previously neutralized to phenolphthalein solution (Kochhar, 1983).Titrated with 0.1 M ethanol sodium hydroxide using phenolphthalein solution as indicator. Calculated the Unsaponifiable matter as a percentage of the substance.

$$\text{Unsaponofied matter} = \frac{\text{Wt of Resisdue} \times 100}{\text{Sample}}$$

Free Fatty Acid: Boiled 250 ml of ethanol (96 %) to remove carbon dioxide, added 0.5 ml of phenolphthalein solution, allowed to cool to 70°C and neutralized with 10g Sodium hydroxide to 100 ml of the neutral ethanol, added 10 g of the RBW and dissolved it quickly by heating under a reflux condenser. Cooled to 70°C and titrated at 70°C with 0.1 M sodium hydroxide (Not more than 0.2 ml is required. If the solution is still pink added in a thin stream 5 ml of hot barium chloride solution previously neutralized to phenolphthalein solution, mix thoroughly and titrate with M hydrochloric acid until the pink color disappears not more than 1.0 ml is required) (Yamauchi *et al*., 1980).

Iodine Value: Taken 1.0 g substance into a 250 ml flask fitted with a ground glass stopper and previously dried or rinsed with glacial acetic acid, and dissolved it in 15 ml of chloroform.Added very slowly 25.0 ml of iodine bromide solution. Closed the flask and kept it in the dark for 30 min. shaking frequently.Added 10 ml of a 100 g/l solution of potassium iodide and 100 ml of water.Titrated with 0.1 M sodium thiosulphate shaking vigorously until the yellow color was almost discharged. Added 5 ml of starch solution and continued the titration by adding the 0.1 M sodium thiosulphate drop wise until the color was discharged (n1 ml of 0.1 M sodium thiosulphate) (Seetharamaiah and Chandrasekhara, 1990).Carried out a blank test under the same condition (n2 ml of 0.1 M sodium thiosulphate).

$$\text{Iodine value} = \frac{1.269 \times (n2 - n1)}{\text{Wt of sample}}$$

Table 1: Standards of Rice Bran Wax

Characteristics	Values
Solubility	Insoluble in water; soluble in ether ethanol & IPA
Melting point	80.5 Celsius
Specific gravity	0.912
Moisture content	0.074%w/w
Saponification value	80.88
Acid value	2.848
Ester value	78.04

Source: (Sabale *et al*., 2007)

Topical dosage form

Among of these modes, the topical dosage forms are preferred because they are protective, emollient and delivered therapeutic agents to exert local activity when applied to the skin or mucous membranes. Topical dosage forms are classified into three major categories.

Solid topical dosage form

Dusting powder: Dusting powders are usually mixtures of two or more substances in fine powder, intended for external application on to the skin (wounds, burns, surgical incision). Powder bases absorb secretions and exert a drying effect, which relieves congestion and imparts a cooling sensation. Bentonite, kaolin, kieselguhr, magnesium carbonate, starch and talc are used as inert bases for dusting powders. Dusting powders are used to prevent and treat minor skin infections caused by small cuts, scrapes, or burns. Some skin infections can also be treated by using dusting powders such as athelete's foot, jock itch, and ringworm (Mittal, 1997).

Semisolid topical dosage form

Cream: Creams are semisolid dosage forms containing one or more drug substances

dissolved or dispersed in a suitable base. This term has traditionally been applied to semisolids that possess a relatively fluid consistency formulated as either water-in-oil (e.g., Cold Cream) or oil-in water (e.g., Fluocinolone Acetonide Cream) emulsions (Rai *et al*., 2019). These are used for cosmetic purposes such as cleansing, beautifying, improving appearances, protective or for therapeutic function. These products are designed to be used topically for the better site specific delivery of the drug into the skin for skin disorders (Chauhan and Gupta, 2020).

Ointment: It is a greasy semisolid preparation of dissolved or dispersed drug. Ointment bases influence topical drug bioavailability due to their occlusive properties of the stratum corneum,which enhances the flux of drug across the skin and they affect drug dissolution and drug partitioning within or from the ointment to the skin, respectively. They may be oleaginous e.g., white ointment; they may be entirely free of oleaginous substances e.g., polyethylene glycol ointment, or they may be emulsions of fatty or wax like material containing relatively high proportion of water e.g., hydrophilic ointment (Samundre *et al*., 2020; Kaushal and Upadhyaya, 2022).

Gel: Gels are transparent or translucent semisolid preparations of one or more active ingredients in suitable hydrophilic or hydrophobic bases. Gels may be clear or opaque, andpolar hydroalcoholic or nonpolar. Gels are prepared by either a fusion process or a special procedure necessitated by the gelling agents, humectants and preservatives (Garg *et al*., 2013).

Paste: It is a stiff preparation containing a high proportion of finely powdered solid such as starch, zinc oxide, calcium carbonate and talc. Pastes are less greasy than ointment.

Liquid topical dosage form

Lotion: An aqueous solution for application to inflamed ulcerated skin. Lotion cools the skin by evaporation of solvents.

Liniment: According to Howard C. Ansel, liniments are alcoholic or oleaginous solutions or emulsions of various medicinal substances intended to be rubbed on the skin with friction. Liniments are used for various therapeutic effects depending on the ingredients they contain (Abuan *et al*., 2014). The oily liniments, therefore, are milder in their action but are more useful when massage is required. Depending on their ingredients, such liniments may function solely as protective coatings. Liniments should not be applied to skin that is bruised or broken (Shah *et al*., 2024).

Cosmetic application of rice:

Rice Bran Wax

1) Emollient property: It is used as an emollient, and is the basic material for some exfoliation particles (Rathod *et al*., 2009).

2) Gelling property: It has been observed that rice bran wax at concentrations as low as 1 wt. % in triglycerides can crystallize to form stable gels (Doan *et al*., 2015)

3) Moisturizing agent: Helps preserve the moisture of the skin, acting as thin film coating the skin to prevent moisture evaporation. Moisturizes and softens skin as well as increases skin elasticity.

4) Protect from Sun Damage: 1.5% (w/w) Rice Bran Wax can increase SPF value by around 23% (Madne *et al*., 2022).

Table 2: Formulation by using Rice bran wax with uses

Formulation	Uses	References
Moisturizing creams	Treat or prevent dry, rough, scaly, itchy skin and minor skin irritations	Maru *et al*., 2012
Ointment base	Skin to soothe or heal wounds, burns, rashes, scrapes, or other skin problems.	Bhalekar *et al*., 2004
Tablet lubricant	prevent sticking and caking of powder during tablet	Kittipongpatana *et al*., 2024
Gel	Helps moisturize the skin and prevents moisture to evaporate out of the skin.	Malviya *et al*., (2017)

CONCLUSION

In conclusion, rice bran wax proves to be a highly effective and versatile excipient for pharmaceutical topical dosage forms. Its excellent emulsifying, thickening, and stabilizing properties enhance the performance and stability of creams, ointments, and lotions. Additionally, its natural origin and biocompatibility make it a superior alternative to synthetic excipients. This study highlights the potential of rice bran wax to improve topical formulations, offering significant benefits to the pharmaceutical industry.

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