**Evaluation of Lipophilic Monoglycerides in Enteric Coating to Provide Further Moisture Protection for Soft Gelatin Capsules**

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**Introduction**

Soft gelatin capsules coated with Methacrylic acid copolymer have a tendency to agglomerate during storage, especially in a humid environment. Reducing this moisture absorbed by the coated capsules can extend the shelf life of the capsules. It was noted that the addition of Glycerol Monooleate (GMO) to a Methacrylic coating could further reduce the moisture absorption by the coated soft gelatin capsules.

BASF has been working on the addition of Glyceryl Monostearate (GMS) to enteric coating dispersion (Kollicoat® MAE 30DP) to provide moisture barrier effect. GMS is hard to process into the coating dispersion. A similar monoglyceride in liquid form would be much easier to incorporate into the coating dispersion. GMS and AMG were tested to see whether they could provide the same benefits. Figure 3 shows the moisture uptake by the capsule coated with these formulations. The results show that both formulations reduce the moisture uptake, but GMS is a better moisture barrier than AMG.

Oleic acid was also tested to moisture barrier function. However, at the same 5% level, Oleic acid was not effective. When the formulation was optimized with 8% Oleic acid, the moisture reduction effect was also optimized. Table 4 summarizes the formulations for various Oleic acid amounts. Figure 4 shows the moisture uptake data.

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**Results and Discussion**

**Incorporation of the lipophilic monoglycerides into the enteric coating Kollicoat® MAE 30DP**

To incorporate the lipophilic monoglycerides into an aqueous coating dispersion, the oil monoglycerides first need to be converted to emulsions. The emulsion was then added to Kollicoat® MAE 30DP to make up the final coating dispersion. Polyol is 80 was used as the emulsifier for this purpose. The optimum range for Polyol is 80 is from 10% to 120% of the monoglyceride weight, depending on the type of monoglyceride.

In Table 1, the formulations for initial trials were presented. It is clear that, due to its lipophilic nature, GMS can help improve the moisture barrier effect. Other monoglycerides, such as Glycerol Monostearate and Acetylated monoglycerides has the same effect as Glycerol Monostearate. Furthermore, these monoglycerides are easier to incorporate into the coating dispersion than the solid GMS.

**Conclusions**

An aqueous coating system based on Methacrylic acid copolymer, Kollicoat® MAE 30DP can be used for moisture barrier coating.

- **Monoglycerides**, such as Glycerol Monooleate, normally used as an anti-stick agent for Kollicoat® MAE 30DP, can enhance the moisture barrier function of the coating.

- **Other monoglycerides**, such as Glycerol Monostearate and Acetylated monoglycerides has the same effect as Glycerol Monostearate. Furthermore, these monoglycerides are easier to incorporate into the coating dispersion than the solid GMS.

- A coating formulation containing Oleic acid also provides moisture barrier function.

- Optimum barrier effect was achieved when the coating dispersion was optimized with the amount of lipophilic monoglycerides added.

- Higher coating levels further reduce moisture absorption.

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**Materials**

- **Kollicoat® MAE 30DP**
- **BASF (Florham Park, NJ)**
- **Fish oil 1000mg capsules**, Capsulework (Ronkonkama, NY)
- **Triethyl Citrate**
- **Vegetable Glycerin, USP**
- **Acetylated Monoglycerides** (AMG), Riken Vitamin Co.
- **Glycerol Monostearate (GMS), Riken Vitamin Co.**
- **Oleic acid, BASF (Florham Park, NJ)**
- **Other ingredients used as received**

**Methods**

Soft gelatin capsules were coated in a Thomas Accela-coater equipped with a 15" perforate pan. The coating conditions are shown in Table 1. The Coating dispersion had an inlet air flow of 10CFM for 1 hour. The moisture pick up was accessed by drying the emptied shells in a 40°C oven for 4 days. The moisture uptake was accessed by drying the emptied shells in a 40°C oven for 4 days. The moisture uptake was measured by weighing the capsules in an oven-dry condition at room temperature.

**Results**

- **Coating levels**
  - **No Monoglyceride**
  - **With GMO**
  - **With AMG**
  - **With GMS**

**Discussion**

- **Introduction**
  - **Objectives**
  - **Materials**
  - **Methods**

**References**