Effects of different cleaning agents on the appearance, smell, and taste of softgel capsules

Wenming Zeng, Denise Doerflein Fulk, Lana L. Woshnak, and Susan Hazels Mitmesser
Pharmavite

This article describes a study investigating the effects of different cleaning agents on the appearance, smell, and taste of softgel capsules in a multivitamin-mineral-fish oil product. The study compares the effectiveness of mineral oil, medium chain triglycerides (MCT) oil, mineral oil with 1 percent lecithin, and MCT oil with 1 percent lecithin at cleaning residue from softgel capsules.

The final step before packaging a softgel product is to clean and polish the capsules to remove any residue [1]. This residue may include lubricants such as mineral oil or MCT oil and leaked fill materials such as OTC or prescription drug substances, vitamins, minerals, glycerin, fish oil, and soybean oil. Some manufacturers clean softgels using ethanol-sprayed cloth towels and then polish them using dry cloth towels. Ethanol is volatile, however, and can have negative impacts on the environment and human health and safety.
Finally, we took a sample for immediate evaluation and packed another sample into 3 HDPE bottles with non-vented caps for a one-month stability study.

We then repeated the procedure using MCT oil, mineral oil with 1 percent lecithin, and MCT oil with 1 percent lecithin.

An internal sensory panel evaluated all the cleaned initial samples and one-month stability samples in terms of luster, smell, taste, and surface residue.

### Results and discussion

The evaluation results for all cleaned initial samples and cleaned one-month stability samples are summarized in Table 1 and Table 2, respectively. The results indicate that MCT oil alone is most efficient at cleaning residue from softgel capsules. Figure 1 shows the appearance of the one-month stability capsules.

<table>
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<tr>
<th>Cleaning agent</th>
<th>Luster</th>
<th>Smell</th>
<th>Taste</th>
<th>Surface residue</th>
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</table>

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</tbody>
</table>

**Table 1**

**Table 2**

**Figure 1**

**Appearance of one-month stability capsules**

a. Capsules cleaned using mineral oil

b. Capsules cleaned using MCT oil

c. Capsules cleaned using mineral oil with 1 percent lecithin
d. Capsules cleaned using MCT oil with 1 percent lecithin

Unlike ethanol, mineral and MCT oils are non-volatile liquids and do not negatively impact the environment or human health and safety. Softgel encapsulation machines typically use mineral or MCT oil to lubricate the gelatin ribbons during operation. Mineral oil and MCT oil are also used to clean both hard and soft solid surfaces [2]. Using mineral or MCT oil to clean softgel capsules may overcome the shortcomings of using ethanol.

Lecithin is an excellent emulsifier in food systems. Moreover, formulators usually add lecithin to a softgel's liquid fill suspension to improve its viscosity during encapsulation. Because of these characteristics, adding lecithin to mineral or MCT oil may improve the oil's ability to clean leaked material from softgel surfaces.

**Study method**

In this study, we used mineral oil, MCT oil, mineral oil with 1 percent lecithin, and MCT oil with 1 percent lecithin to clean a multivitamin-mineral-fish oil softgel product in a pilot-scale Technophar drying basket. We then evaluated samples under initial conditions and under one-month stability conditions (40°C and 75 percent relative humidity) to determine which cleaning agent was most efficient at removing residue from the softgels.

For the lecithin-containing cleaning agents, we added 5 grams of lecithin oil into a beaker containing 495 grams of mineral oil and mixed well to obtain a mineral oil with 1 percent lecithin. We also added 5 grams of lecithin oil into a beaker containing 495 grams of MCT oil and mixed well to obtain an MCT oil with 1 percent lecithin.

To prepare the softgels for the study, we preweighed 7.0 kilograms of softgels and placed them into the Technophar drying basket. We broke 15 additional softgels and added the contents to the basket of capsules, then tumbled the basket for 30 minutes at 20 rpm. Next, we poured 500 milliliters of mineral oil into a plastic bag, placed 4 oil-absorption paper towels into the bag, shook the bag to saturate the towels, and squeezed the residue oil out of each towel. We then placed the towels into the basket with the softgels and tumbled the basket for 90 minutes. Then we removed the oiled towels, added 4 dry oil-absorption towels into the basket, and tumbled for another 90 minutes.
To understand why MCT oil was better than mineral oil at cleaning residue from the softgels, consider their molecular structures. Mineral oil is a hydrophobic, non-polar solvent that is a mixture of liquid hydrocarbons obtained from crude oil by different methods of distillation and refining [2].

MCTs are triglycerides whose fatty acids have an aliphatic tail of 6 to 12 carbon atoms [2]. Like all triglycerides, MCTs are composed of a glycerol backbone and three fatty acids, as shown in Figure 2. The fatty acids found in MCTs are medium-chain fatty acids. MCT oil is a polar solvent, meaning that its molecules have a slight electrical charge due to their structure. Fish oil, which is abundant in docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) [3] (Figure 3), is also a polar liquid.

The fill in this study contained fish oil, vitamins, and minerals. Fish oil and vitamins are polar molecules, while minerals are ionic compounds. Because MCT oil is a solvent with similar polar properties, it can dissolve and clean all the fill materials from the capsule surface. Mineral oil, on the other hand, is a hydrophobic, non-polar solvent, so it cannot completely clean all of these materials, leaving the softgels with a dull surface appearance.

Now let’s look at why adding lecithin to the mineral oil or MCT oil didn’t help to remove residue from the softgels. Lecithin is a phospholipid that consists of glycerol, two fatty acids, a phosphate group, and choline, as shown in Figure 4.

Lecithin has a polar head region that contains a trimethyl-ammonium-phosphate zwitterion and hydrophobic tails [4]. Due to its hydrophilic property, lecithin may absorb water from its environment, and that water can dissolve some water-soluble fill ingredients. Water-soluble fills can stick to the capsule surface, making it more difficult to clean, which is why the softgels cleaned using mineral oil with 1 percent lecithin or MCT oil with 1 percent lecithin still showed surface residue.

Conclusions

The sample evaluations indicate that MCT oil alone is the most efficient agent at cleaning the residue from multivitamin-mineral-fish oil softgels. Mineral oil was less efficient at cleaning and polishing the softgels due to its non-polar property. Adding 1 percent lecithin oil to either mineral oil or MCT oil did not aid in cleaning the residue from the softgels.

References

randomized, double-blind, placebo-controlled study,"

Wenming Zeng, PhD, is a senior formulator of research and
development, Denise Doerflein Fulk is manager of research and
development, Lana L. Wosbnak is division vice-president of
research and development, and Susan Hazels Mitmesser, PhD,
is vice-president of science and technology at Pharmavite,

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