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A Case Study on Utilizing Soy and Whey Protein Polymers: Advances in Enteric Coatings for Improved Delayed-Release Pharmaceuticals

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INTRODUCTION & AIM

Pharmaceutical enteric coating plays a crucial role in preventing the disintegration of pharmaceutical dosage forms in the stomach. This is particularly important for drugs unstable in acidic pH or designed to act in the small intestine. While conventional synthetic polymers have been widely used for enteric coatings, there is growing interest in exploring naturally derived proteins as an alternative. This study focused on two natural polymers: soya protein and whey protein isolates, first by determining the gastro-resistance properties of films prepared from these proteins. Then, the right casting solutions will be made to make polymeric films, and disintegration tests will be used to see how well they stand up to acidic pH. Second, crate drug pellets coated with the most effective protein-based film were previously prepared, and their performance was assessed using the USP apparatus I (basket). The results demonstrated that the coated pellets (SA and SAG) exhibited excellent gastro-resistance properties. Specifically, the percentage release of the coated pellets met the USP criteria: less than 10% release in the first 2 hours under acidic conditions, followed by at least 80% release within 45 minutes in the buffer phase. In contrast, uncoated pellets showed immediate release, with over 69% dye released during the initial 2 hours. Notably, the SA and SAG-coated pellets demonstrated remarkable resistance to acidic pH, releasing only 1% and approximately 2% of the dye faster than uncoated pellets. These findings highlight the potential of SA and SAG coating films for efficient delayed release or enteric coating applications.

METHOD

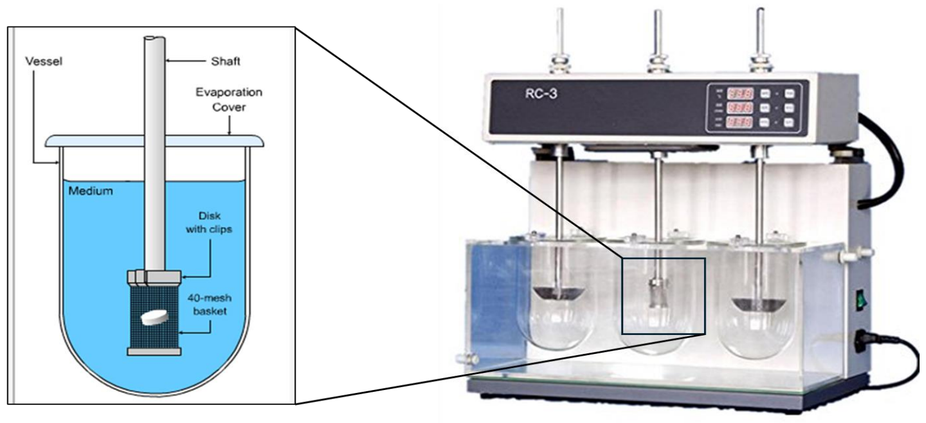

Figure 1: shows schematic of the USP dissolution apparatus used for Dissolution Testing

RESULTS & DISCUSSION

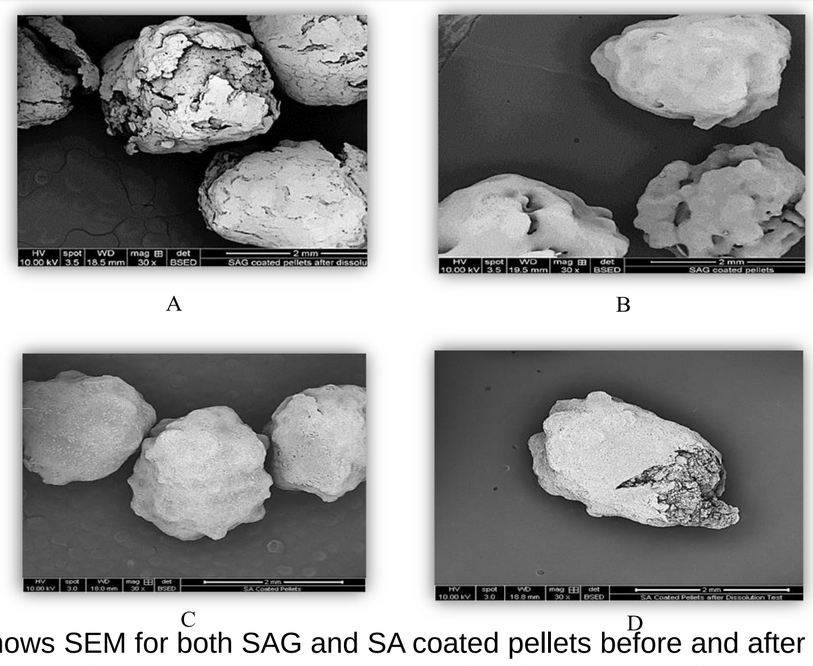

Figure 2: Shows SEM for both SAG and SA coated pellets before and after dissolution test.
A. SAG coated pellets before dissolution test B. SAG coated pellets after dissolution test
C. SA coated pellets before dissolution test D. SA coated pellets after dissolution test.

RESULTS & DISCUSSION

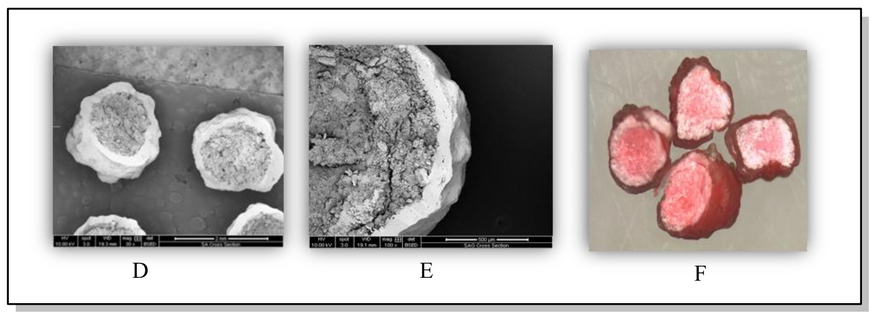

Figure3: Shows A. SEM cross section of SA coated pellets at 100x. B. SEM cross section of SA coated pellets at 30x. C. Microscopic image for SA coated pellets. D. SEM cross section of SAG coated pellets at 100x. E. SEM cross section of SAG coated pellets at 30x. F. Microscopic image for SAG coated pellets.

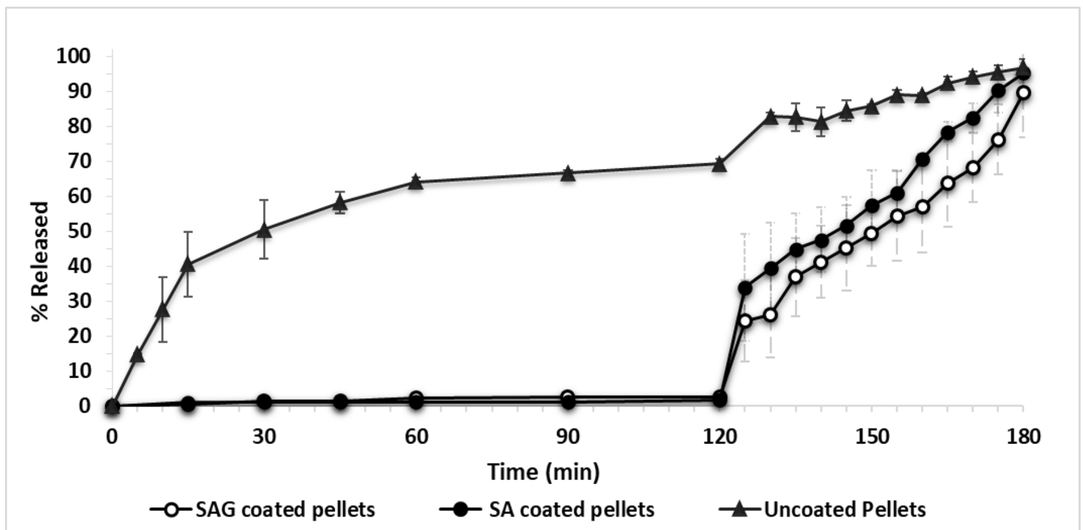

Figure 4: Comparison of % dye release profiles for uncoated pellets and coated pellets (SA and SAG) in 0.1 M HCl pH (1.2) for 2 hr followed by addition of phosphate buffer pH 6.8 for 1 hr. The data are expressed as average of three trials

CONCLUSION

The results of developing enteric coating by applying natural polymers from (soy protein). The former protein was used to make the two-coating film. The dissolution experiment shows that two films, SA and SAG, have properties that make them suitable for the digestive tract. They stay intact for two hours in acidic pH and release the dye when they reach pH 6.8 in the digestive tract. Hence, there is a potential interest in the functional as a coating material for delaying drug release.

Moreover, it could be used for nutraceutical products. However, one limitation of that is that it counters the current project. Formulations that used either whey protein solely or blended with zein protein could not provide successful results. In the future, more research is needed to manufacture an enteric coating from protein-based films such as WPI and SPI. However, these proteins can be used as dietary supplements and applied in pharmaceutical dosage forms that might benefit the usage.

FUTURE WORK / REFERENCES

Despite the promising results, the study acknowledges limitations in the current project. The formulations using whey protein alone or blended with zein protein were studied in debt. Future research is needed to optimise protein-based films like WPI and SPI for enteric coating applications