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The Innovative Use of Micronized Hydroxypropyl Methylcellulose as a Pore Former in Dry Powder Coatings of Ethylcellulose Barrier Membrane Coatings on Multi-Particulates

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PURPOSE

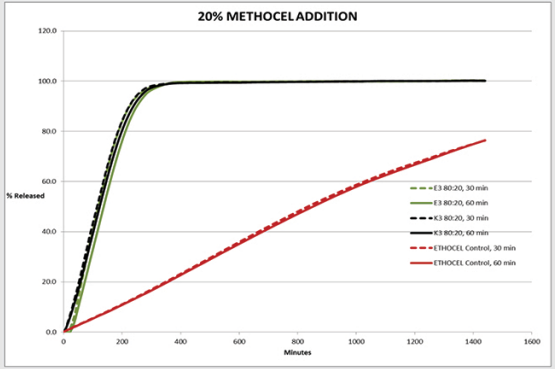
Ethylcellulose is commonly used throughout the pharmaceutical industry for barrier membrane coatings for sustained drug release. In many formulations that utilize ethylcellulose coatings, soluble pore formers are used to modify and speed up the release of API from the coated material. Hydroxypropyl Methylcellulose (HPMC) is a common pore former in these formulations that is easily blended into traditional solution preparations of ethylcellulose and applied at precise ratios to produce predictable, repeatable drug release. The recent development of a novel ethylcellulose grade for use in dry powder coatings of multiparticulates has offered the pharmaceutical industry a vastly improved method for applying barrier membrane coatings in a safe, fast and efficient process. This study investigated utilizing micronized HPMC as a dry pore former in dry powder coatings of ethylcellulose.

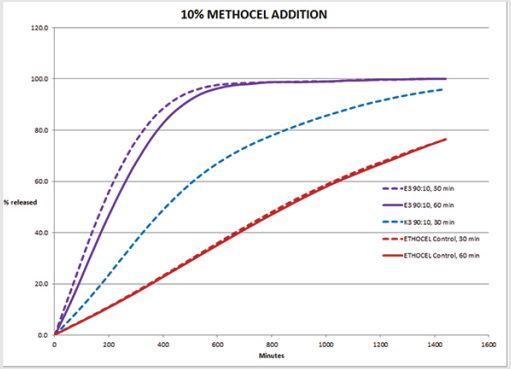
METHOD

Acetominophen (APAP) was dry powder coated onto sugar spheres (#20 – 25; Colorcon Inc., USA) using polyvinyl pyrrolidone (PVP) (K29-32, ISP Inc., USA) as binder on a Granurex GXR-35 rotor process (Freund-Vector Corp., USA). A drug to binder ratio of 97:3 w/w was maintained. Two grades of METHOCEL™ (HPMC), E3 and K3 were micronized and blended at ratios of 10%, 15% and 20% with ETHOCEL™ HP(The Dow Chemical Company, USA). These blends were dry powder coated onto the APAP beads with dibutyl sebacate (DBS) as a plasticizer using the same rotor process as above. Another batch was coated with 20% weight gain of ETHOCEL HP alone as a control. Once the APAP sugar spheres were coated to 20% weight gain of ETHOCEL/METHOCEL blends, samples were cured at a 50°C product temperature for 30 and 60 minutes in the GXR-35. Dissolution and SEM were evaluated for curing influence on drug release

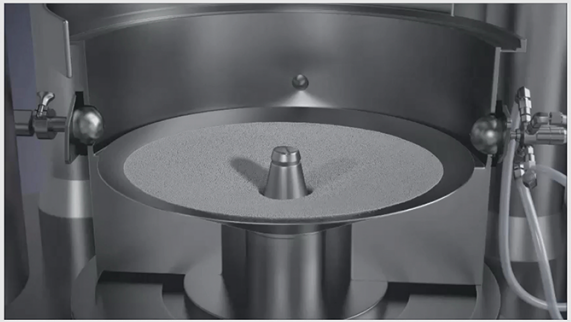
RESULTS

Initial experiments demonstrate that the addition of the micronized METHOCEL was successful in modifying the release of the APAP from the sugar beads. Initial results showed that the addition METHOCEL E3 resulted in a faster drug release than the addition of the METHOCEL K3 at the 10% addition level, but both grades performed the same at the 20% addition level. Regardless of the amount of HPMC addition to the ETHOCEL HP coating, the process efficiency, time and yields were unaffected from the baseline process with no addition. No agglomeration was present in any of the trials. Samples have been placed on stability, and 3 month and 6 month data will be reported when available.





PROCESS VIDEO



CONCLUSION

Using the dry powder layering process on a rotor coater allows for fast, efficient and solvent-free coatings for ethylcellulose. The ability to add micronized HPMC grades to the dry powder ethylcellulose gives formulators freedom to modify the release rates from the coatings with the same flexibility that is available with the solution based coatings that are currently widely in use throughout the industry. At levels of 20% addition and higher, the effect of the HPMC chemistry on drug release is eliminated. Since the addition of the dry HPMC does not affect the coating process, the formulation and drug release can be customized precisely without modifying the overall coating process parameters.

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