Formulation and Development of Oral Dry Powder for Suspension using Taste Masked Ornidazole Particles Prepared with Kollicoat® Smartseal 30 D

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Purpose
The main objective was to find taste masking effectiveness of Kollicoat® Smartseal 30 D for intensely bitter active, Ornidazole and to formulate into dry powder for suspension.

Methods
Ornidazole was coated in a fluid bed processor using both bottom and top spray methods with Kollicoat® Smartseal 30 D, which is an aqueous dispersion of methyl methacrylate- diethyl-aminoethyl methacrylate copolymer. Appropriate quantities of other excipients were mixed with the coated and uncoated Ornidazole to prepare powder for reconstitution. Studies like taste, in vitro dissolution in different media, particle size and its distribution, particle characteristics; physical properties of suspension (color, pH, relative sediment volume and redispersibility over 7 days) were conducted.

Results
Effective taste masking was achieved with 40% and 50% w/w weight gain for Ornidazole (180-200 microns) with top & bottom spray coated techniques respectively. This was confirmed with volunteer study. Efficiency of the taste masking was improved with increasing coating levels, which was attributed to increasing film thickness and its coverage over Ornidazole particles. To formulate a suspension that is completely taste masked, a right balance of formulation pH and coating levels was needed. The pH value was optimized in range of 7-8 and coating levels to minimum 80% w/w. The dissolution studies indicated that there was no release till 110 minutes in pH 6.8 phosphate buffer. This was attributed to the pH dependent solubility of the polymer, which is soluble upto 5.5 and decreasing permeability after this pH. Thus, no bitter taste was observed in the mouth owing to its pH range of 6-7. At the same time complete release was observed in 0.1 N HCl. The formulated suspension gave milky white color and showed no sedimentation during 24 hours. A slow sedimentation during storage was observed and it could be easily re-dispersed after 7 days.

Conclusion
Taste masking of Ornidazole was achieved with Kollicoat® Smartseal 30D and successfully formulated into dry powder for suspension.