Effectiveness of Moisture Barrier Coatings on Various Tablet Cores

PURPOSE

A pharmaceutical tablet may be protected from high humidity through appropriate packaging. A bottle is convenient and commonly used, however, the tablet is exposed to the environment each time the consumer opens the bottle. Opadry® amb, aqueous moisture film coating system, gives the protection needed for moisture-sensitive cores. This study was conducted to compare the moisture barrier properties of Opadry amb, methacrylic acid copolymer film coating, HPMC plus stearic acid-based film coating, and HPMC-based film coating. Three types of tablet cores; standard placebo, low hygroscopic (dicalcium phosphate), and waxy (carnuba wax based) were tested.

METHODS

An experiment to simulate the opening and reopening of a bottle of tablets was performed at the University of London School of Pharmacy using the commercial Dynamic Vapor Sorption (DVS) instrument from Surface Measurement Systems UK. During the experiment, the environment was temperature controlled and the humidity was adjusted by using two flow controllers; one for dry air and the other for air at 100% relative humidity (RH). The instrument provides excellent humidity control without any condensation difficulties. The tablet is suspended from a Cahn Microbalance and the weight is monitored.

Standard placebo, low hygroscopic and waxy cores were coated with either HPMC film, methacrylic acid copolymer film coating , HPMC plus stearic acid film coating, or Opadry amb aqueous moisture barrier film coating system. Using the DVS instrument, tablets were exposed to three cycles going from 0% RH to 75% RH over a period of 24 hours. The weight gain and loss during each cycle was recorded.

RESULTS

Cores coated with Opadry amb showed a very clear reduction in water sorption. The other film coatings did not provide a significant barrier (Table 1). As would be expected, the water sorption to the waxy cores and the low hygroscopic cores was not substantial.

CONCLUSION

Cores coated with Opadry amb provide a reduction in water sorption compared to tablets coated with alternative systems. It can be concluded that Opadry amb is the most effective moisture barrier film coating system.

Table 1

MOISTURE SORPTION AND DESORPTION AT 75% RH AND 40ºC

	Standard Placebo Cores	Low Hygroscopic Cores	Waxy Cores
Tablets Coated with HPMC-Based Film			
% loss (cycle 1)	2.044	0.124	0.235
% uptake	3.543	0.135	0.505
% loss (cycle 2)	3.651	0.148	0.489
% uptake	3.592	0.128	0.482
% loss (cycle 3)	3.611	0.138	0.478
Tablets Coated with Methacrylic Acid Copolymer Film			
% loss (cycle 1)	0.698	0.148	0.195
% uptake	2.450	0.349	0.584
% loss (cycle 2)	2.228	0.358	0.524
% uptake	2.314	0.342	0.518
% loss (cycle 3)	2.432	0.351	0.513
Tablets Coated With HPMC plus Stearic Acid-Based Film			
% loss (cycle 1)	1.157	0.121	0.1696
% uptake	3.023	0.292	0.6589
% loss (cycle 2)	2.973	0.307	0.6378
% uptake	2.951	0.289	0.6261
% loss (cycle 3)	2.983	0.298	0.6229
Tablets Coated with Opadry amb Film Coating System			
% loss (cycle 1)	0.103	0.085	0.0668
% uptake	1.710	0.214	0.5275
% loss (cycle 2)	0.761	0.220	0.4171
% uptake	0.838	0.210	0.4069
% loss (cycle 3)	0.522	0.217	0.4058

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