Use of Maximum Fluid Delivery Rate Measurements to Assess the Productivity of Moisture Barrier Film Coatings

PURPOSE

Aqueous moisture barrier film coating systems are commonly applied to tablet formulations to prevent or reduce environmental moisture uptake by the tablet[1] and, therefore, enhance drug stability within the core formulation. The aim of this study was to develop a small-scale method predicting film coating productivity of moisture barrier film coatings. Maximum fluid delivery rate was used to evaluate the productivity and inherent tack of a formulation.

METHODS

Maximum Fluid Delivery Rate (MFDR)

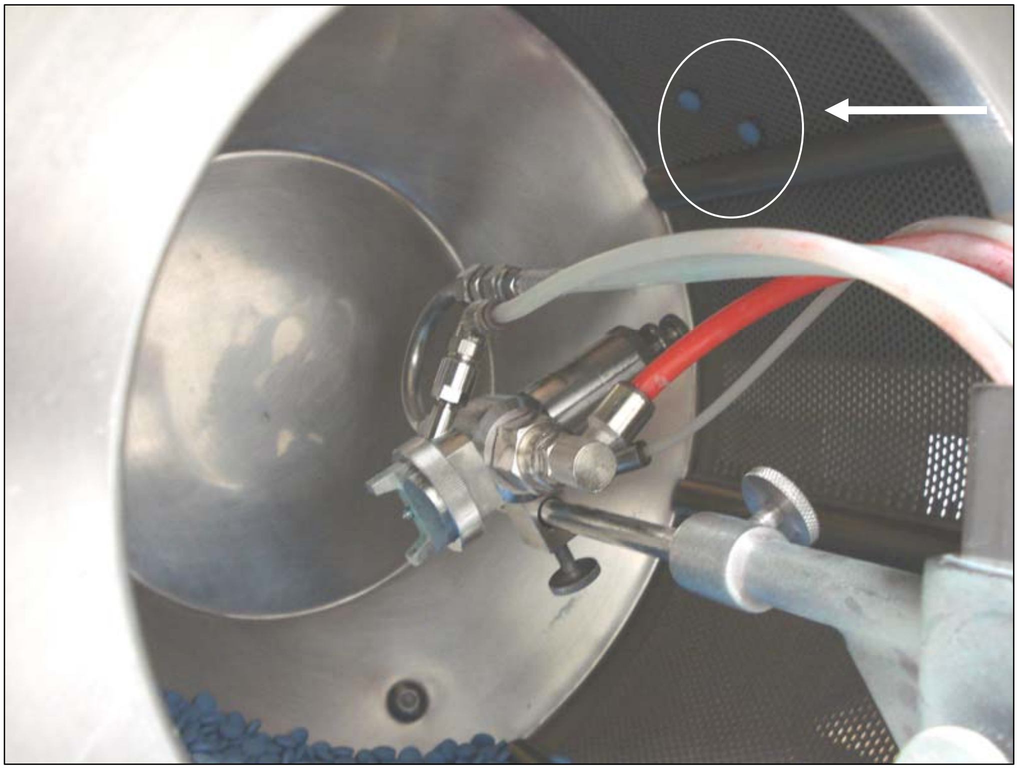
Maximum fluid delivery rate (MFDR) is defined as the maximum grams per minute (g/min) of coating suspension that can be sprayed onto the tablet bed during typical coating process conditions, without causing the tablets to stick to the coating pan or agglomerate. The MFDR in this study was determined using a 1.5 kg charge of standard convex placebo tablets (10 mm diameter), which were spray coated in an O'Hara LabCoat II fully-perforated, side-vented coating pan equipped with a 15" pan insert and one spray gun (Schlick model 931 fitted with a 1.2 mm nozzle). The coating process parameters used are shown in Table 1.

Table 1.Coating Process Parameters

Process Parameters	
Inlet temperature (°C)	65
Tablet bed temperature (°C)	45
Airflow (m^3/hr)	250
Atomizing air pressure (bar)	1.5
Pan speed (rpm)	22
Spray gun to bed Distance (cm)	10
Pattern air (bar)	1.5

The fluid delivery rate was gradually increased to the point where individual tablets stuck to the inside of the coating pan while completing a full revolution (Figure 1). At this point, the spray rate was reduced to obtain a rate at which the tablets did not stick to the inside the pan. This spray rate was then recorded as the MFDR.

Figure 1. Photograph of tablets stuck to the inside of the coating pan while the pan is rotating



Moisture Vapor Transmission Rate (MVTR)

The Moisture Vapor Transmission Rate measures the rate of passage of water vapor through a substance, in this case a film coating formulation. Free films of 100 µm ± 10% thickness were prepared by spraying the coating dispersion onto a polyethylene terephthalate (PET) substrate (Colorcon in-house method) and used for MVTR testing, in a WPA-100 unit (VTI Corporation, USA), fitted with a 6.39 cm^2 test cell. The film was first dried to an equilibrium dry state at 25°C with a dry nitrogen purge gas flowing at a rate of 200cm^3/min for 45 minutes. Then moisture vapor was introduced to the purge gas to develop relative humidity of 80% on one side of the test film. The moisture content on the opposite side of the test film was monitored, and the equilibrium rate of moisture transmission through the film was determined over a period of time. The test period was completed either when the measured transmission rate deviated by less 0.005 g/water/day/100 $inches^2$ for a period of five minutes or the total time allowed for the test had elapsed (typically up to 4 hours), whichever occurred first. Three PVA-based film coating dispersions were evaluated in this study; Opadry® amb, aqueous moisture barrier film coating system, Opadry® II, high performance film coating system (PVA-based), and a developmental film coating system. These formulations were prepared at 20% solids in water and applied to placebo cores under the conditions listed in Table 1. The MFDR and MVTR performance of each film coating system was then determined.

RESULTS

Figure 2.The MVTR trace for Opadry II (PVA-based) free film

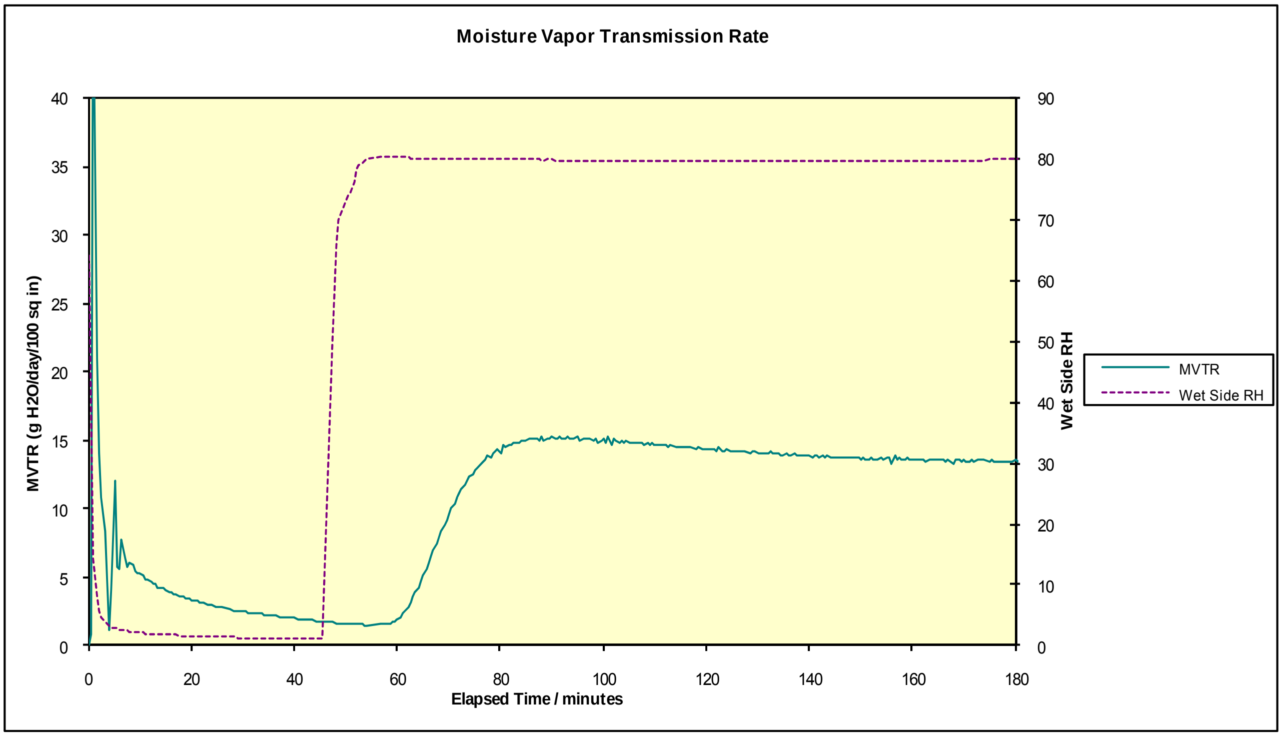


Figure 3.The MVTR trace for Opadry amb free film

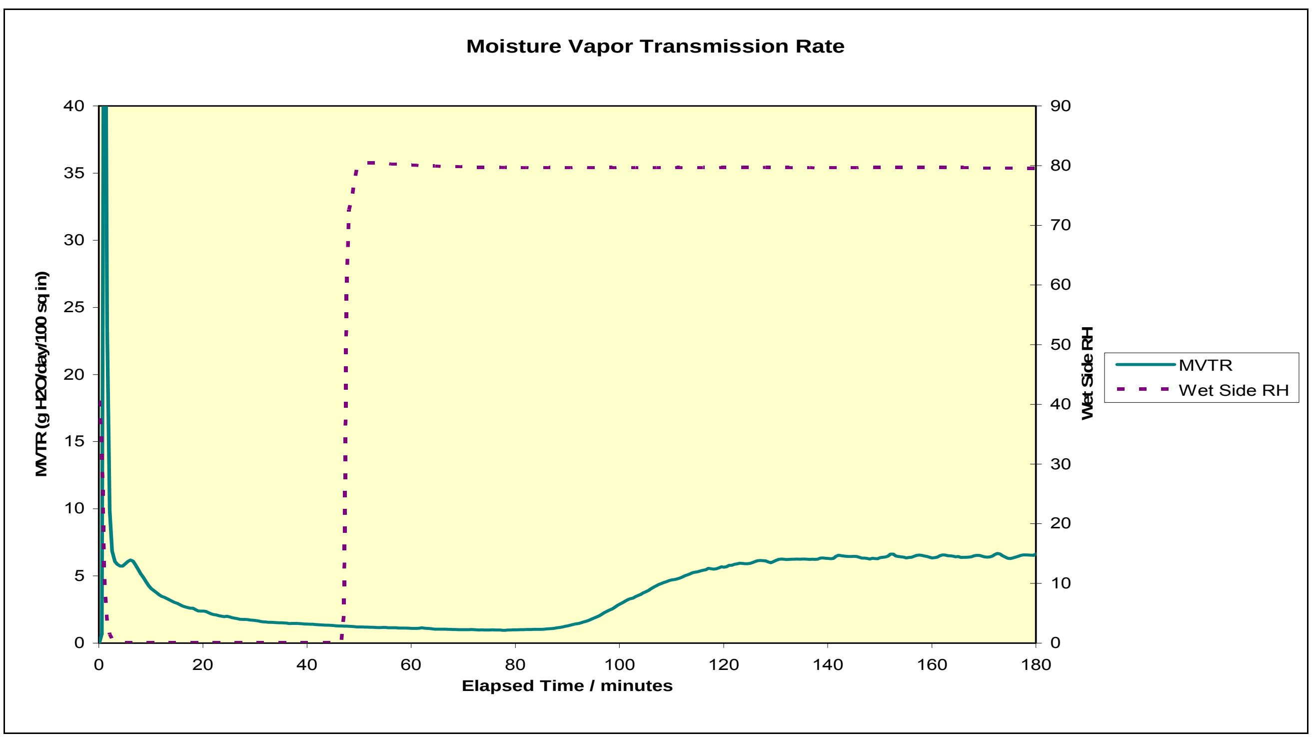


Figure 4.The MVTR trace for developmental formulation free film

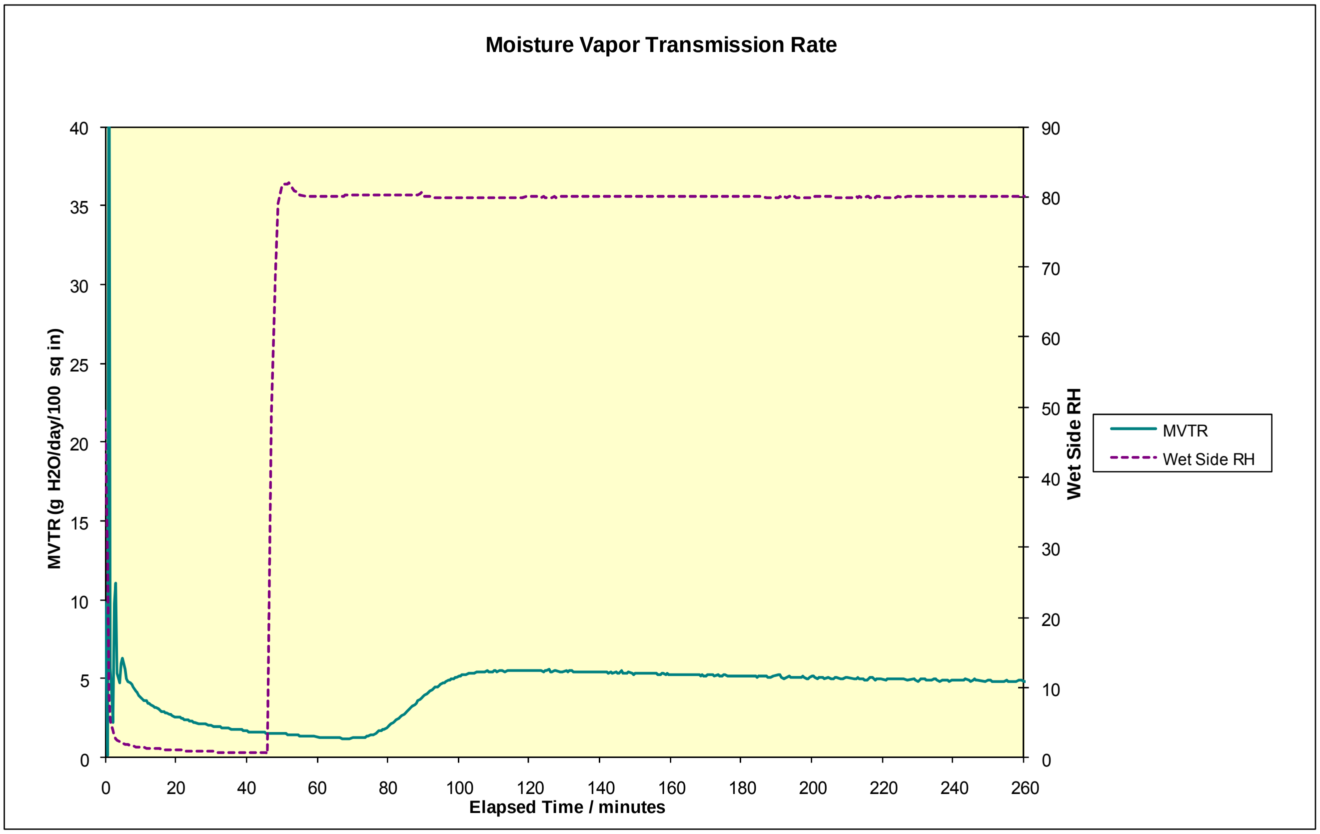


Table 2.The MFDR and MVTR values for the coating formulations

Formulation	Maximum Fluid Delivery Rate g/min	Moisture Vapor Transmission Rate g/water/day/100 inches^2
Opadry II (PVA-based)	34	13.5
Opadry amb	11	6.4
Developmental formulation	**22**	**4.8**

Table 2 shows the MFDR and MVTR for the three formulations studied here. Even though the Opadry II (PVA-based) system has excellent productivity, the moisture barrier properties are not as effective as Opadry amb or the developmental formulation. On the other hand, the developmental formulation exhibited both lowest MVTR value and excellent productivity.

CONCLUSIONS

MFDR is a simple quantitative method to differentiate the productivity of film coating formulations under typical coating conditions. By combining MFDR values as an indicator of productivity with an analysis of the film coating moisture vapor transmission rate (MVTR), it allowed optimizing a film coating formulation (developmental formulation) to meet both the manufacturing and moisture barrier performance requirements for moisture sensitive tablets.

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REFERENCES

1. O.Bley, J. Siepmann, R.Bodmeier, Importance of glassy-to-rubbery transitions in moisture-protective polymer coatings, Eur. J. Pharm. Biopharm. 2009; 73: 146-153.

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