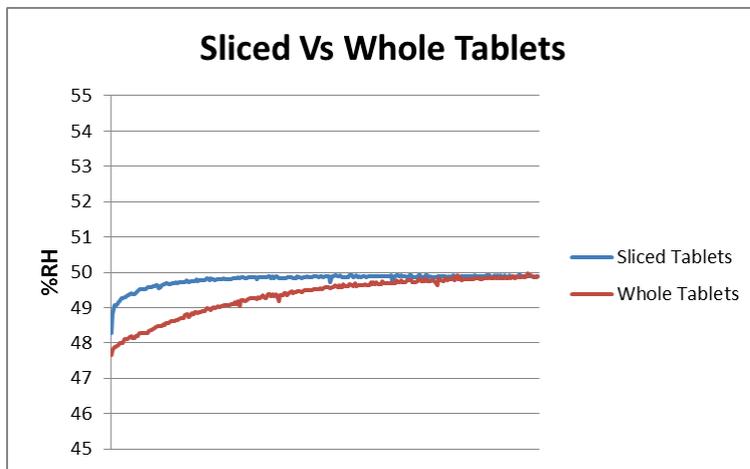


Visualizing Moisture Release Activity

In a case where we discovered “hidden moisture” in film-coated tablets that had been placed on stability testing (Case Study “C1_Latent Moisture Content Leading to Hydrolysis in Stability Batches”), this prompted an investigation to confirm that the moisture was in fact present in the tablet matrix. Conventional moisture test methods were not sensitive enough for this investigation.

We approached this problem by exploiting the versatility and sensitivity of the Relequa® Moisture Profiling system. Since it was evident from an increase in the Water Vapour Equilibrium Point (WVEP) that the stability batches had gained moisture, the challenge was to devise a way in which we could “see” this moisture.

Moisture profiles were generated with whole tablets from a stability trial and compared with tablets from the same pack that were sliced in half lengthways immediately before adding to the Relequa® test chamber. By overlaying the Moisture Profiles we saw an instant direct comparison. Immediately, the sliced tablets were seen to be releasing moisture much faster than the whole tablets.



In effect we were able to “visualize” the difference in the rate of moisture release showing that the exposed matrix in the sliced tablets had a much faster release of moisture.

We concluded that we had a situation where moisture was truly trapped within the tablet matrix. It may also be the case that the tablet film-coat slowed moisture release from the whole tablets sufficiently to accentuate the difference in moisture release making the observation more apparent and readily detected.

Note that the same WVEP is achieved for both the sliced and whole tablets, which demonstrates that the “moisture status” of the test samples is identical as would be expected from a material that has been “conditioned” to the same extent.

This case shows the instantaneous comparative result that is possible, and unique, to the Relequa® Moisture profiling system. This type of analysis has the power to provide a “new understanding” of test samples, saving lengthy and costly investigations into moisture related issues.