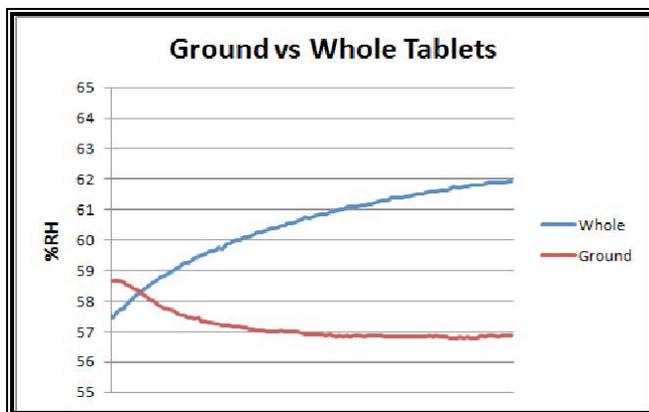


## Elucidation of Analytical Error Due to Moisture Trapped in a Tablet Matrix

Tablets from stability batches had a moisture related problem and conventional testing did not yield any clues to the problem.

Using Relequa® Moisture Profiling™, newly manufactured batches were compared with the stability batches. The investigation found that compared to the new batches, the stability batches had a higher Water Vapour Equilibrium Point (WVEP) that was close to the chamber humidity condition (60%RH). This provided evidence that the packaging was not adequate and moisture ingress had occurred (see our poster on packaging and moisture ingress for more information: **Study of a Range of Blister Packaging Materials Using the New Technique of Moisture Profiling to Give Early Indications of Moisture Barrier Properties**)

Using our highly sensitive Relequa® Moisture Profiling™, we generated moisture profiles of whole tablets from the stability trial and tablets from the same pack ground into powder. Immediately, the whole tablets were seen to be releasing moisture but the tablet powder gained moisture.



The decreased WVEP demonstrates that the **moisture status** of the tablets had changed very quickly during grinding due to moisture loss.

EP.2.9.39 specifically warns about moisture uptake or loss leading to analytical errors. We can see in this case how such errors can arise by considering a typical content assay calculation:

In a typical HPLC assay the average weight of 20 tablets ( $A_v$ ) is used in the assay calculation:

$$Std \times (A_v/W_s) \times (P_s/P_{Std}) \times 100\%$$

In this equation that the weight of the tablets is used on the top line. The trapped moisture is instantly lost when tablets are powdered and not accounted for in the sample weight ( $W_s$ ). The result is a falsely high assay value.

Lengthy investigations and considerable cost could have been avoided over conventional moisture tests by using the sensitivity of Relequa® Moisture Profiling.