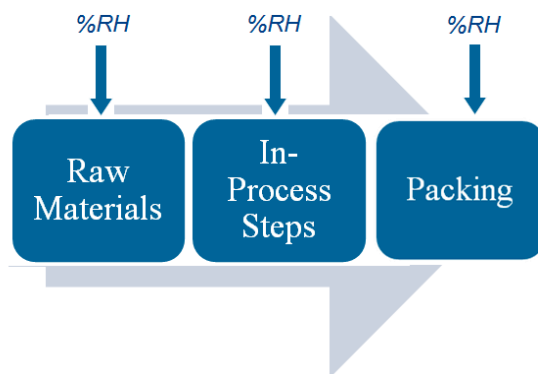


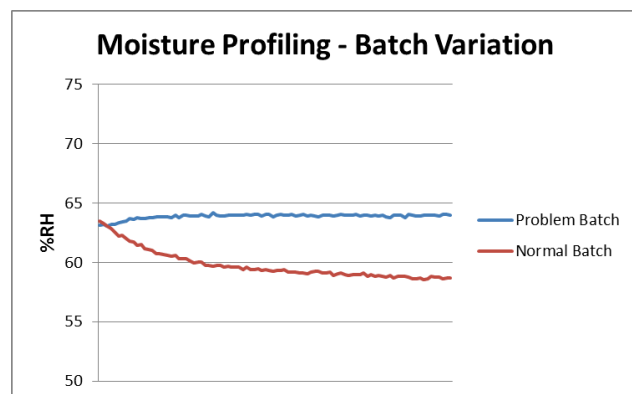
Latent Moisture Content Leading to Hydrolysis in Stability Batches

Not surprisingly, many of the moisture issue cases we come across, or are presented directly to us, are moisture problems arising from stability trials. However, the issues are generally the same across the entire manufacturing process. In fact, any point where materials are exposed to environmental conditions.



This case was presented as inconsistencies in stability batches of the same product. The product, a film-coated tablet packed in blisters, was showing an increase in hydrolysis products over the initial months of stability testing. More batches of the same product packed in the same way were placed on stability. This time, very little hydrolysis was seen and these batches were still well within specification after 2 years.

Using the Relequa® Moisture Profiling system, we analysed batches from routine manufacture, stability batches and the 2 year old retained samples from the first manufacturing runs. Our investigation found that even after prolonged storage, the retained samples still contained residual moisture and had a Water Vapour Equilibrium Point (WVEP) of well over 60%. All the other batches had a WVEP below 60%.



This instantly provided an explanation for the higher level of hydrolysis in the initial development batches: Within each blister pocket, a “high humidity chamber” was created as each tablet released ‘free-moisture’. Clearly, the problem was there at the very beginning and was traced to poor efficiency in the drying step during film-coating.

These types of investigations led us to develop the highly sensitive Relequa® Sample Moisture Test. This test is performed by a single click on the Relequa software control screen and valuable information is gained about the free-moisture status of a product in just a few minutes and considerable cost can be saved.