Applications Notes

Moisture in Pharmaceutical Powders

It is important that moisture levels are accurately maintained throughout the wet granulation or drying process within the fluid bed dryer. This ensures consistent product formation in the tableting and pelleting processes that follow and ensure the drug’s effectiveness. Additionally, continual monitoring and control of moisture will increase productivity and maximise the efficiency of the operation.

Pharmaceutical Manufacturing Processes

Granulation Process – A water based solution is slowly sprayed onto the excipients to ensure even distribution, air is simultaneously pumped through the bed of powder to gently lift and mix the ingredients.

Drying Process – This commences after the aqueous solution has been added (when preceded by a granulation operation). When the batch reaches the desired moisture content, the air shuts off and the bowl of powder is transferred to the next operation.

Measurement and Location

Traditionally moisture content is approximated by measuring the temperature of the exiting air, this can prove unreliable as it is dependent upon the relative humidity and temperature of the incoming air. To further confirm that the moisture has reached the required level a sample is removed for laboratory testing.

Using the MCT 360, a NIR on-line moisture analyser, moisture can be measured instantaneously “in situ” using either a sapphire viewing window or probe with an air purge to ensure product doesn’t adhere to the window. Alternatively, if there are multiple fluid bed dryers, an MCT 600 laboratory instrument can be set up on a cart, and transported to each Dryer to obtain instantaneous readings on samples extracted from the bowl.

Measurement Performance

<table>
<thead>
<tr>
<th>Moisture Range (%)</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-10</td>
<td>+/- 0.1%</td>
</tr>
<tr>
<td>10-25</td>
<td>+/- 0.2%</td>
</tr>
</tbody>
</table>

Moisture profile – Fluid bed dryer