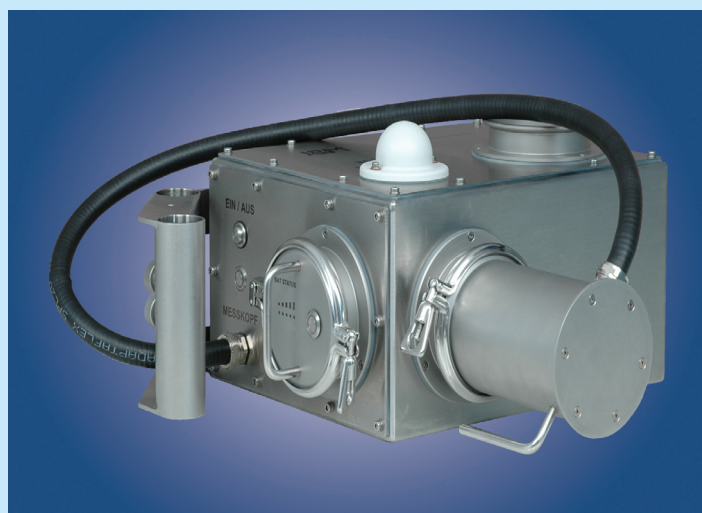


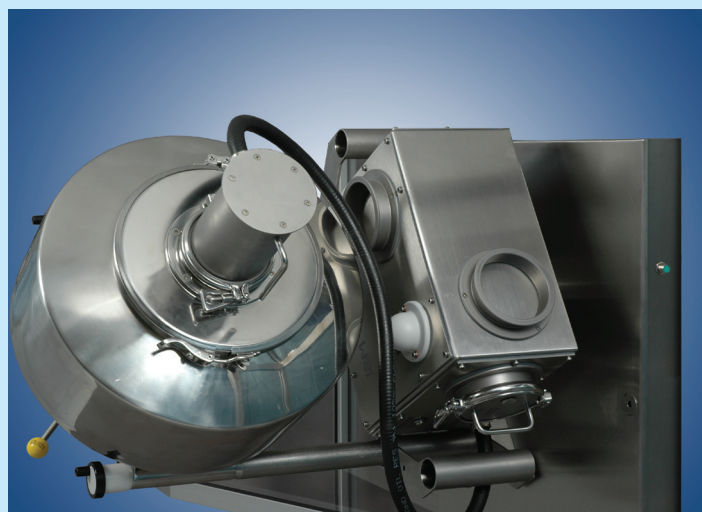
NIR-spectroscopy for blend uniformity monitoring and dynamic endpoint determination **Process Analytical Technology (PAT)**

One of the most common unit operations in preparation of pharmaceutical solid dosage forms is the physical blending of the active drug substance with one or more excipients.



**Fig. 1: J&M process spectrometer (NIR) with IRIS-7 Probe measurement head.**

The end point of this process is material homogeneity and percentage assay as measured by sampling and off-line analysis of the powder. Removal of samples is currently done with a sampling probe to withdraw samples from different locations of a blender. This method is influenced by the skill of the operator and often provides false representation of the sample due to desegregation and disruption of the powder bed during sampling and transport. Furthermore, sampling and off-line analysis causes long cycle time for operating and optimizing the blending process, due to the FDA's 1996 proposal to amend the good manufacturing practice regulations commercial-batch final blends need to be tested routinely for blend homogeneity. Near Infrared (NIR) spectroscopy is a very powerful tool in a variety of applications involving powder characterization.



**Fig. 2 and 3: J&M process spectrometer (NIR) attached to different blenders.**

Near Infrared (NIR) spectroscopy can be used for on-line monitoring of blend processes. It saves time and money by reducing the cycle time, as the need for time consuming sampling (possibility of sampling errors) and routine off-line analysis of blend homogeneity is eliminated. Also better equipment utilization is permitted.

## Your approach to implement PAT for blend monitoring

### Spectrometer with Measuring Head

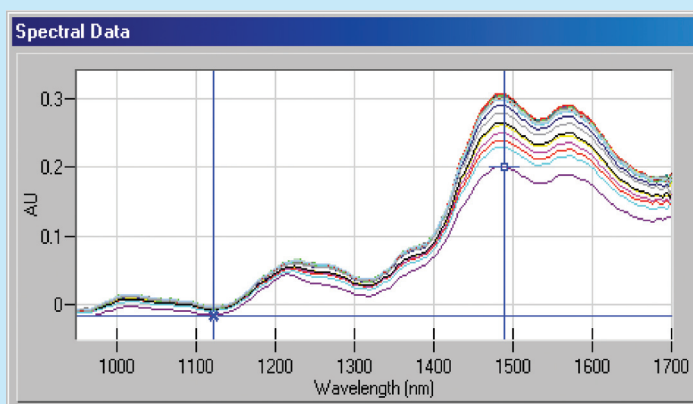
- InGaAs diode-array with thermoelectric cooler
- Wavelength 900 nm to 2500 nm or 1100 nm to 2100 nm
- Number of pixels 256
- Wavelength accuracy < +/- 0,5 nm
- Light source Tungsten
- Reflectance head (Measuring Head)
- Power management LI-Battery, two hours operation

### Enclosure (example)

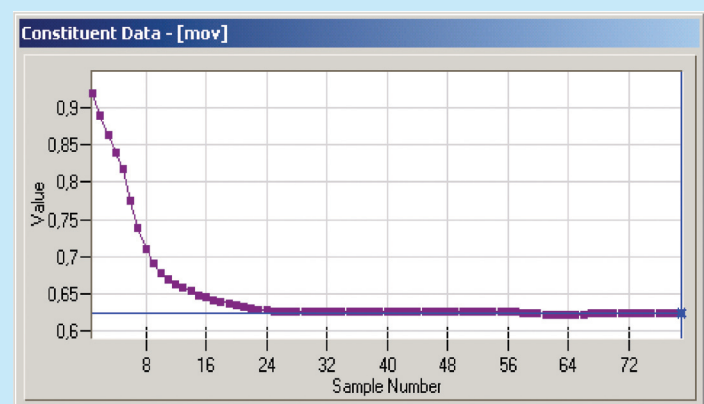
- Enclosure construction 316L Stainless steel
- Enclosure size of spectrometer 400 mm H x 580 mm W x 150 mm D
- Size of measuring head 120 mm diameter x 160 mm H, excluding 4" hygienic flange and handle
- Enclosure, connecting umbilical Flexible stainless steel with PVC cover, 1.0 meters in length
- Enclosure ratings cGMP compliant, IP 65
- Customer specific enclosures also available



**Fig. 4: Detachable NIR Spectrometer mounted on a mobile rack**



**Fig. 5: Spectral data example from a blender**



**Fig. 6: Number of measurement points per revolution, approx. 60 to 65, (Trend at 1200 nm)**

### Applications

Dynamic endpoint determination and monitoring blend uniformity in pharmaceutical-, chemical-, food industries, nearly unlimited ...

Please note: Due to technological progress all specifications can be changed without a further note.