

## Refractometers for Powder - Particle Size Analysis

In May 2015 Rudolph Research Analytical released additional capabilities for all pharmaceutical level refractometers. The J257, J357, and J457 refractometers come standard with a method for measuring the refractive index of powders as required by a particle size analyzer.

Particle size analysis is important in developing and producing drugs as particle size has a direct impact on a drug's final product performance. Particle size has a direct relationship to pharmaceutical product dissolution rates, absorption rates and final product uniformity. Decreasing particle size is a help when working with non-water soluble chemicals. Thus particle size measurement techniques and methods must be accurate and traceable in both the drug development stage and during production manufacturing to ensure quality control.

Rudolph Research Analytical is a world leader in refractometers designed for pharmaceutical applications. While there are many companies making refractometers for measuring soft drink, orange juice and other food products there are very few other instruments that have been designed with pharmaceutical needs in mind.



## Rudolph Refractometers used in Pharmaceutical Powder and Particle Size Analysis

In particular the J257/J357/J457 offer;

- Wide range from 1.26 to 1.70 meaning the instruments can measure every material in the USP/EP.
- 21 CFR Part 11 data storage system that is integrated into the instrument, no external software is needed.
- Accuracy levels required in pharmaceutical labs to Index  $\pm 0.00002$  RI
- SmartMeasure system that monitors correct sample loading and cleaning.

Adding this capability gives pharmaceutical laboratory considerable advantages. While it is possible to find RI measurements of some materials on the web there are some issues related to taking this approach. Using the actual measured value (rather than the nominal published value) eliminates many possible sources of error. The second issue is you are relying on an unverified source in a procedure where all measurements results need to be traceable back to an operator and method - a pharmaceutical company cannot just write down a number found on the web. All the features that make the J Series the instrument of choice for pharmaceutical liquids and waxes are now added to powders.

This measurement can also be done at the same conditions that the particle size analyzer is set to;

- The refractometer can be chosen with a wavelength to match the particle size analyzer
- Refractive index is very temperature sensitive and the J Series refractometer has variable built in temperature control. It can be set to measure at the same temperature the particle size analyzer operates at.

For more details contact Rudolph Research at [info@rudolphresearch.com](mailto:info@rudolphresearch.com)

