BUCK Scientific

Application Note #IR3002

A 5-minute Screening Method for Incoming Raw Materials in Pharmaceutical Manufacturing

Problem

Normal quality control procedures involve accepting a "lot" of a raw material from a supplier and then performing a series of tests to determine if the material is suitable for use in a manufacturing process. For the drug manufacturing industry, as well as many others, this is both a critical and time-consuming (and occasionally costly) step in the process. If the sample is not homogeneous or is segregated, there will be errors. Many of the standard methods for these tests are very labor-intensive and operator-dependent manual methods, adding additional variability. If the material is deemed unacceptable, additional costs are incurred to return the material, since the shipper usually leaves the premises before the testing is completed. Time, money and ultimately quality are expensive commodities in the manufacturing quarter.

Principle

Organic molecules have the ability to absorb unique wavelengths of radiation from the infra-red spectrum and then generate absorption band spectra. These spectra are quite specific to each compound, actually creating a "fingerprint" for a given compound. The power of digital CPU-based software, relative to classical analog charts, gives the analyst the ability to rapidly compare the spectrum of one compound to that of another in mere seconds, and then calculate the percentage difference, if any.

Practice

A new batch of incoming samples is placed on the inert crystal of the PLC-11M reflectance Prism Cell accessory and scanned with the Buck Scientific Model IR system. The spectrum is processed using GRAMS®/IR Software to create an absorbance scan. A "library" of known materials is made by scanning previous lots of both acceptable (good) and rejected (bad) product. The spectrum of incoming material is "searched" and compared to this library and a list of matches is shown. If the majority of the "hits" are good, the material is accepted and the truck unloaded. Should the hit-list come up mostly bad, the result is faxed to the supplier with a little note and the shipper is sent to return the material. The entire procedure, from initial collection of the sample to final results, is less than 5 minutes! If there is any question regarding the conclusions made from the analysis, there are several macro routines available for the GRAMS/IR software, including spectral equivalency. This compares 2 spectra and calculates the percentage difference between them. By assigning a maximum tolerance specification to this test, a quick PASS / FAIL assay can be made with tremendous precision.

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