

## **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**

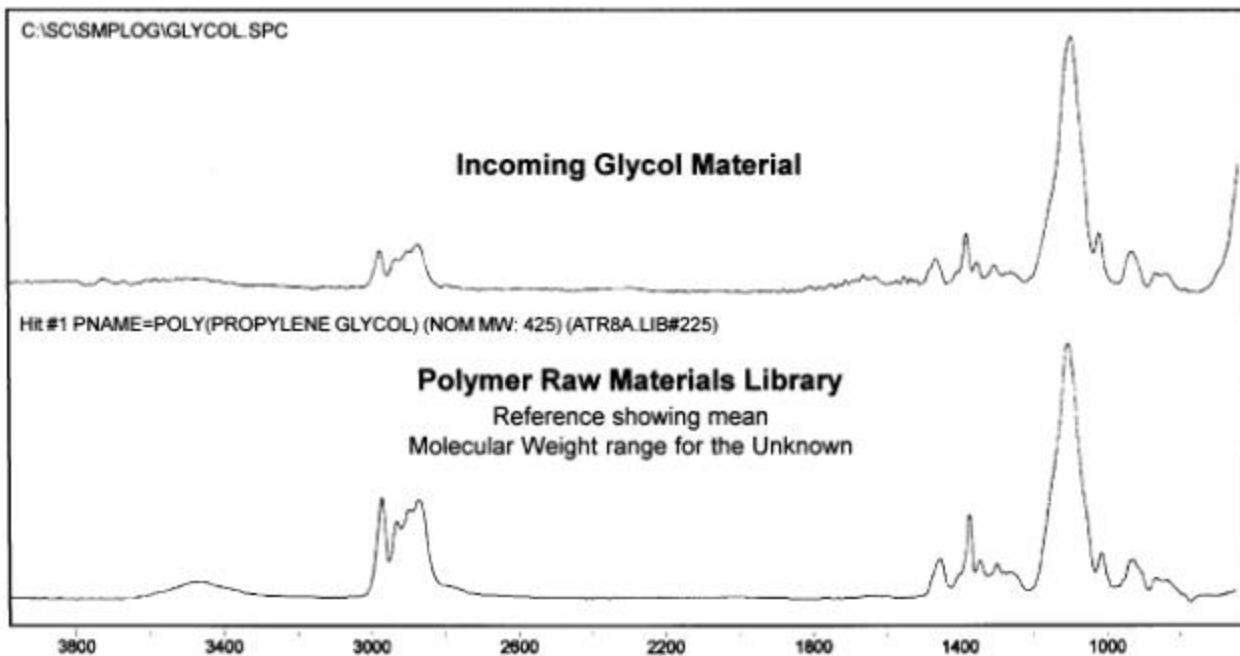
Organic molecules have the ability to absorb unique wavelengths of radiation from the infra-red spectrum and then generate absorption band spectra. These spectra are quite specific to each compound, actually creating a “fingerprint” for a given compound. The power of digital CPU-based software, relative 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<sup>®</sup>/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.

Search Method for C:\SC\SMPL\GLYCOL.IDS  
 Sample Name = GLYCOL.SPC  
 Search Date = 8/22/95 1:18 AM  
 Mask Used = None

Text Search: None  
 Peak Search: None  
 Full Spectrum Search: Euclidian Distance  
 Custom Search: None



Hit List

Number	Hit Quality	SPC Identification
1	.35203	PNAME=POLY(PROPYLENE GLYCOL) (NOM MW:425)
2	.35203	PNAME=POLY(PROPYLENE GLYCOL) (NOM MW:725)
3	.35749	PNAME=POLY(PROPYLENE GLYCOL) (NOM MW:1,000)
4	.38611	PNAME=POLY(PROPYLENE GLYCOL) (NOM MW:4,000)
5	.39357	PNAME=POLY(VINYL ETHER) (Tg=-30)
6	.39846	PNAME=POLY(PROPYLENE GLYCOL) (NOM MW:2,000)
7	.40089	PNAME=POLY(VINYL METHYL ETHER) (n= 35)
8	.4033	PNAME=POLY(EPICHLOROHYDRIN) (NOM MW: 1,500)
9	.4151	PNAME=POLY(PROPYLENE GLYCOL) (NOM MW:3,000)

Hit List of Library  
 Matches with  
 Full Range of MW

Spectral library search comparison with a list of the best matches for the unknown sample, showing the closest molecular weight and chain length. The arithmetic algorithms that compare the sample's spectrum to the library references can be set automatically or can be defined by the operator.



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