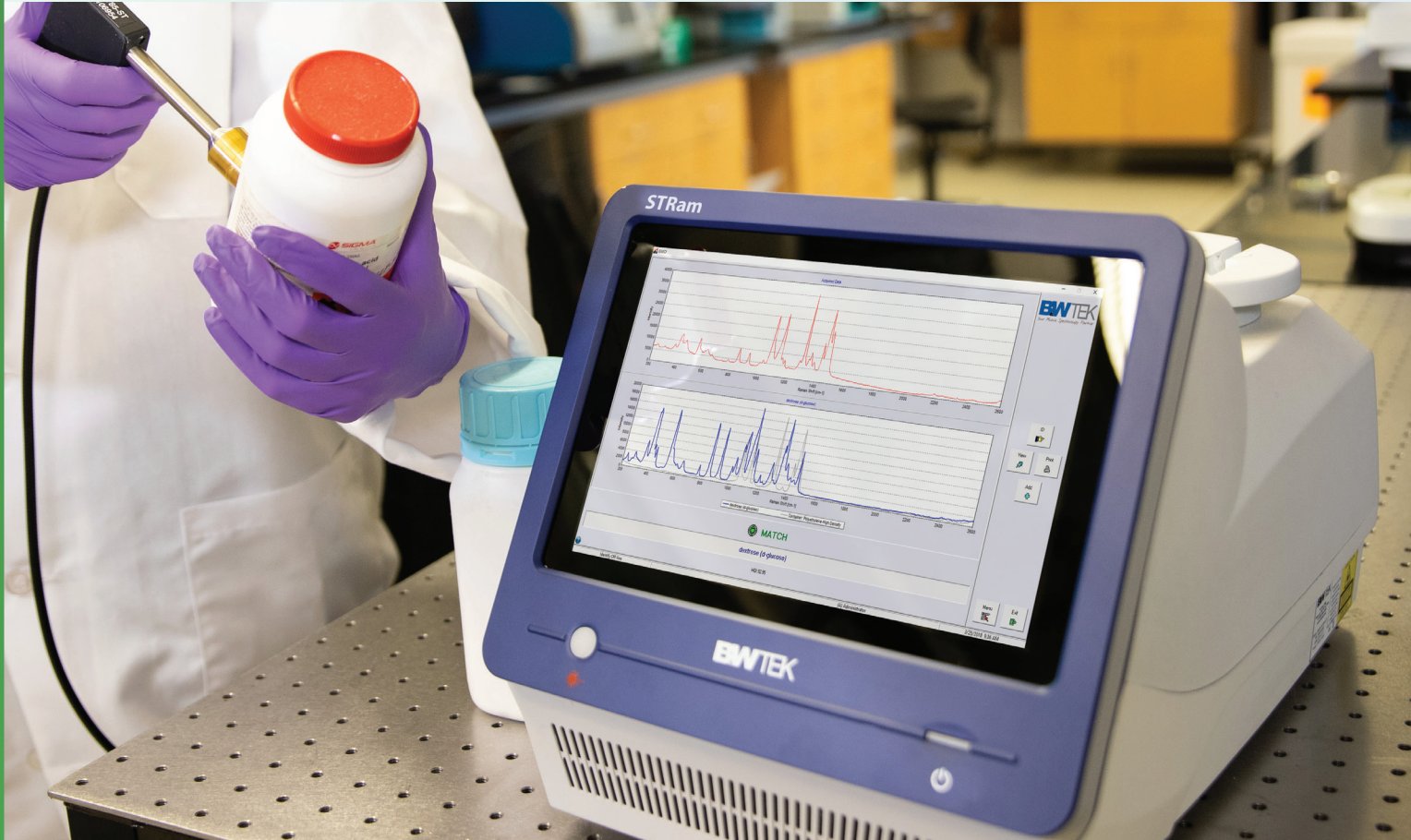


Identification of Starting Materials in Pharmaceutical industry using STRam®-1064



Introduction

100% starting materials identification testing is one of the FDA's directives as per 211.84 for FDA regulated industries such as Pharmaceutical, Vaccines, Cosmetics, Tobacco, Animal veterinary products, Food, etc. **STRam®-1064** is a Raman analyzer uniquely suited for this purpose. It uses the patented **STRaman®** technology to measure samples through thick packaging materials such as plastics, multilayer kraft paper sacks, and HDPE containers, and a long wavelength laser to suppress fluorescence. The ID algorithm isolates the sample signature by subtracting that of the packaging material and compares that with library spectra to achieve identification. Among the benefits are:

- ★ **STRam®** can be used anywhere: in labs, warehouses, processes, fields.
- ★ Rapid analysis.
- ★ No need to open the material package, avoiding contamination.
- ★ FDA/21CFR Part 11 compliant software.
- ★ Identification analysis allows the use of both commercial and user-created libraries.
- ★ Wide Range of applications – from temperature- sensitive samples to fluorescent samples

In this note, identification/verification of raw materials used in the pharma/regulated environment as well as in laboratory are demonstrated using **STRam®-1064**, without opening the packages.



Samples

- 1 Dextrose in a paper sack A (3 layers of brown kraft paper, 1 layer of PE film). (Fig. 1)
- 2 Dextrose in a paper sack B (1 layer of brown kraft paper, 1 layer of PE film). (Fig. 2)
- 3 Calcium chloride dihydrate in plastic bags (1 layer of blue PE, 1 layer of clear PE film). (Fig. 3)
- 4 Magnesium chloride hexahydrate in plastic bags (1 layer of blue PE, 1 layer of clear PE film).
- 5 Sodium Lactate 60% USP in a thin HDPE (0.92mm) and a thick HDPE (2.45 mm) container. (Fig. 4)

Method Development

Library spectra of pure samples of dextrose, calcium chloride dihydrate, magnesium chloride hexahydrate, sodium lactate 60% and of package materials are collected in the lab, and operation methods are developed, which include acquisition parameters: Laser power 100%, Integration time range from 10 to 80 seconds per sample for solids samples and 10 to 60 seconds for sodium lactate 60 sample.

Sample Test

Tests for dextrose, calcium chloride dihydrate and magnesium chloride hexahydrate are done in the raw material warehouse of a pharmaceutical company. Test for sodium lactate 60% was done in the B&W Tek HQ (Plainsboro, USA). No sample preparation was required. The samples are scanned without opening the packing bags using the methods developed in the laboratory.

Figure 1. Multilayered paper sack A for dextrose.



Figure 2. Dextrose in paper sack B.



Figure 3. Calcium chloride dihydrate in plastic bags.

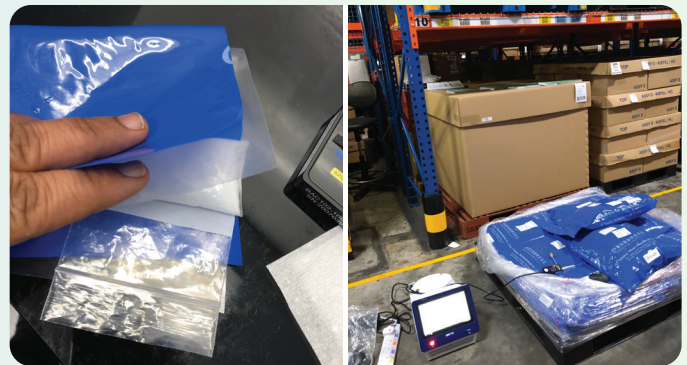


Figure 4. Sodium lactate 60 in HDPE containers.



Results

Table 1. Test results for dextrose, calcium chloride dihydrate and magnesium chloride hexahydrate (solid).

Material	Results
Dextrose in paper sack A	Pass (HQI 80 ~ 88) (Figure 5)
Calcium chloride dihydrate in plastic bags	Pass (HQI 94 ~ 95) (Figure 6)
Dextrose in paper sack B	Pass (HQI 74)
Magnesium chloride hexahydrate in plastic bags	Pass (HQI 90)

Table 2. Test results for sodium lactate (liquid)

Material	Results
Sodium lactate in a thick HDPE container	Pass (HQI 80 ~ 88) (Figure 5)
Sodium lactate 60 in a thin HDPE2 container	Pass (HQI 99)*

* Tests were done with a Focus Adaptor (RST-FA-xx) and Surface Regulator (RST-SR) attached.

Figure 5. Identification result of dextrose in paper sack A

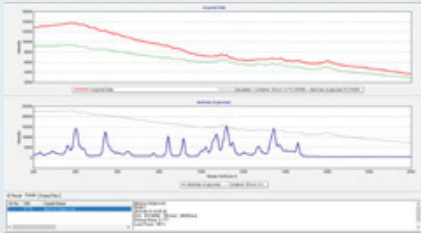


Figure 6. Identification result of calcium chloride dihydrate through plastic bags

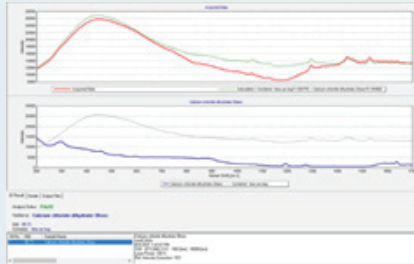


Figure 7. Identification result of sodium lactate 60% in thick HDPE2 container



Conclusion

STRam®-1064 is used in a pharmaceutical plant warehouse to successfully verify raw material through package materials. The method is fast and easy to use and can be done without the need for any sampling. The materials tested are correctly identified through multiple layers of packaging that include kraft paper, blue, white and clear plastic bags. Furthermore, liquid samples were correctly identified through HDPE container of different thicknesses.

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