



RAPID

Pharmaceutical ID Verification of Excipients and APIs through Unopened Non-Transparent Containers



Improve testing throughput and safety without opening the packaging

Pharmaceutical raw material identity verification is essential but can be highly resource intensive. Opening sacks, bottles, FIBCs and barrels requires a flow-controlled sample-handling booth where each container is opened, tested or sampled and re-sealed before the booth is cleaned for re-use. For sterile production the risk of contamination adds to the cost and difficulty of sampling and testing each container. RapID is a unique instrument that allows ID of the contents of unopened containers in seconds.

Raman through Non-Transparent Containers

Raman spectroscopy is used for material verification because of its selectivity, ease of use, robustness and acceptance by USP and Ph. Eur. Conventional (handheld) Raman requires a clear line of sight to the sample, which limits viable containers to thin glass vials or thin transparent plastics. However, most materials arrive in multi-layer paper sacks, plastic bottles, thick brown glass bottles or other opaque containers. Handheld Raman and NIR techniques are not compatible with these types of unopened packaging.

Cobalt's RapID instrument uniquely avoids the need to open even multi-layer paper sacks by using spatially offset Raman spectroscopy (SORS). SORS measures a high-quality Raman spectrum of the contents directly through the container wall. RapID can identify many excipients and APIs through common packaging materials with no sampling requirement. For a comparison of handheld Raman capabilities versus SORS through 3 layers of paper, see Figure 1.

Fig 1: Mannitol

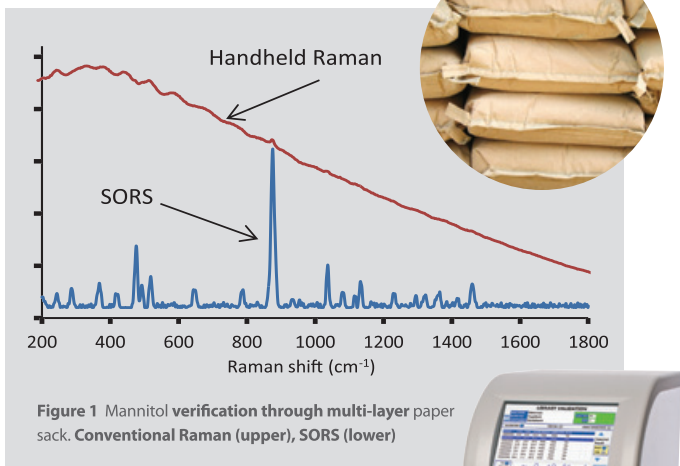


Figure 1 compares the spectrum obtained with an unopened 3-layer brown paper sack of mannitol by conventional (handheld) Raman and by RapID. Handheld instruments are defeated by the container fluorescence but RapID measures the contents' Raman spectrum for easy and unambiguous ID verification.

Increase Testing Throughput by up to 10x

Common excipients such as lactose (Figure 2) and citric acid (Figure 3) can be identified in 10-20 seconds through multi-layer paper or plastic sacks. Excipients that are difficult or impossible for hand-held instruments, e.g., HPMC, MCC (Figure 4) and gelatine are easily possible with RapID. For sterile production, e.g., injectable or IV products, opening the excipient containers may have a critical impact on production integrity. Parenteral excipients such as phenol often arrive in 1 or 2 litre brown glass bottles which RapID can ID in 5 seconds per container (Figure 5).

Fig 2: Lactose

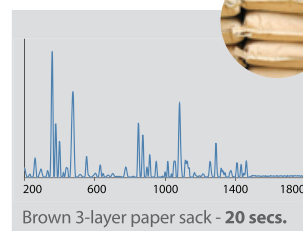


Fig 3: Citric acid

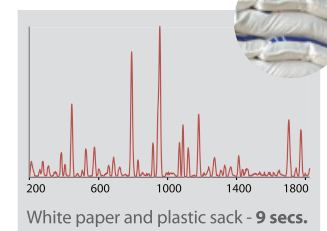


Fig 4: MCC

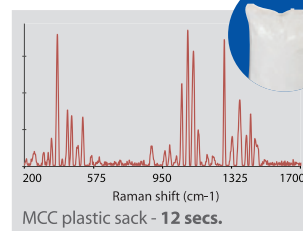
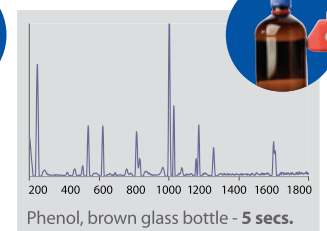


Fig 5: Phenol



Summary

RapID is the only instrument that enables non-invasive ID without opening the original packaging in the warehouse. By reducing the resource and steps required for ID, RapID's overall testing throughput can be 5-10x faster per container than with a handheld Raman instrument.

Tel: +44 1235 856555

to arrange a full product demonstration.

Cobalt Light Systems Limited

174 Brook Drive. Milton Park, Abingdon, Oxfordshire OX14 4SD

United Kingdom T: +44 1235 856555 F: +44 1235 856556

email: info@coballight.com