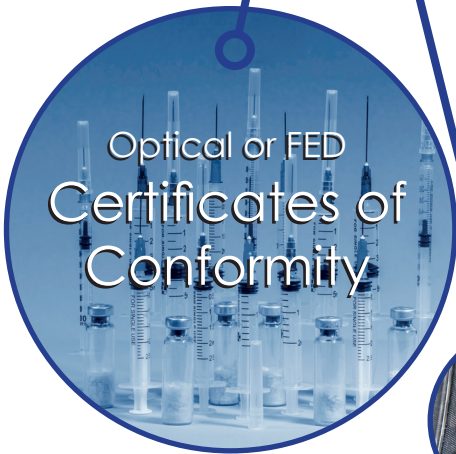


# High-Precision, Laser-Drilled **Positive Controls** for CCIT



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# Supporting your Quality Control measures with certified positive control samples

International regulatory standards demand deterministic testing methods to confirm the integrity of pharmaceutical packaging. The majority of non-destructive package integrity tests rely on a known-type defect (or positive control package) to verify the accuracy and reliability of the test and to calibrate the test equipment.

Oxford Lasers specialises in producing high-precision, positive control samples for this purpose by laser-drilling packaging to create certified defects.

## Confidence and traceability – certificates of conformity

As requested, we provide certificates of conformity (CoC) of our laser-drilled samples by either optical microscopy or flow effective diameter (FED). Our equipment is calibrated to national reference standards enabling you a robust audit trail for full traceability of your batch-release samples and align your manufacturing efforts with FDA cGMP, EU Annex 1 and USP 1207.

## How does it work?

Oxford Lasers will laser drill a calibrated micro hole into your packaging to create a 'positive control package'. These positive control packages are placed back into your production line for quality control measures – enabling you to test, calibrate, and confirm your leak detection monitoring system.

Defects can be created in a specific location (or locations) to recreate specific localised leaks (like on the neck of an ampoule) or a particular feature could be drilled, depending on the integrity test requirements. Oxford Lasers will work with you on the best choices for your CCIT positive control needs.



# Laser drilling directly into packaging

## Types of packaging

- Vials and bottles (glass and polymers including cryogenic materials)
- Syringes (all formats including luer lock and slip tip hubs)
- Autoinjector PFI syringes and cartridges
- Ampoules
- IV bags
- Laminate pouches
- Blister packs

## Types of material

Glass, polymers, metals

## Capabilities

- Laser-drilling of samples with hole size down to  $2\mu\text{m}$  ( $6 \times 10^{-4} \text{ cm}^3/\text{s}$  per USP 1207) in glass and pinholes – Polymers directly down to  $5\mu\text{m}$
- Leak detection index classification 3 to 6



## Don't want to directly laser drill into the packaging - Try pinholes!

When laser drilling the packaging is not required – or not practical – standard pinholes can be used as an alternative. Speak to us about our off-the-shelf or customized laser-drilled pinholes suited to your CCIT needs.

*Proudly serving industry  
and academia since 1977*

## **High-Precision Laser Micromachining**

For over 45 years, Oxford Lasers has been at the forefront of laser technology. Always innovating, we provide industry and academia with high-precision laser-based systems and services. Because of our in-depth knowledge, we ensure that our global customers harness the advantage of advanced laser technology by providing the right tool and technique for the job.

### **From Contract Services to Advanced Laser Systems**

We provide high-precision laser micromachining contract services from our purpose-built production laboratory. Capabilities include laser microdrilling, microcutting, micromilling, and surface laser processing in a vast array of materials including glass, ceramics, polymers and metals. Oxford Lasers also designs and builds fully automated laser micromachining systems fit for both R&D and pilot production tasks through to industrial production laser systems. Whether you require a stock tool or a custom-built system, Oxford Lasers is the laser system integrator to go to for precision micromachining solutions.

## **Contact us**

### **United Kingdom**

Oxford Lasers Ltd  
8 Moorbrook Park  
Didcot, Oxfordshire  
OX11 7HP  
+44 (0) 1235 810088  
[oxford.ltd@oxfordlasers.com](mailto:oxford.ltd@oxfordlasers.com)

### **USA**

Oxford Lasers Inc.  
2 Shaker Rd., Unit A101  
Shirley, MA 01464  
+1 800 222 3632 (Toll free)  
+1 978 425 0755  
[oxford.ltd@oxfordlasers.com](mailto:oxford.ltd@oxfordlasers.com)

[www.oxfordlasers.com](http://www.oxfordlasers.com)

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