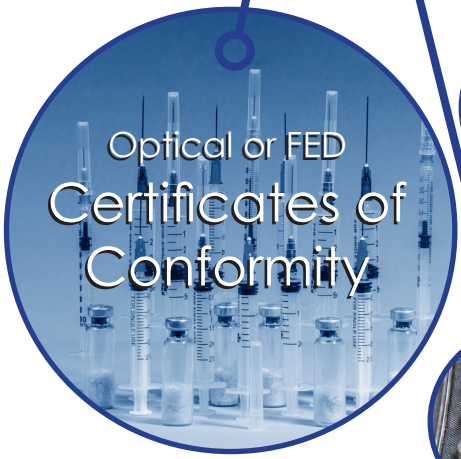
Precision Laser Drilling
Positive Controls for CCIT

OXFORD LASERS

Certified Defects Down to 2µm

Optical or FED
Certificates of Conformity



Glass
Polymers
Metals

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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 certfiied 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.

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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 2µm ($6x10^{-4}$ cm^3/s per USP 1207) in glass and pinholes – Polymers directly down to 5 µm
- 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.

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