

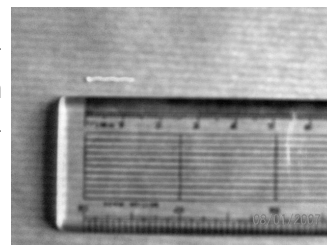
Technical
Note
20074

Pharmaceutical Contamination



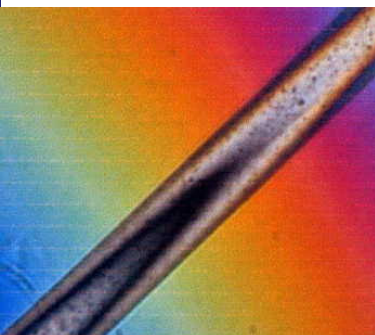
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In this case, a long, thick fibre was found embedded in a tablet. The manufacturer was keen to identify potential sources of the rogue contaminant



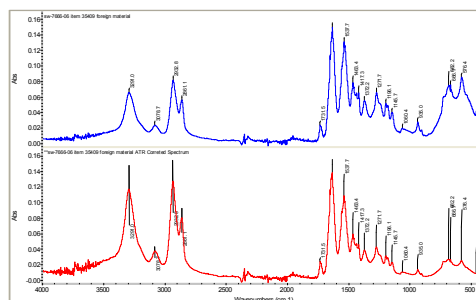
Key Words

- Pharmaceutical
- Identification
- Contamination
- Rogue
- Foreign
- Microscopy
- PLM
- ATR
- FTIR



Identification of the fibre using PLM showed that the fibre was nylon. Under optical microscopy, the fibre was found to have a square to rectangular cross-section and did not contain any delustrant. The surface of the fibre was particularly rough.

ATR-FTIR analysis of the fibre confirmed the chemical class as Nylon 6 one of the most commonly produced types of Nylon.



The combination of the morphological information together with the non-destructive chemical analysis strongly pointed to an industrial source of contamination, and initial suggestions that the contaminant was damaged PTFE tape were quickly discounted.

An in-house investigation revealed that brushes used in the tablet production process were likely sources of the contamination. A brush was a potential source that was entirely in keeping with strong synthetic fibres (such as nylon filament) that have rough surfaces, rectangular to square cross-sections and contain little to no delustrant particles.

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