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Review Article

Detection and Analysis of Microplastics in Pharmaceutical Products

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ABSTRACT

Microplastics (MPs) are emerging contaminants of environmental and public-health concern, with increasing attention to their potential presence in pharmaceutical products and healthcare materials. Pharmaceutical manufacturing involves polymers in packaging, tubing, filters, containers, and processing equipment, which may contribute to particle generation and contamination during production, handling, transportation, and storage. Reliable detection requires complementary analytical techniques to characterize particle size, morphology, polymer identity, and mass concentration. Microscopy, FTIR, Raman spectroscopy, SEM, Py-GC/MS, and TED-GC/MS provide complementary information for microplastic identification and quantification. Recently developed matrix-relevant reference materials containing polypropylene in water-soluble tablets offer a valuable approach to pharmaceutical method development and validation. Furthermore, microplastics and nanoplastics may enter the human body through pharmaceutical products and medical procedures, although exposure levels and clinical implications remain insufficiently established. Standardized analytical methods, appropriate reference materials, and effective contamination-control strategies are therefore essential for reliable pharmaceutical analysis and future risk assessment.

INTRODUCTION

Plastic materials are extensively used in pharmaceutical manufacturing because of their flexibility, strength, chemical resistance, low weight and suitability for packaging and processing. They may occur in containers, closures, tubing, transfer lines, filters, seals and single-use systems. These materials provide important functional advantages, but mechanical abrasion, repeated movement, thermal stress, ageing and surface degradation may generate small fragments or fibres. [2,4]

Microplastics are commonly discussed as plastic particles below approximately 5 mm, although definitions and lower size boundaries vary among studies. The

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broad size range creates a major analytical challenge: larger particles can be observed using microscopy, while smaller particles may require micro-spectroscopy, advanced imaging or mass-based methods. Nanoplastics are even more difficult because their dimensions can fall below the practical limits of conventional particle-counting approaches. [3,6,7]

In pharmaceutical analysis, it is necessary to distinguish unintended plastic particles from active pharmaceutical ingredients, excipients, coating materials, environmental particles and laboratory contamination. Therefore, a suitable analytical method should provide chemical confirmation in addition to physical characterization. This has encouraged the development of multimethod workflows combining microscopy, spectroscopy and thermal or mass-spectrometric techniques. [4,6] **3. Sources of Microplastic Contamination**

3.1 Manufacturing equipment

Pharmaceutical manufacturing can involve extensive contact between product streams and polymeric components. Tubing, hoses, seals, gaskets and filters may undergo mechanical stress during mixing, pumping and transfer. Surface wear can generate particles whose composition may correspond to the material of construction. A risk assessment should therefore identify all product-contact polymeric components and evaluate whether their use, cleaning and mechanical operation could contribute particulate contamination. [2,3]

3.2 Packaging materials

Primary packaging is another potential source because pharmaceutical products may remain in contact with packaging materials for long periods. Containers, closures, liners, blister materials and flexible bags may be exposed to mechanical stress during filling, sealing, transportation and opening. Comparing the polymer composition of product-associated particles with packaging materials can support source investigations. [2,4]

3.3 Raw materials, water and environment

Raw materials, process water and manufacturing environments may provide additional contamination pathways. Airborne fibres and particles can enter exposed samples, while plastic laboratory materials can contaminate analytical preparations. Because microplastic concentrations may be low, procedural blanks are essential for distinguishing sample-derived particles from laboratory background. [6,9]

4. Dosage Forms and Matrix Effects

Tablets can often be dissolved or dispersed before filtration, allowing insoluble polymer particles to be isolated. However, coatings and insoluble excipients can remain on the filter and interfere with analysis. Capsules may introduce shell materials that need to be distinguished from unintended contamination. Liquid products may contain suspended excipients that interfere with filtration, while creams and ointments can require removal of oils and waxes before particle analysis. [1,2,6]

The sample-preparation method should therefore be optimized for each dosage form. Recovery studies using known polymer particles should establish whether the procedure removes the pharmaceutical matrix without dissolving, fragmenting or losing the particles. [6]

5. Sample Preparation and Contamination Control

Sample preparation is a critical source of analytical bias. An ideal procedure should remove matrix components, concentrate the particles, preserve their morphology and polymer identity, and minimize contamination. Depending on the product, approaches can include dissolution, filtration, centrifugation, density separation and chemical or enzymatic digestion. [4,6]

Filtration is particularly useful when the pharmaceutical matrix can be dissolved or separated. The filter captures particulate material for subsequent microscopic and spectroscopic analysis. Filter composition is important because the membrane itself can contribute particles or interfere with spectra. Procedural blanks should therefore be processed using the same conditions as samples. [6,7]

Aggressive digestion conditions may damage susceptible polymers. Recovery experiments should consequently use representative polymers and particle sizes. Smaller particles can be preferentially lost during

transfer, washing and filtration, producing a size-dependent recovery bias. [4,6]

Contamination control should include covered samples, clean handling, suitable laboratory clothing, glass or metal equipment where feasible, procedural blanks and equipment blanks. All materials used during sampling and preparation should be documented because unexpected polymer signals may originate from laboratory consumables rather than the pharmaceutical product. [6,7]

6. Microscopic Techniques

6.1 Optical microscopy

Optical microscopy provides rapid information on particle number, approximate size, colour and morphology and is useful for initial screening. Its principal limitation is that visual appearance cannot reliably confirm polymer identity. Transparent or irregular particles may be misclassified, and non-plastic particles may resemble microplastics. [4,6]

6.2 Scanning electron microscopy

SEM provides high-resolution information on particle surface morphology, cracks, roughness and shape. It is particularly useful for reference-material characterization. Putzu et al. incorporated SEM into the characterization of polypropylene tablet reference materials, demonstrating the value of combining morphology with spectroscopic and thermal measurements. [1]

SEM alone does not definitively establish polymer identity. Elemental information can be obtained with energy-dispersive X-ray analysis, but common polymers may have similar elemental composition. SEM is therefore best used with FTIR, Raman or mass spectrometry for chemical confirmation. [4,6]

7. Fourier-Transform Infrared Spectroscopy (FTIR)

FTIR identifies polymers through characteristic infrared absorption bands associated with molecular vibrations. Unknown particle spectra can be compared with reference spectral libraries to determine polymer type. Micro-FTIR imaging extends the approach by allowing automated mapping and chemical classification of multiple particles. [4,6]

Major advantages include chemical specificity, established spectral libraries and the possibility of relatively non-destructive analysis. However, particle size, matrix residues, substrate effects and water can affect spectral quality. The practical detection limit also depends on instrument configuration and measurement mode. [4,6]

ATR-FTIR is useful for direct characterization of larger particles and reference materials. The recent pharmaceutical reference-material study used ATR-FTIR as one component of a multimethod strategy for confirming polypropylene composition. Orthogonal characterization strengthens confidence because the material is evaluated using different physical principles. [1]

8. Raman Spectroscopy

Raman spectroscopy provides molecular fingerprints through inelastic scattering of laser light and is complementary to FTIR. Raman microscopy can provide high spatial resolution and is therefore attractive for smaller particles. The technique can identify many common polymer types when suitable spectra are obtained. [4,5]

Fluorescence is a major limitation. Pharmaceutical excipients, pigments, additives and weathered materials can produce fluorescence that masks Raman signals. Selection of excitation wavelength, control of laser power, spectral preprocessing and library matching can improve performance. [5]

Recent Raman developments include advanced Raman imaging, surface-enhanced Raman spectroscopy and chemometric classification. These approaches may improve sensitivity and throughput, but pharmaceutical matrices require dedicated validation before routine quality-control application. [5]

9. Py-GC/MS and Thermal Analysis

9.1 Pyrolysis-GC/MS

Py-GC/MS is a destructive technique in which polymer material is thermally decomposed into characteristic products that are separated by gas chromatography and identified by mass spectrometry. It is useful for polymer-specific bulk analysis and can be valuable when

particles are too small or numerous for complete microscopic characterization. [4,6]

Its limitation is that the original particles are destroyed, so the method does not provide the same particle-by-particle morphology or count information as microscopy or imaging spectroscopy. Matrix components can also generate interfering pyrolysis products, making blanks and appropriate standards important. [6]

9.2 TED-GC/MS

Thermal extraction/desorption-GC/MS provides polymer-specific mass information by thermally releasing characteristic compounds for chromatographic and mass-spectrometric analysis. It complements particle-based spectroscopy but requires specialized instrumentation and does not provide complete morphology information. [1,6]

9.3 TGA and DSC

Thermogravimetric analysis measures mass changes during programmed heating and can support estimation of polymer content. Differential scanning calorimetry provides information on thermal transitions. These methods are useful for bulk characterization and reference materials but are generally destructive and can be affected by overlapping transitions or matrix components. [1,6]

10. Emerging Analytical Technologies

Hyperspectral imaging combines spatial and spectral information and may permit high-throughput screening of large numbers of particles. Chemometrics and machine learning can assist in automated polymer classification and image recognition. These approaches are promising but depend strongly on representative training data and independent validation. [4,5]

Future pharmaceutical systems may use automated Raman or FTIR imaging, artificial intelligence-assisted classification, portable spectroscopy and sensor-based screening. Such technologies could reduce analysis time and support at-line monitoring. However, regulated use will require validation for specificity, sensitivity, robustness and matrix interference. [5,12]

Electrochemical and other miniaturized sensor technologies are emerging as potential rapid approaches. Their portability is attractive, but their chemical specificity and ability to distinguish microplastics from pharmaceutical excipients need further evaluation. [12,13]

11. Reference Materials

Reference materials are essential for method development because analysts require samples with known polymer identity, particle size and concentration. Without appropriate reference materials, it is difficult to determine whether poor recovery reflects the method or whether a sample genuinely contains a different particle burden. [1,6,7]

Putzu et al. developed water-soluble tablet reference materials containing polypropylene particles predominantly in the 1–100 μm range. The materials were evaluated for homogeneity and stability and characterized using several complementary methods. This approach is highly relevant to pharmaceutical analysis because it mimics a dosage-form matrix rather than testing polymer particles in isolation. [1]

Future reference materials should include multiple polymer types, different particle sizes and shapes, and stable concentrations that are appropriate for validation. Certified reference materials could substantially improve interlaboratory comparison and regulatory confidence. [1,7]

12. Method Validation and Quality Assurance

Validation should be matched to the intended measurement endpoint. Particle-count methods should assess specificity, recovery, repeatability, particle-size capability, blank contamination and reproducibility. Mass-based methods should additionally consider calibration, linearity, precision, detection capability and measurement uncertainty. [6,7]

Spike-and-recovery experiments can be performed by adding known polymer particles to representative pharmaceutical matrices and processing them through the complete workflow. Recovery should be evaluated across relevant particle sizes because losses can occur through adsorption, transfer, filtration or digestion. [4,6]

Specificity is especially important when a formulation intentionally contains polymers, such as coating or

controlled-release materials. Analysts must distinguish intentionally added formulation polymers from unintended microplastic contamination. Spectroscopic confirmation and comparison with the formulation composition are therefore essential. [2,4]

13. Standardization and Regulatory Considerations

Methodological heterogeneity is one of the main barriers to comparing microplastic studies. Different particle-size limits, extraction procedures, filters, identification criteria and reporting units can produce substantially different results. Standardized procedures are therefore necessary for meaningful surveillance. [6,7]

ISO 24187:2023 provides general principles for microplastic analysis in environmental matrices, including sampling, sample preparation and particle-size classification. Although it is not a pharmaceutical-specific standard, it provides a useful foundation for harmonization. Pharmaceutical applications still require dosage-form-specific validation and product-quality criteria. [7]

The pharmaceutical literature emphasizes the need for regulatory guidance addressing contamination monitoring, standardized analytical methods and mitigation strategies. Future standards may need to specify terminology, size categories, polymer identification, blank limits, recovery requirements and reporting units. [2,3]

14. Human Health and Toxicological Considerations

Potential biological effects depend on particle size, shape, polymer composition, surface chemistry, dose and exposure route. Experimental studies have investigated oxidative stress, inflammation, cellular interactions and other mechanisms, but the presence of a particle does not automatically establish a clinically significant adverse effect. [8,10]

WHO reviews have emphasized uncertainty in exposure assessment and health-risk characterization and have identified improved analytical methods as a research priority. These findings are relevant to pharmaceutical analysis because reliable exposure measurement is necessary before a meaningful risk assessment can be made. [8,9,15]

Healthcare exposure may differ from environmental exposure because medical products and procedures can provide direct routes into the body. The 2026 healthcare review reports that pharmaceuticals, intravenous systems, injections, implants and other medical materials can contribute to direct exposure, while also emphasizing that toxicological and analytical evidence remains incomplete. [3]

A 2026 systematic review of in vivo human evidence reported growing evidence of micro- and nanoplastic detection in human samples but emphasized methodological limitations and uncertainty in causal interpretation. Pharmaceutical risk assessment should therefore distinguish exposure detection from demonstrated clinical harm. [10,11]

15. Sustainable Pharmaceutical Manufacturing

Microplastic control should be integrated into sustainable pharmaceutical manufacturing. Plastics provide important benefits in sterile processing, packaging and material compatibility, so complete elimination is not always practical. Risk-based material selection, reduced unnecessary plastic contact, improved equipment design and monitoring may provide more realistic solutions. [2]

Sustainability should also consider the complete lifecycle of pharmaceutical plastics. Improved waste management, material substitution where feasible and optimized processing can reduce plastic release. Analytical monitoring can determine whether manufacturing changes actually reduce particulate contamination. (2,14)

16. Comparative Evaluation

Method	Main information	Strengths	Limitations	Destructive	Recommended role
Optical microscopy	Size/shape/count	Simple and rapid	Cannot confirm polymer	No	Screening
SEM	High-resolution morphology	Excellent surface detail	Expensive; not chemically specific alone	No/limited	Morphology
FTIR/μ-FTIR	Polymer fingerprint	Established and library-supported	Particle-size/matrix limits	Usually no	Routine identification
Raman/μ-Raman	Polymer fingerprint	High spatial resolution	Fluorescence/laser effects	Usually no	Small-particle confirmation
Py-GC/MS	Polymer-specific mass	Sensitive bulk chemistry	Destructive; no morphology	Yes	Bulk confirmation
TED-GC/MS	Thermal polymer markers	Mass-based information	Specialized instrumentation	Yes	Reference/method studies
TGA/DSC	Thermal behaviour	Useful bulk characterization	Overlapping transitions	Yes	Complementary
Hyperspectral imaging	Spatial + spectral data	Potential high throughput	Cost and validation	Usually no	Future automation

17. Future Perspectives

The future of pharmaceutical microplastic analysis is likely to involve multimodal and automated measurement. Imaging combined with spectroscopy can provide particle size, morphology and chemical identity in one workflow, while automated classification can increase throughput. [4,5,12]

Artificial intelligence may improve spectral matching, particle segmentation and classification, but models must be trained on realistic pharmaceutical matrices and validated using independent datasets. A model trained only on pristine polymers may not perform well with weathered, aged or matrix-coated particles. [5,12,14]

Portable spectroscopy, microfluidic separation and sensor technologies may eventually support rapid in-process or at-line screening. Their implementation in regulated pharmaceutical laboratories will depend on demonstrated specificity, sensitivity, robustness and reproducibility. [5,13]

Reference materials will remain a major priority. The recent tablet study provides a useful model for producing dosage-form-relevant standards. Future materials should include different polymers, particle shapes and size ranges, including smaller particles that remain analytically challenging. [1]

CONCLUSION

Microplastic contamination is an emerging analytical issue in pharmaceutical manufacturing and healthcare. Potential sources include processing equipment, packaging, raw materials, environmental exposure, handling and storage. The analytical challenge is increased by low concentrations, diverse particle sizes, complex polymer chemistry and interference from pharmaceutical matrices.

FTIR and Raman spectroscopy provide important chemical identification, while microscopy and SEM provide complementary physical characterization. Py-GC/MS, TED-GC/MS and thermal analysis provide bulk chemical information. The evidence supports a validated multimethod strategy rather than dependence on one technique.

For pharmaceutical quality control, the most important priorities are contamination prevention, validated sample preparation, procedural blanks, recovery studies, reference materials, clear reporting and orthogonal confirmation. ISO 24187:2023 provides a useful general framework, while pharmaceutical-specific analytical standards and regulatory criteria remain an important future need.

Detection should be interpreted separately from clinical risk. Current evidence demonstrates exposure and biological concern, but the magnitude and clinical

significance of pharmaceutical microplastic exposure remain incompletely characterized. Continued collaboration among analytical chemists, pharmaceutical scientists, toxicologists, manufacturers and regulators is required.

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