

PHARMACEUTICAL WASTE Impacts and Management

Pharmaceutical waste, including prescription and over the counter (OTC) drugs, present a unique disposal challenge. For years, the common direction was to flush unused or unwanted drugs down the drain to prevent poisoning or unintended use. However, it is now widely known that flushing pharmaceuticals down the drain is harmful to human health and the environment.

How do pharmaceutical wastes enter the environment?

Municipal wastewater is the main route that introduces human pharmaceuticals into the environment after normal use and disposal of unused medicines.¹ Other significant sources include hospital wastewater, wastewater from pharmaceutical manufacturing and landfill leachate.² In addition, application of sewage sludge from these wastewater treatment systems applied to agricultural fields can contaminate soil and further generate impacted surface runoff.³ Additionally, veterinary pharmaceuticals can enter ecosystems via manure application or aquaculture (fish farming).⁴⁻⁶

What risks do pharmaceutical wastes present?

Improper disposal of pharmaceutical wastes can present a host of problems to pharmaceutical companies, public health, and ecosystems. Non-compliant disposal can lead to fines, license revocation, and even criminal prosecution, as well as damage to a company's brand and reputation. Beyond the costs to the business, improperly managed pharmaceuticals can threaten drinking water supplies and be persistent in the environment.

Flushed down the drain, pharmaceuticals mostly pass through typical wastewater treatment plants or septic systems. Complex organic molecules present in pharmaceuticals may not readily degrade in the wastewater treatment systems and can result in the contamination of surface water bodies and groundwater systems. Once in water bodies, pharmaceuticals can impact biological activity (such as high toxicity and endocrine disruptors impacts on fish species reproduction) in ecosystems particularly in long-term exposure²⁻¹⁰ or pass into drinking water systems impacting human health. U.S. EPA researchers found concentrations of 56 active pharmaceutical ingredients (APIs) from samples collected at 50 large municipal wastewater treatment

plants across the U.S.¹¹ A U.S. Geological Survey of 139 water streams across the country found at least one Organic Wastewater Contaminant (OWC) in 80% of streams.¹²

Landfilling pharmaceuticals presents its own risk. They can be carried in water (precipitation) that percolates through the landfill, called leachate. This leachate, typically collected and treated in on-site or off-site wastewater treatment plants, again provides a pathway for the pharmaceuticals to reach water bodies.

Drugs that not disposed properly and left in the home present risks of accidental poisoning, misuse, and potential deliberate abuse. Roughly 94% of those receiving opioid prescriptions report having leftover unused opioids.¹³ The storage of unwanted or expired opioids in the home increases the risk of overdosing or accidental poisonings, killing more Americans than cocaine and heroin combined.¹⁴ According to the U.S. Department of Health and Human Services, in 2019 over 10 million Americans misused prescription opioids. Over 136 people died every day from opioid-related drug overdose.¹⁵ External stressors can increase drug abuse. During the COVID-19 pandemic, opioid-driven overdose deaths increased 38.4% from the 12-month period leading up to June 2019 compared with the same up to May 2020. "The disruption to daily life due to the COVID-19 pandemic has hit those with substance use disorder hard," said CDC Director Robert Redfield, M.D.¹⁶

How does thermomechanical treatment mitigate these risks?

Thermomechanical Treatment Facilities (TTFs, also known as waste-to-energy, (WTE)) effectively destroy organic compounds like those in non-hazardous pharmaceutical wastes. Secure destruction is achieved through a properly engineered combustion process and the environmental impact is minimized through proper functioning and maintenance of air pollution control equipment.¹⁷ The U.S. EPA, when considering options for the management of certain pharmaceuticals, concluded their management in a TTF to be "environmentally protective."¹⁸ A pharmaceutical and personal care product (PPCP) test burn program at a TTF conducted by the Maine DEP demonstrated low volatile organic compound (VOC) emissions and effective destruction.¹⁹

“[T]he emissions from the ecomaine [WTE] facility, whether combusting controlled substances or not, result in very low levels of VOCs and air toxics. The stack exhaust shows levels of most compounds actually below what is routinely measured in the ambient air in the Portland area. The ash results indicate a greater than 99.9% destruction of PPCPs during the combustion process.”¹⁹

Results from the Maine Department of Environmental Protection

How are air emissions controlled and monitored?

To minimize emissions, TTFs employ a carefully controlled combustion process with temperatures >2,000°F, coupled with sophisticated air pollution control equipment. 99.9% of what comes from the stack are normal components of air, including water vapor, nitrogen, oxygen and carbon dioxide (CO₂). Air emissions from TTFs are heavily regulated by both the U.S. EPA and state environmental agencies. Reworld’s facilities perform well within these limits (Figure 1). Emissions from TTFs are monitored through both continuous emissions monitoring systems (CEMS) and routine stack tests (performed at least once a year). CEMS monitor flue gases continuously for carbon monoxide (CO), nitrogen oxides (NOx), sulfur dioxide (SO₂), opacity, and carbon dioxide and/or oxygen. Facility operators monitor these parameters and adjust as needed to ensure proper operation and compliance.

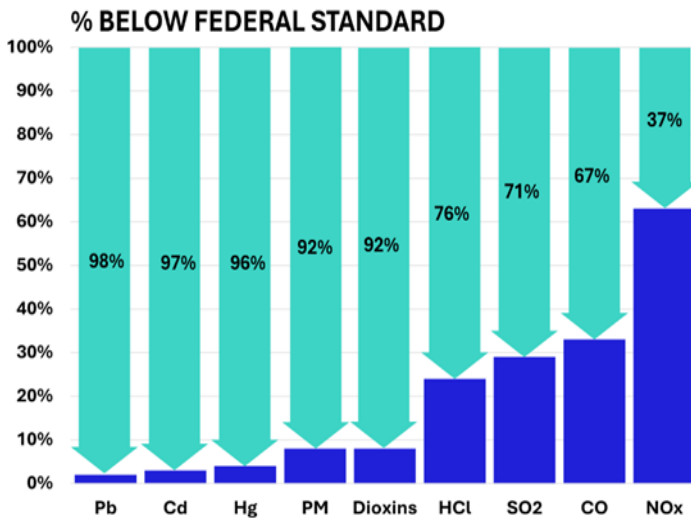


Figure 1. Reworld TTF 2020-2023 performance vs. federal air emission standards

Other regulated pollutants are checked through a rigorous stack testing program performed by a regulator-approved third party. The operating parameters under which the stack test is conducted (e.g., activated carbon addition rate, steam flow rate) set the standard for the facility’s operation until the next stack test is completed. Operating the combustion process and air pollution control equipment in accordance with these standards ensures compliance.

Is TTF ash hazardous?

The thermomechanical treatment of waste – including non-hazardous pharmaceutical waste – results in ash that is sent to landfills for final disposal or for use as alternative daily cover (ADC). TTF ash is routinely tested to confirm that it is non-hazardous per U.S. EPA regulations using the Toxicity Characteristic Leaching Procedure (TCLP) defined by U.S. EPA Method 1311.²⁰ The TCLP test uses an acid solution to simulate worst-case leaching conditions that might occur in a landfill containing decaying waste streams. If the ash is deemed hazardous due to the presence of heavy metals or other contaminants, it must be disposed of as hazardous waste.²¹ No ash from Reworld’s operating U.S. TTFs has ever been determined to be hazardous.

“Toxicity is defined through a laboratory procedure called the Toxicity Characteristic Leaching Procedure (TCLP) (Method 1311). The TCLP helps identify wastes likely to leach concentrations of contaminants that may be harmful to human health or the environment.”²²

USEPA on Toxicity

Have pharmaceuticals been safely managed in TTFs before?

Destruction through controlled combustion, such as in TTFs, is commonly used to meet the U.S. Drug Enforcement Agency’s non-retrievable standard for controlled substances collected from consumers. The US EPA Office of Resource Conservation & Recovery (ORCR) and Office of Solid Waste & Emergency Response recognized TTFs as an appropriate management approach for collected household pharmaceuticals.²³ In 2010, Reworld launched its Prescription for Safety (Rx4Safety) program, developed in cooperation with the Product Stewardship Institute

(PSI) and the Prescription Pill and Drug Disposal Program (P2D2), as well as community drug take-back programs. Since then, more than 20.8 million pounds of pharmaceutical waste has been collected and destroyed. Reworld's Healthcare Solutions group collects this waste primarily through prepaid mail-back boxes, liners, and in-store kiosks and safely destroys them in TTF operations.

What other benefits do TTFs offer?

Unlike a typical hazardous waste incinerator, TTFs are specially designed to safely dispose non-hazardous waste while recovering energy and metals and

offsetting the need for fossil fuels, while avoiding landfill methane. TTFs are located in close proximity to dense population centers where waste is generated. This reduces transportation related costs and environmental impacts as well.

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