

Human Health Benchmarks for Pharmaceuticals (HHB-Rx)

The U.S. Environmental Protection Agency (EPA), in coordination with the Federal Workgroup on Pharmaceuticals in Water, has developed human health benchmarks for 374 pharmaceuticals.

What is a Benchmark?

Human health benchmarks are not regulations or enforceable levels. States, Tribes, and others can use these benchmarks to determine if the levels found in water need further investigation.

If levels of a pharmaceutical in water are at or below EPA's human health benchmark, harmful effects are unlikely.

EPA Developed Benchmarks for Pharmaceuticals

EPA selected these 374 pharmaceuticals because they are approved by the U.S. Food and Drug Administration (FDA) and have the potential to occur in source waters (i.e., surface and groundwater) or treated drinking water. They include prescribed medications and over-the-counter pharmaceuticals. The availability and use of prescription and non-prescription pharmaceuticals have evolved rapidly in recent years. EPA used readily available data to draft this list and is opening a public comment period to gather new information from stakeholders and update as appropriate.

For each pharmaceutical, two benchmark values were developed: one for the general population (i.e., all ages) and one for infants. If a pharmaceutical occurs in drinking water at levels higher than the benchmark, additional water monitoring or research could be conducted to help ensure the protection of Americans' drinking water.

EPA used the lowest oral therapeutic dose from FDA approved labels to develop each benchmark. For example, the FDA label for amoxicillin recommends the lowest dose to treat infection in adults is 250 mg every 8 hours. EPA used this dose to come up with a daily level of exposure (per kilogram of bodyweight) and then considered how much water a person drinks every day to calculate the benchmark.

In the future, EPA may update the existing benchmarks if FDA drug labels change. The agency may also add benchmarks for additional pharmaceuticals based on new information.

Additional Information

To view the table of benchmarks and supporting information go to:

<https://www.epa.gov/sdwa/human-health-benchmarks>