

Ecological and human health risk assessment of antibiotics and anti-cancer drugs found in the environment.

Trial registration is **free**. To ensure the success of this exercise, participants undertake to:

- return results in any integrity without tampering or collusion,
- o return results according to schedule,
- o provide that requested such associated metadata.

If a participant did not provide the information requested, the organizers would reserve the right not to issue conclusions (results and evaluations of performance) coming from the treatment of the test data.

Caution: the number of participants is limited. If too many candidates, a selection of participants will be conducted.

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About PHARMAS (www.pharmas-eu.org)

Pharmas is an **European project** funded in the frame the call FP7-ENV-2010-ENV.2010.1.2.2-2: Human health and environmental effects of exposure to pharmaceuticals released into the environment.

The project aims to identify the potential risk and hazard of selected pharmaceuticals sold globally, including the metabolites and transformation products that may be formed during the life cycle of a pharmaceutical product. It will concentrate on two classes of human pharmaceuticals, namely antibiotics and anti-cancer drugs. In order to conduct sound risk assessments, including providing estimates of uncertainty, it will be necessary to obtain accurate data on both exposure concentrations and effects levels. Hence, new data on both environmental concentrations and effects on aquatic organisms will be produced during the project. The stable transformation products of the selected pharmaceuticals will also be investigated. A prototype web-based classification system will be developed during the project with the intention of enabling all EU citizens to make their own informed decisions about the risk posed by human pharmaceuticals to their health and to the health of the environment. The results will able EU regulators and policy makers to make better informed decisions on the issue of pharmaceuticals in the environment.



PHARMAS Ecological and human health risk assessment of antibiotics and anticancer drugs found in the environment.

Organizes

INTERLABORATORY EXERCISE

September 2011

for

the determination of ANTIBIOTICS IN RESOURCES AND DRINKING WATER





Objectives and Schedule

Analysis of the emerging parameters in water collides with the knowledge of the performance of the analytical methods in the absence of normative texts and related collaborative trials. Measurement campaigns of pharmaceutical products in water (resource and consumption) have already carried out and it is necessary today to insure the robustness of associated protocols, and the reliability of the measured concentrations. In this context:

PHARMAS project

organizes an

INTERLABORATORY EXERCISE

The aim of which is :

- **To allow** the laboratories having developed techniques of analyses on antibiotics residues in water **to compare** their methods
- **To dispose** of information on the **analytical performance and uncertainties** concerning the analysis of these substances **in resource and tap waters,** at concentration levels typically found.

The conditions of the exercise are as follow:

- **Free trial** for participating laboratories
- o Treatment of the results **anonymously**.

Invited to participate in this test are **laboratories having developed competence** in pharmaceutical residues analysis in waters. They will implement their usual methodology, and/or the methodology proposed by the organizers.

Schedule planned for the exercice :

June 30th 2011: end of registration September 1st 2011: test material delivery September 30th 2011: deadline for results sending December 31th 2011 : distribution exercise report

Materials and Substances

Target substances will be chosen among the following candidates:

Tetracycline, Oxytetracycline, Chlortetracycline, Doxycycline, Ofloxacin, Ciprofloxacin, Levofloxacin Cefuroxim, Ceftriaxone, Trimethoprim, Erythromycin

Trial materials will be constituted by:

- o **One** standard solution for instrument control
- o Three fortified samples of surface water and treated water

Fortification of samples will be done at expected concentration present in these matrices, i.e. > 100 ng/L in surface water and > 25 ng/L in treated water

Participants will receive

- o **1 flak** of reference solution
- o **3 flasks** of water samples

And will carry out 3 measurements for each sample.

The trial will be implemented according to ISO 13528 – ISO/CEI 17025 – ISO/CEI 17043 norms.

The exercise report will detail the implementation of the trial, result of stability and homogeneity test of the samples and the statistic analysis of the data:

- Mean and median of observed concentration among the participants
- Standard deviations, variance, variation coefficient by comparison with the true values
- Upper and warning limit
- z and zeta score