



ECO-PHARMACO- STEWARDSHIP (EPS)

**PILLAR 2 - MANUFACTURING:
EFFLUENT MANAGEMENT
(ABSTRACT)**



A Risk Based Tool to Manage Active Pharmaceutical Ingredients in Manufacturing Effluent

The article “A Risk Based Tool to Manage Active Pharmaceutical Ingredients in Manufacturing Effluent” has been submitted and accepted-to-be-published with revisions in the journal “Environmental Toxicology & Chemistry”.

ABSTRACT

This publication describes guidance intended to assist pharmaceutical manufacturers in assessing, mitigating and managing the potential environmental impacts of active pharmaceutical ingredients (APIs) in wastewater from manufacturing operations, including those from external suppliers. The tools in this publication are not a substitute for compliance with local regulatory requirements, but rather are intended to help manufacturers achieve the general standard of “no discharge of APIs in toxic amounts.” The approaches detailed herein identify practices for assessing potential environmental risks from APIs in manufacturing effluent and outline measures that can be used to reduce the risk including selective application of available treatment technologies. These measures are either commonly employed within the industry or have been implemented to a more limited extent based on local circumstances. Much of the material is based on company experience and case studies discussed at an industry workshop held on this topic; as such, much of the text of this manuscript does not cite published literature.



AESGP, the Association of the European Self-Medication Industry, is the representation of manufacturers of non-prescription medicines, food supplements and self-care medical devices in Europe. It is composed of national associations and the main multinational companies manufacturing self-care products. AESGP is the voice of more than 2,000 companies operating in the consumer healthcare sector in Europe, affiliated with AESGP directly or indirectly through the national associations.

www.aesgp.eu



European Federation of Pharmaceutical
Industries and Associations

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. Through its direct membership of 33 national associations and 40 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 1,900 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world.

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Medicines for Europe represents the generic, biosimilar and value added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members employ 160,000 people at over 350 manufacturing and R&D sites in Europe, and invest up to 17% of their turnover in medical innovation. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients.

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