



Derivation of Safe Exposure levels

Establishing permitted daily exposure levels for active pharmaceutical ingredients

When manufacturing medicinal products in shared facilities, cross-contamination is an important consideration. Derivation of safe exposure levels is a mandatory requirement, as per the European Medicines Agency (EMA) guideline released in November 2014, which applies to all medicinal products being introduced into shared manufacturing facilities.

In order to determine safe levels of one medicinal product in another, Permitted Daily Exposure (PDE) values are calculated in accordance with the latest EMA guidelines and Good Manufacturing Practices (GMP). PDE derivation is based on a structured, scientific evaluation and interpretation of available pharmacological (including efficacy), toxicological and clinical data.

We work closely with our clients to:

- Identify their medicinal products for which PDE levels are needed
- Define a strategy of PDE derivation for relevant routes – in accordance with applicable guidelines and client requirements – and collect all necessary data
- Determine the Point of Departure (PoD) to be used for PDE calculation(s)
- Compile the results in a detailed report

Our consultants have significant experience with a number of medicinal products – including different modes of action – and writing reports in line with the EMA guideline. They are well versed in preparing assessment reports based on scientific rationale to support the safety and risks for extractable/leachable compounds, impurities and other substances found in medicines.

About Us

Toxicologists with a Business Mind

ToxMinds BVBA is a product safety and regulatory affairs firm located in Brussels, Belgium. Our passion and motivation is the use of good science, but we also understand the reality of our tightly regulated chemicals world. With our broad industry experience, we support our customers in bringing safe, regulatory compliant and publicly acceptable products to the market.

We provide chemical safety, regulatory and product stewardship support to the following industries:

Industrial
Chemicals



Cosmetic &
Consumer Products



Biocides



Agrochemicals



Green
Biotechnology



Thanks to the international nature of our team we interact with our clients in various languages including English, German, French, Italian, Spanish, Portuguese or Hindi.



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