Does the EDQM provide the quantitative composition of Ph. Eur. reference standards?

Answer:

The majority of Ph. Eur. reference standards are pure substances dispatched in small-volume containers. They are for use in control laboratories only.

Some mixtures are also sold by the EDQM. These are identified, for example, as ‘for system suitability’ or ‘for peak identification’. They are usually active substances mixed with impurities potentially present in medicinal products on the market. The concentration of the impurities is too low to be considered hazardous to occupational health when used for the intended purpose. Therefore, the EDQM assesses the risk based on the main substance and does not provide the quantitative compositions of mixtures on the SDS.

Downstream users are responsible for managing the risks arising from their own uses of the substances.