



QUALITY CONTROL FOR THE PHARMACEUTICAL INDUSTRY

Quality control of pharmaceutical products is an important matter for industrials and testing laboratories. The evaluation of the analytical performance of laboratories is essential to ensure the accuracy of the analytical results. Laboratories' participation in proficiency tests allows these performances to be evaluated.

Created in 1970, BIPEA is a scientific and independent non-profit organization providing Proficiency Testing programs and Reference Materials in the fields of food, feed, environment, cosmetics, pharmaceuticals and hygiene.

BIPEA is ISO 17043 accredited (scope 1-1495 available in www.cofrac.fr), ISO 9001 certified and gathers more than 2500 testing laboratories, in 120 countries.

In the field of pharmaceuticals, BIPEA offers 3 proficiency tests:

- PT 104 "[Microbiology of pharmaceutical process water](#)" : enumeration of total viable aerobic germs .
- PT 97 "[Purified water for pharmaceutical applications](#)" : Endotoxins & TOC are offered for analysis on a purified water sample.
- PT 98 « [Residual solvents in excipients](#) » : Ethylene oxide and Dioxane on a Polyethylene glycol sample are offered for analysis.

These three programs are designed according to the pharmacopoeia requirements (European, American, Japanese pharmacopoeia, or any other pharmacopoeia).

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