

What measures do I need to take before using an analytical procedure that is given in Ph. Eur. monographs?



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Answer:

As indicated in the *General Notices*, the analytical procedures given in monographs have been validated in accordance with accepted scientific practice and recommendations on analytical validation. Unless otherwise stated in the monograph, users are not required to validate these procedures.

When implementing a Ph. Eur. analytical procedure, users must assess whether and to what extent its suitability under the actual conditions of use needs to be demonstrated according to relevant monographs, general chapters and quality systems.

In this context, general chapter 5.26. *Implementation of pharmacopoeial procedures* is published for information. It provides guidance on setting up an approach for the implementation of analytical procedures given in Ph. Eur. monographs. The approach set out in the general chapter is valid only when used in accordance with the principles laid down in the *General Notices* (including a suitable quality system).

Approaches other than the one described in general chapter 5.26 may also be appropriate to ensure successful implementation. Users are ultimately responsible for the implementation process and its successful outcome needs to be demonstrated and documented to the satisfaction of the competent authority.