

Can I use a reagent or analytical procedure other than the one published in the Ph. Eur.?



You are here:

[EDQM FAQs](#) / [EDQM FAQs in English](#) / [EUROPEAN PHARMACOPOEIA & INTERNATIONAL HARMONISATION](#) / [General Chapters and Monographs](#) / [COMPLIANCE WITH A MONOGRAPH](#) / Can I use a reagent or analytical procedure other than the one published in the Ph. Eur.?

Answer:

This question is addressed in the Ph. Eur. *General Notices*. The tests and assays described are the official analytical procedures upon which the standards of the Ph. Eur. are based. With the agreement of the competent authority, alternative analytical procedures may be used for control purposes, provided that they enable an unequivocal decision to be made as to whether compliance with the standards of the monographs would be achieved if the official procedures were used (cross-validation). In the event of doubt or dispute, the analytical procedures of the Ph. Eur. are alone authoritative. It is not the role of the EDQM to approve alternative procedures or reagents.