

Certification of Substances Division

Title:	Cases of falsification of data in the context of the CEP procedure
Reference Document:	PA/PH/CEP (12) 11 EN

In the framework of the EDQM inspection programme for companies who have requested or are holders of a Certificate of Suitability to the European Pharmacopoeia monographs (CEP), inspectors have come across several cases where data had been falsified, in some cases extensively and even systematically. The falsifications consisted of deliberately altering or creating data; be it in the CEP application, in batch records or any other records in order to hide a gap in information between the records and the true state of affairs.

In case of critical/major deficiencies in GMP or in CEP dossiers, the Certification Ad Hoc Committee usually decides to temporarily suspend CEP(s). However, in such particularly serious cases, the Ad Hoc Committee has decided to immediately withdraw the CEP(s) concerned. To date, four companies have been the subject of such decisions.