Should all tests referred to in a CEP be performed for routine analysis/batch release?



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Answer:

It is not necessarily the case that all tests described in a monograph or a CEP must be performed before a product is released. However, CEP applicants and holders are reminded that in the event of doubt or dispute, the requirements of European Pharmacopoeia, chapter 1. General Notices (1.1. General Statements), which also apply to any additional test(s) included in a CEP, are alone authoritative.