

# Application dossier

- Are alternative methods accepted?
- Can some tests be omitted?
- Should all tests referred to in a CEP be performed for routine analysis/batch release?
- Is a certificate of suitability equivalent to a certificate of analysis?
- How should I deal with different grades of the same substance?
- How should I deal with recovery of materials in a dossier?
- Does skip testing need to be declared in CEP application dossier?
- What should we do if we manufacture an active substance using a fermentation process that uses materials of fish origin, including peptones?
- What should we do if we manufacture an active substance using a fermentation process that uses peptones that are not of fish origin?
- What should we do if we manufacture an active substance that does not use a fermentation process but does use a material of fish origin?
- Is it possible to apply for a Chemical CEP with reference to a specific polymorphic form when no statement on polymorphism is included in the corresponding individual Ph. Eur. monograph?