

Does the Certification procedure apply to herbal drugs and herbal drug preparations?



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Answer:

The Certification procedure also applies to herbal drugs and herbal drug preparations covered by a Ph. Eur. monograph. The information to be submitted for applying for a certificate of suitability is described in the document [Content of the dossier for herbal drugs and herbal drug preparations quality evaluation \(PA/PH/CEP \(02\) 6\)](#), which should be read in conjunction with the current versions of the EMA Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products (CPMP/QWP/2820/00 Rev. 2) and the EMA Guideline on quality of herbal medicinal products/traditional herbal medicinal products (CPMP/QWP/2819/00).

For more information, see [How to read a CEP \(PA/PH/CEP \(15\) 31\)](#).