

IMPLEMENTATION OF GENERAL CHAPTER 2.2.46 FOR IN-HOUSE PROCEDURES



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When using an in-house analytical procedure, i.e. a non-pharmacopoeial analytical procedure, general chapter 2.2.46 is not mandatory.

Any reference to and/or application of general chapter 2.2.46 for quality control of substances or medicinal products using chromatographic procedures not described in relevant Ph. Eur. monographs is subject to approval by the competent authority as part of the assessment of a marketing authorisation application.