Can some tests be omitted?



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Answer:

When it can be demonstrated that a test specified in the monograph of the Ph. Eur. is not necessary for a named compound because the impurity/solvent /compound cannot be present with the route of synthesis or is not used, the certificate may mention the omission of the test for the routine control of the named compound, provided that the justification for the omission is suitably explained and demonstrated in the dossier.

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