

How should I deal with different grades of the same substance?



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Answer:

When more than one grade is produced, the manufacturer may select from one of the following options regarding physical characteristics (e.g. monograph does not restrict the substance to one polymorphic form):

-Apply for a single certificate: in this case, the dossier shall demonstrate that the specifications and the impurity profile are the same for each grade and shall include a detailed description of the steps of the process to obtain each grade and a batch analysis for each of them.

- Apply for separate certificates: in this case, individual dossiers shall be submitted for each grade.

In all cases, the certificate will indicate the specific grade(s) in a subtitle as well as any relevant additional specification (e.g. limit and test for controlling polymorphic purity).

Separate certificates will be issued if the difference in grades implies a difference in impurity profile, a difference in tests and/or limits for impurities (e.g. if different solvents are used or if the specifications are different for impurity limit(s)).

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