

How can I get confirmation that a specific grade (e.g. micronised, milled, etc.) described in my CEP dossier is approved by the EDQM?



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Answer:

If a specific grade is requested by an applicant and this is subsequently approved by the EDQM, it will be listed as a subtitle on the CEP and the corresponding quality information related to the grade claimed will be included in the approved specification (section 3.2.S.4.1) which is mentioned on the CEP 2.0.

Any information relating to a grade that has not been claimed or that has been claimed but not approved should be deleted from the CEP dossier and the corresponding specification should not be included in section 3.2.S.4.1.