

Which countries accept certificates of suitability?



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Answer:

Certificates of suitability (CEPs) are accepted in all EU member states and in signatories to the Convention on the elaboration of a European Pharmacopoeia (including the United Kingdom but not including Ukraine). Some non-EU states may have additional requirements. A current list of the Ph. Eur. members is available on the [EDQM website](#). CEPs may be accepted in other countries (outside the EU or Ph. Eur. members) at the discretion of the authorities in those countries. In such cases, the competent authorities will decide on the scope of the acceptance of CEPs and the conditions they may apply to them. For example, in addition to the CEP, there may be a requirement to provide a Drug Master File (open part or full content) or other supporting documents. It is therefore important to check the acceptability and conditions associated with the use of a CEP in these countries in advance. We recommend that you contact the competent authority in the relevant country for details of their requirements, as these could change without prior notice.

Based on information received from regulatory authorities and trade associations, the following countries accept CEPs, some with conditions:

Albania, Algeria, Australia, Azerbaijan, Canada, Georgia, Ghana Israel, Kyrgyzstan, Malaysia, Moldova, Morocco, New Zealand, Saudi Arabia, Singapore, South Africa, Tunisia, and Uzbekistan.

CEPs are also accepted (with conditions) by the Taiwan Food and Drug Administration.

Please note that this is not an exhaustive list.