The procedure for the Certification of Suitability to the European Pharmacopoeia (CEP)

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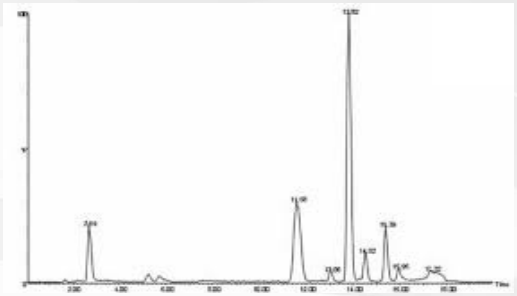
Legal basis

- In Europe, all medicinal products need a marketing authorisation granted by licensing authorities of the respective countries
- Based on a marketing application demonstrating the quality, safety and efficacy of the medicinal product
- The quality of an active substance is « approved » via the medicinal product in which it is contained

Legal basis (2)

- For an active substance, the pharmaceutical company shall demonstrate:
  - compliance of the substance with the corresponding Ph. Eur. monograph
  - that the quality of the substance is suitably controlled by the monograph



Legal basis (3): GMP

- Active substances used in medicines in EU have to be manufactured under Good Manufacturing Practices (GMP)
- Pharmaceutical companies are responsible for ensuring this ⟶ they have to ensure audits of their suppliers
- The authorities inspect the sites that are identified « at risk »

The CEP procedure

is a way to demonstrate suitability of monographs

A 2-tiered approach:

- Evaluation of dossiers
- Inspection of manufacturing sites


Certificate of suitability
No. Reference CEP

The Certification procedure

- Assessment of the quality of pharmaceutical substances
- Centralised at the EDQM
- An official certificate (CEP) is granted
  - The procedure is optional
  - Open to manufacturers regardless of where they are located
  - Recognised by authorities in Europe and beyond

Evaluation of dossiers

- Technical dossier sent by the manufacturer of a pharmaceutical substance
- Review of the dossier
  - With the participation of quality assessors from authorities in Ph. Eur member states
- If the evaluation is positive, a CEP is granted
- The CEP is then introduced into the Marketing Application for the medicinal product
  - Replaces information on the quality of the substance and facilitates marketing authorisations for Authorities and for Industry

EDQM Inspection programme

- The CEP procedure includes an inspection programme for companies having a CEP
- Risk-based selection of sites to be inspected
  - Inspections carried out with official inspectors from European member states
- Programme focussed on Asia (reflects distribution of CEP holders)

Inspection programme (2)

- Inspection results:
  - Positive: official GMP certificate is granted
  - Negative: European “Statement of non-compliance”, suspension/withdrawal of the CEP; the authorities in Europe, international partners and the public are informed
- Information sharing with authorities worldwide

Certification- Key figures

- More than 5800 CEP applications received for >850 different substances
- Currently more than 3800 valid CEPs (list available in the public database www.edqm.eu)
- More than 1000 manufacturers from 50 different countries
- >275 sites inspected, in 26 countries

Thank you for your attention

European Directorate for the Quality of Medicines and Healthcare (EDQM)

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