
Certification of Substances Department

Certificate of suitability

No.

Name of the substance:

Name of holder:

Site(s) of production:
SEE ANNEX 1

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site(s) of production listed in annex, we certify that the quality of the substance is suitably controlled by the current version of the monograph no. 693 of the European Pharmacopoeia, current edition supplements, only if it is supplemented by the test(s) mentioned below, procedure(s) given in annex.

Test for residual solvents by gas chromatog

Methanol

FACT SHEET
Certification of Suitability

European Directorate for the Quality of Medicines & HealthCare

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
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The Certification procedure

The Certification procedure is the process by which manufacturers of pharmaceutical substances which are covered by a monograph may obtain a Certificate of suitability to the monographs of the European Pharmacopoeia (CEP). Using CEPs, manufacturers can demonstrate that the quality of a substance is suitably controlled by the respective monograph of the European Pharmacopoeia (Ph. Eur.) and is in compliance with current regulatory requirements. This procedure provides a centralised evaluation of the documentation describing the manufacture and control of the pharmaceutical substance, and the certificate granted may be used in many countries. Two alternative procedures exist in Europe, according to which the same data can be filed either in an Active Substance Master File (ASMF), to be submitted to each national competent authority (NCA), or in the relevant part of the quality dossier of a marketing authorisation application (MAA).

How is a CEP granted?

To obtain a CEP for a pharmaceutical substance, a manufacturer of the substance submits an application to the European Directorate for the Quality of Medicines & HealthCare (EDQM) describing the manufacturing process for the substance in question and the quality control methods applied, including for the determination of impurities. A network of experienced quality assessors nominated by NCAs and the EDQM then assesses the data provided. The EDQM grants a CEP when the assessors' conclusion is positive. A CEP can then be introduced in any MAA for a medicinal product in which the substance from this specific source is included.

Who accepts CEPs?

CEPs – which are referred to in European Union (EU) pharmaceutical legislation – are recognised by the European Pharmacopoeia member states and by a number of other countries, such as Australia, Canada, New Zealand, Saudi Arabia, Singapore and South Africa, and regulatory organisations, including the Taiwan FDA and the World Health Organization. An increasing number of licensing authorities worldwide accept CEPs to support (fully or partially) the data related to the quality of active substances used in medicinal products.

Added benefits of the Certification procedure

The CEP procedure centralises the evaluation of the quality of pharmaceutical substances for the benefit of regulatory authorities and industry alike, thus saving time and resources and ensuring harmonisation in the assessment of data. This also means that information on the quality of the substances on the European market can be used to identify which monographs may require revision at any given time, ensuring that the Ph. Eur. is kept up to date.

The inspection programme

Inspections ensure that GMP (Good Manufacturing Practice) is applied and that the information supplied in the CEP application is accurate. The EDQM inspection programme is an integral part of the Certification procedure. It is carried out under the mandate given to the EDQM by the European Commission in application of Directives 2001/83/EC and 2001/82/EC, which set out the EU code relating to medicinal products for human and veterinary use, respectively.

Certain manufacturing and/or distribution sites of active substances covered by CEPs are scheduled for inspection on the basis of a risk assessment. The inspection programme is drawn up by the EDQM and is adopted by the Certification Steering Committee. Inspections are jointly carried out by GMP inspectors from the competent authorities in the European Economic Area (EEA)[1] or in countries which have a mutual recognition agreement (MRA) with the EU in the GMP sector and by EDQM inspectors having the same qualifications.

The EDQM carries out on-site inspections mainly in Asia, reflecting the current production of substances for pharmaceutical use. In addition, the EDQM obtains information on GMP compliance of manufacturing sites from competent authorities from international partners. Since 2022 the EDQM has implemented a complementary tool called RTEMIS (Real-Time Remote Inspections) to evaluate a company's GMP compliance. This new type of inspection involves a distant assessment comprising full and live interactions with the inspected company.

1. The European Economic Area is an economic union consisting of 30 European states: the 27 member states of the European Union and three of the four member states of the European Free Trade Association (EFTA): Iceland, Liechtenstein and Norway.