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

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

## Reference Standards & Logistics Department

# ORIGIN OF GOODS

### URSODEOXYCHOLIC ACID FOR SYSTEM SUITABILITY CRS

The **European Pharmacopoeia** (being elaborated by the Council of Europe – European Directorate for the Quality of Medicines & HealthCare or EDQM) is a single reference work for the **quality control of medicines** in the signatory states of the Convention on its elaboration.

The official standards published within provide a legal and scientific basis for quality control during the development, production and marketing processes.

They concern the qualitative and quantitative tests and assays to be carried out on medicines and/or on the raw materials used in production of medicines. All producers of medicines and/or substances for pharmaceutical use must therefore apply these quality standards in order to market their products in the signatory states of the Convention.

To apply these tests and assays, users must use these official reference standards.

Data received with the substance indicates the following:

| Code catalogue | Batch number | Material origin | Country of non-preferential origin for components |
|---|---|---|---|
| Y0001163 | 6 | Synthetic | France |

**Information applies to batch number and sub-batches.*

- The material is not of animal origin;
- The material is chemically synthesized;
- The above material does not contain any animal, microorganism or cell culture product;
- The above material was not derived from and was not exposed to any animal, microorganism or cell culture product at any step in the production process;
- The goods are in quantities of no greater than 20mL or 20g for each individually packaged unit.

**EDQM Reference Standards are supplied for laboratory test and assay only as described in the European Pharmacopoeia.**

**They are <u>not</u> intended for use in humans or animals as drugs, medical devices, dietary supplement or food.**

The goods transported shall be considered of "diplomatic origin" with special status and the Council of Europe EDQM shall be considered as manufacturer of these goods, although its components may originate from different countries in the world.
The Council of Europe cannot provide the Certificate EUR1 / movement certificate / certificate of origin. The special status of the transferred goods does not prevent the customs authority from granting the importer a release only after it has itself settled and paid the duties and taxes.

In case of question, please contact the EDQM via its HelpDesk available from its website at www.edqm.eu.

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