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

Molgramostim 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.

Code catalogue	Batch number	Material origin	Country of non-preferential origin for components
Y0000251	2	Molgramostim CRS is produced by a recombinant DNA technology (*E coli Rosetta 2 (DE3) Novagen 71397-3*), method using *GM-GSF gene from human colon cDNA expressing molgramostim with amino acid sequence as described in Ph. Eur. 1641.*	Argentina

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

- The material will be used only *in vitro*;
- The material is produced by recombinant DNA technology and vector is not considered pathogenic for livestock or avian species;
- The goods are in quantities of no greater than 20mL or 20g for each individually packaged unit;
- The organism does not contain genes or express antigens of livestock or poultry disease agents;
- The preparation does contain animal derived additives: *Bovine milk derived components from New Zealand and/or Australia.*

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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