

DIVISION OF REFERENCE STANDARDS & SAMPLES (DRS)

ORIGIN OF GOODS

Somatropin/desamidosomatropin resolution mixture

The European Pharmacopoeia is the official intergovernmental body responsible for establishment of quality standards for medicines in Europe. Compliance with the standards is mandatory for any medicine to be sold in Europe. In many cases, to test compliance, pharmaceutical manufacturers have to use a reference substance.

All substances supplied by the European Directorate for the Quality of Medicines are supplied exclusively as European Pharmacopoeia Reference for use as standards or reference materials in tests and assays carried out in accordance with the official methods of the European Pharmacopoeia and **for no other purpose**.

Purpose of Material: this shipment contains drug samples for investigational use only and is intended for laboratory testing only.

NOT FOR FOOD

NOT FOR HUMAN CONSUMPTION

FOR LABORATORY USE ONLY

I give you the origin for the following substance:

Code catalogue	Batch number	Origin
Y0000711	2	Somatropin / desamidosomatropin resolution mixture is produced by a recombinant DNA technology (<i>E. coli</i>) method using an insert containing the human growth hormone gene sequence

- The material is produced by recombinant DNA technology and vector is not considered pathogenic for livestock or avian species;
- The organism does not contain genes or express antigens of livestock or poultry disease agents.
- The preparation does not contain any animal derived additives, such as albumin.

Best regards,

Dr. Fanny MOUTIER-GAME
Head of Dispatching Section
Division of Reference Standards and Samples

