

DIVISION OF REFERENCE STANDARDS & SAMPLES (DRS)

ORIGIN OF GOODS

Gadobutrol monohydrate CRS

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 solely for laboratory testing in vitro.

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
Y0001803	2	Synthetic

- The material is not of animal origin;
- The material is for in vitro use only;
- The material does not come from a facility where work with exotic viruses affecting livestock and avian species is conducted;
- The material does not produce antigens or contain genes of livestock or avian disease agents or does not produce monoclonal antibodies directed against livestock or avian disease agents;
- The above materials do not contain any animal or cell culture derived products or additives such as albumin or serum.

Best regards,

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

