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:

<table>
<thead>
<tr>
<th>Code catalogue</th>
<th>Batch number</th>
<th>Origin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y0001542</td>
<td>5</td>
<td>Insulin glargine is produced by a recombinant DNA technology (E. coli), method using a human insulin gene sequence modified by inserting Glycine to position A21 in the A-chain and inserting Arginine to positions B31 and B32 of the B-chain.</td>
</tr>
</tbody>
</table>

- The material is not of animal origin;
- 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 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