European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

To the Customs authorities

All chemical substances or biological preparations supplied by the European Directorate for the Quality of Medicines & Healthcare 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.

Since CRS (Chemical Reference Standard) and BRP (Biological Reference Preparation) are officially certified by the European Pharmacopoeia Commission, which adopts the reports establishing their suitability to the intended use, it should be noted that no certificates of analysis are provided with the reference products or substances.

In the same way, no expiry date is indicated because the reference standards comply with the requirements of the corresponding monographs and are monitored regularly. The "information" column of the catalogue indicates an official date on which the batch is no longer valid as a CRS/BRP for all batches that have been just replaced. Hence "batch 1 valid until 30 June 2007" means that batch 1 is no longer official as of 1 July 2007.

The specificity of pharmacopoeial reference standards has been officially recognised by ISO (ISO Guide 34 *General requirements for the competence of reference material producers* and ISO Guide 35 *Reference materials - General and statistical principles for certification*): pharmacopoeial reference standards are established by pharmacopoeial authorities following the general principles of the ISO guides but a different approach is used when giving the user information usually provided by the certificate of analysis and expiration date; the uncertainty of any assigned value is not given since allowance is made for this in the limits and tolerances in the official test requirements for which they are used.

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