Department of Reference Standards & Logistics (DRSL)

Statement replacing a Certificate of Analysis (CoA) & Expiry date

To those concerned

Reference Standards supplied by the European Directorate for the Quality of Medicines & Healthcare (EDQM) are supplied exclusively as European Pharmacopoeia Reference Standards for use as official 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.

Additional information may be found in chapter 5.12 “Reference Standards” of the European Pharmacopeia.

Since the European Pharmacopoeia Commission, which adopts the reports establishing their suitability to the intended use, officially certifies CRS (Chemical Reference Standard), BRP (Biological Reference Preparation) and BRR (Biological Reference reagent), it should be noted that **no certificates of analysis (CoA) are provided**.
Information required to use the standard is provided in a document called “Information Leaflet” that is available from our online catalogue.

In the same way, no re-test or expiry date is given since the re-test programme monitors continued fitness for use. A batch validity statement (BVS) for each European Pharmacopoeia reference standard is available from the European Pharmacopoeia reference standards catalogue.
The "additional information" column of the catalogue indicates an official date on which the batch is no longer valid as a CRS/BRP for all batches that have been replaced.
Hence "batch 1 valid until 30 June 2021" means that batch 1 is no longer official as of 1 July 2021.

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