EDQM reference standards monthly newsletter – October 2025

2 new Ph. Eur. reference standards and 10 replacement batches released in October 2025

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New and replacement batches of Ph. Eur. reference standards

The European Directorate for the Quality of Medicines & HealthCare (EDQM) announces the release of:

- 2 new European Pharmacopoeia (Ph. Eur.) reference standards:

Catalogue code	Name	Unit quantity	Price
Y0002527	CEDARWOOD OIL FOR SYSTEM SUITABILITY HRS	300 µL	79 EUR
Y0002540	TESTOSTERONE ENANTATE FOR SYSTEM SUITABILITY A CRS	0.04 MG	79 EUR

- 10 replacement batches for Ph. Eur. reference standards:

Catalogue code	Name	Batch	Unit quantity	Price
T0800000	THEOPHYLLINE CRS	2	210 MG	79 EUR
Y0001711	FLUOCINOLONE ACETONIDE FOR PEAK IDENTIFICATION CRS	2	15 MG	79 EUR
Y0000241	CLOBAZAM IMPURITY A CRS	2	15 MG	79 EUR
Y0001403	VIGABATRIN IMPURITY E CRS	2	10 MG	79 EUR
Y0002292	CICLOSPORIN FOR SYSTEM SUITABILITY A CRS	2	1 MG	79 EUR
Y0001689	IMMUNOGLOBULIN (ANTI-A, ANTI-B ANTIBODIES TEST NEGATIVE CONTROL) BRP	2	46 MG	200 EUR
Y0001370	OLANZAPINE CRS	3	200 MG	79 EUR
Y0000238	PERINDOPRIL TERT-BUTYLAMINE CRS	4	40 MG	79 EUR
Y0001722	ROSUVASTATIN IMPURITY G CRS	6	0.004 MG	79 EUR
F0450000	FRAMYCETIN SULFATE CRS	9	26.97 MG	79 EUR

Information on reference standards removed from catalogue

Issue 11.8

Following the implementation of Issue 11.8, the following standards were officially withdrawn (or replaced) on 1 July 2025.

Catalogue code	Name	Comments
F0188500	FLUMETASONE PIVALATE	These standards will nevertheless remain available for sale, subject to

Catalogue code	Name	Comments
Y0000372	THIAMAZOLE IMPURITY A	sufficient stock, until 1 January 2026. Likewise, they will remain in the catalogue for a period of 12 months (i.e. until 1 July 2026) to allow users to print the batch validity statement (BVS). See "Change in the policy for withdrawing reference standards from sale" for more details.

Information on reference standards with a future removal from catalogue

Issue 12.1

Following the implementation of Issue 12.1, the following standards will be officially withdrawn (or replaced) from 1 January 2026.

Catalogue code	Name	Comments
D0738000	DEXTRAN 40 FOR PERFORMANCE TEST CRS remplaced by DEXTRAN 40 FOR SYSTEM SUITABILITY	These standards will nevertheless remain available for sale, subject to sufficient stock, until 1 July 2026. Likewise, they will remain in the catalogue for a period of 12 months (i.e. until 1 January 2027) to allow users to print the batch validity statement (BVS). See "Change in the policy for withdrawing reference standards from sale" for more details.
D0739000	DEXTRAN 60/70 FOR PERFORMANCE TEST CRS remplaced by DEXTRAN 60/70 FOR SYSTEM SUITABILITY	
Y0002249	FLUTICASONE PROPIONATE FOR SYSTEM SUITABILITY CRS replaced by FLUTICASONE PROPIONATE FOR SYSTEM SUITABILITY A CRS	

Change of sales units

- None.

Information on change of amount per unit

- None.

Information on change of price

As of 1 January 2026, the prices of EDQM reference standards will increase. We have not taken this decision lightly and would like to explain the reasons behind this change.

In recent years, the costs associated with producing and delivering reference standards have risen significantly. These include:

- transportation – the global rise in fuel prices, combined with other logistical challenges, has substantially increased our shipping and handling expenses;
- materials – the cost of the raw materials required to produce reference standards has risen steadily;
- equipment – advances in technology and the need for state-of-the-art equipment to ensure the highest quality standards have led to higher capital expenditures;
- energy – the increase in energy prices has impacted our operational costs across all stages of production.

Despite these obvious challenges, we have strived to absorb the rising costs. However, to continue providing the high-quality reference standards that you rely on, it has become necessary to adjust our prices.

Starting on 1 January 2026, the new reference standard prices will be as follows:

Current price	Price as of 1 January 2026
€79	**€90**
€90	**€110**
Other prices remain unchanged.	

We understand that price increases can be challenging, and our team is on hand to answer any questions you may have and to provide any support you may need.

Thank you for your understanding and your continued trust in the EDQM. We remain dedicated to supporting your work and to advancing the quality of medicines and healthcare worldwide.

Information on change of EDQM storage/shipping conditions

Based on new stability information, storage and shipping conditions has been changed on 10 August 2025 for the following reference standard:

- BETACAROTENE FOR SYSTEM SUITABILITY CRS (Y0002073) batch 2 is stored at + 5°C (previously -20°C) and shipped at ambient temperature (previously -20°C)

Information on International Chemical Reference Substances (ICRS) and International Standards for Antibiotics (ISA)

ICRS

None

ISA

None

Gradual rollout of a new primary label for European Pharmacopoeia reference standards

We would like to inform you that the EDQM will gradually introduce a new primary label for European Pharmacopoeia reference standards.

This introduction will take place in several stages and will affect new reference standards (batch 1) placed on the market from the end of July 2025 onwards. It will then be gradually rolled out to all other reference standards during 2026.

This new label has been designed to meet the requirements of Regulation (EC) No 1272/2008 (CLP). It will allow additional information to be included, such as:

- the CAS number of the substance (if available),
- the chemical name,
- safety pictograms (if any).

Other key information will of course remain, but in a clearer and more harmonised visual format.

Standards labelled before this date will not be relabeled, so two labels' layouts will coexist for a certain period of time.

Our team remains at your disposal should you have any questions.

Content of the European Pharmacopoeia RS catalogue

The EDQM proposes more than 3 100 Ph. Eur. RS including a wide range of highly characterised chemical reference substances (CRS), herbal reference standards (HRS) and biological reference preparations (BRP), as well as reference spectra for the tests and assays to be carried out in accordance with the official methods prescribed in the Ph. Eur.

The Ph. Eur. RS catalogue is updated on a daily basis and gives access not only to all the Ph. Eur. RS, but also to:

- batch validity statements (BVSs) for each reference standard;
- Safety Data Sheets and Safety Data Statements for hazardous biologicals;
- leaflets (downloadable PDFs).

For your convenience, the Ph. Eur. RS catalogue is published daily and can be downloaded in in PDF format and in XML format.

When stocks of a given reference standard are low, the EDQM reserves the right to limit the quantities sold to each user to ensure that as many users as possible will receive at least some of the quantities available. Restrictions on quantities are applied at the time the purchase order is received.

Following a request from many users, the quantities allowed in case of sales restrictions now appear in the online catalogue as well as in the catalogue in XML format.

The EDQM is also responsible for the establishment, preparation, storage and distribution of WHO ICRSs and ISAs.

How to place an RS order

If you wish to place an order, you can send your request to the EDQM either:

- via the WebStore;
- or by e-mail to orders@edqm.eu (in this case, please ensure that your order, on your company letterhead, states both the catalogue code and substance name and is attached to your e-mail).

A video has been prepared to help users ordering through the RS WebStore.

Helping users test *Pharmeuropa* draft texts with "qualified samples"

In some cases, "qualified samples" are made available by the EDQM when a new issue of *Pharmeuropa* is released to allow users to check the changes (e.g. to the related substances test) proposed during the public enquiry and best prepare for the implementation of the monograph.

After use, users are kindly requested to share their results with the EDQM.

Where a qualified sample is available, it is described in the briefing note of the *Pharmeuropa* monograph and may be ordered free of charge by making a request via the EDQM HelpDesk.

To place an order via the EDQM HelpDesk, please select "European Pharmacopoeia" and choose the category "Question about General Chapters and Monographs". For rapid processing, please:

- provide your full shipping address;
- specify the title of the corresponding Ph. Eur. monograph;
- include "Qualified sample" in the subject of the query.

Consult the HelpDesk User Manual for more information on how to use the EDQM HelpDesk.