

EDQM reference standards monthly newsletter

- December 2025

*5 new Ph. Eur. reference standards and
16 replacement batches released in December 2025*



Contents

New and replacement batches of Ph. Eur. reference standards	2
Information on reference standards removed from catalogue	3
Information on reference standards with a future removal from catalogue	3
Change of sales units	4
Information on change of amount per unit	4
Information on change of price	4
Information on change of EDQM storage/shipping conditions	4
Information on International Chemical Reference Substances (ICRS) and International Standards for Antibiotics (ISA)	5

See also:

- [Content of the Ph. Eur. RS catalogue](#)
 - [How to place an RS order](#)
 - [Helping users test *Pharmeuropa* draft texts with "qualified samples"](#)
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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:

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

Catalogue code	Name	Unit quantity	Price
Y0002522	DICLOXA CILLIN IMPURITY D CRS	15 MG	79 EUR
Y0002544	ROPINIROLE FOR PEAK IDENTIFICATION 4 CRS	10 MG	79 EUR
Y0002516	DEXTRAN 40 FOR SYSTEM SUITABILITY CRS	50 MG	79 EUR
Y0002507	DEXTRAN 60/70 FOR SYSTEM SUITABILITY CRS	50 MG	79 EUR
Y0002422	CANNABIDIOL FOR CANNABIS CRS	50 MG	150 EUR

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

Catalogue code	Name	Batch	Unit quantity	Price
Y0001456	NITRENDIPINE FOR PEAK IDENTIFICATION CRS	2	10 MG	79 EUR
L0800000	LYNESTRENOL CRS	2	50 MG	79 EUR
Y0001931	QUERCITRIN CRS	2	15 MG	79 EUR
Y0001161	CARBASALATE IMPURITY B CRS	2	5 MG	79 EUR
Y0002285	CROSCARMELLOSE SODIUM CRS	2	20 MG	79 EUR
Y0000636	MODAFINIL FOR SYSTEM SUITABILITY CRS	2	0.1 MG	79 EUR
Y0000121	NAFTIDROFURYL IMPURITY B CRS	3	25 MG	79 EUR
Y0001253	LEVETIRACETAM CRS	4	120 MG	79 EUR
Y0001087	TETRA-O-ACETYL-MANNOSE TRIFLATE CRS	4	180 MG	79 EUR
Y0000758	CLOZAPINE FOR PEAK IDENTIFICATION CRS	4	0.41 MG	79 EUR
Y0001019	CISPLATIN IMPURITY B CRS	4	15 MG	79 EUR
E2499900	ETOENAMATE CRS	4	50 MG	79 EUR
Y0000383	ALL-RAC-ALPHA-TOCOPHEROL FOR PEAK IDENTIFICATION CRS	4	50 MG	79 EUR
P2152015	PIVMECILLINAM IMPURITY C CRS	4	20 MG	79 EUR
S0500000	SILICONE ELASTOMER CRS	5	2000 MG	79 EUR
C0225000	CALCITRIOL CRS	14	10 MG	1000 EUR

Information on reference standards removed from catalogue

Issue 12.1

Following the implementation of Issue 12.1, the following standards were officially withdrawn (or replaced) on 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	

Information on reference standards with a future removal from catalogue

Issue 12.2

Following the implementation of Issue 12.2, the following standards will be officially withdrawn (or replaced) from 1 April 2026.

Catalogue code	Name	Comments
Y0000069	METRONIDAZOLE BENZOATE - REFERENCE SPECTRUM replaced by METRONIDAZOLE BENZOATE CRS	These standards will nevertheless remain available for sale, subject to sufficient stock, until 1 October 2026. Likewise, they will remain in the catalogue for a period of 12 months (i.e. until 1 April 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.
Y0001470	BENZOIC ACID CRS	
Y0000475	CARBOPROST TROMETAMOL CRS replaced by CARBOPROST TROMETAMOL FOR ASSAY CRS and CARBOPROST FOR SYSTEM SUITABILITY CRS	

Change of sales units

- None.

Information on change of amount per unit

- None.

Information on change of price

The price of EDQM reference standards has increased since 1 January 2026. We did not take 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.

Since 1 January 2026, the new reference standard prices are as follows (corrigendum of 10 November 2025):

Former price	Price as of 1 January 2026
€79	€90
€90	€110
€100	€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

- None

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

ICRS

None

ISA

None

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 [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](#).