

EDQM reference standards monthly newsletter

- January 2026

*3 new Ph. Eur. reference standards and
17 replacement batches released in January 2026*



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See also:

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

New and replacement batches of Ph. Eur. reference standards

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

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

Catalogue code	Name	Unit quantity	Price
Y0002524	DODECYL GALLATE FOR ID AND ASSAY CRS	110 MG	90 EUR
Y0002543	1,4-BENZOQUINONE CRS	350 MG	90 EUR
Y0002546	SUCROSE FOR TOC TEST CRS	620 MG	90 EUR

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

Catalogue code	Name	Batch	Unit quantity	Price
Y0001643	CAPECITABINE IMPURITY A CRS	2	15 MG	90 EUR
Y0001587	ATOMOXETINE FOR IMPURITY A IDENTIFICATION CRS	2	10 MG	90 EUR
Y0000219	HUMAN ANTI-D IMMUNOGLOBULIN BRP	2	40 MG	110 EUR
Y0002299	NEBIVOLOL HYDROCHLORIDE CRS	2	35 MG	300 EUR
Y0002221	TICAGRELOR IMPURITY E CRS	2	15 MG	90 EUR
Y0000737	FLAVOXATE IMPURITY A CRS	3	15 MG	90 EUR
Y0000664	METHOTREXATE IMPURITY E CRS	3	15 MG	90 EUR
Y0001356	NICERGOLINE IMPURITY D CRS	3	20 MG	90 EUR
P2152000	PIVMECILLINAM HYDROCHLORIDE CRS	4	70 MG	90 EUR
D2953000	DITHRANOL CRS	4	55 MG	90 EUR
P0320000	PENICILLAMINE DISULFIDE CRS	4	100 MG	90 EUR
Y0001143	TERBINAFINE FOR SYSTEM SUITABILITY CRS	4	10 MG	90 EUR
Y0000546	THIOCTIC ACID CRS	4	110 MG	90 EUR
T2009000	TRILAURIN CRS	4	2520 MG	90 EUR
C0650000	CEFADROXIL CRS	5	150 MG	90 EUR
O0150000	OMEPRAZOLE CRS	6	50 MG	90 EUR
Y0001067	AMLODIPINE FOR PEAK IDENTIFICATION CRS	6	10 MG	90 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Following the implementation of Issue 12.1, the following standards were officially withdrawn (or replaced) on 1 January 2026.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	

Catalogue code	Name	Comments
P3100000	PROCAINE HYDROCHLORIDE CRS replaced by PROCAINE HYDROCHLORIDE FOR ID AND ASSAY CRS	

Issue 12.3

Following the implementation of **Issue 12.3**, the following standard will be officially withdrawn (or replaced) from **1 July 2026**.

Catalogue code	Name	Comments
Y0000143	MALIC ACID - REFERENCE SPECTRUM replaced by MALIC ACID CRS	This standard will nevertheless remain available for sale, subject to sufficient stock, until 1 January 2027 . Likewise, it will remain in the catalogue for a period of 12 months (i.e. until 1 July 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.

Additional withdrawn

The following standards will be officially withdrawn from **1 April 2026** with no availability for sale. Nevertheless, they will remain in the catalogue until **1 October 2026**.

Y0001623 HEPATITIS A VACCINE ELISA DETECTION ANTIBODIES SET – BRR

Y0001624 HEPATITIS A VIRUS COATING REAGENT FOR ELISA - BRR

Change of sales units

- None.

Information on change of amount per unit

- None.

Information on change of price

- None.

Information on change of EDQM storage/shipping conditions

Based on new stability information, storage and shipping conditions will be changed on **15 February 2026** for the following reference standard:

- CALCIUM FOLINATE FOR SYSTEM SUITABILITY A CRS (Y0002404) batch 1 remains stored at -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

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](#).