

EDQM reference standards monthly newsletter

- March 2026

*10 new Ph. Eur. reference standards and
17 replacement batches released in March 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:

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

Catalogue code	Name	Unit quantity	Price
Y0002528	CARBOPROST TROMETAMOL FOR ASSAY CRS	40 MG	300 EUR
Y0002575	HISTAMINE FOR SYSTEM SUITABILITY CRS	0.2 MG	110 EUR
Y0002580	LINAGLIPTIN IMPURITY F CRS	10 MG	300 EUR
Y0002572	LINAGLIPTIN IMPURITY I CRS	10 MG	300 EUR
Y0002567	LINAGLIPTIN IMPURITY A CRS	10 MG	300 EUR
Y0002568	LINAGLIPTIN IMPURITY B CRS	10 MG	300 EUR
Y0002570	LINAGLIPTIN IMPURITY G CRS	10 MG	300 EUR
Y0002571	LINAGLIPTIN IMPURITY L CRS	10 MG	300 EUR
Y0002566	LINAGLIPTIN IMPURITY J CRS	90 MG	90 EUR
Y0002590	WILD PANSY FOR SYSTEM SUITABILITY HRS	1.1 G	90 EUR

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

Catalogue code	Name	Batch	Unit quantity	Price
P3100000	PROCAINE HYDROCHLORIDE CRS	2	100 MG	90 EUR
Y0002191	VITEXIN-2"-O-RHAMNOSIDE CRS	2	10 MG	150 EUR
Y0001976	DEFERIPRONE CRS	2	120 MG	90 EUR
Y0002258	N-NITROSO-DIETHYLAMINE CRS	2	1 ML	90 EUR
Y0002159	RHEIN CRS	2	25 MG	90 EUR
Y0001316	TROPICAMIDE FOR PEAK IDENTIFICATION CRS	2	10 MG	90 EUR
B1168020	D-HIS-BUSERELIN CRS	3	0.5 MG	90 EUR
Y0000327	AZELASTINE IMPURITY B CRS	3	5 MG	90 EUR
P2155014	PLASTIC ADDITIVE 14 CRS	4	250 MG	90 EUR
Y0001459	TRIAMCINOLONE ACETONIDE FOR SYSTEM SUITABILITY CRS	5	10 MG	90 EUR
Y0002050	BETACAROTENE CRS	5	110 MG	90 EUR
C0688000	CEFOXITIN SODIUM CRS	6	100 MG	90 EUR
Y0001163	URSODEOXYCHOLIC ACID FOR SYSTEM SUITABILITY CRS	6	1.26 MG	90 EUR
Y0001635	DICLOFENAC FOR SYSTEM SUITABILITY CRS	7	1 MG	90 EUR
Y0001542	INSULIN GLARGINE CRS	7	15 MG	90 EUR
B1220000	IBUPROFEN IMPURITY B CRS	12	1.15 ML	90 EUR
Y0000641	AZITHROMYCIN FOR SYSTEM SUITABILITY CRS	14	0.05 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Following the implementation of **Issue 12.1**, the following standards were officially withdrawn (or replaced) on **1 January 2026**.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 replaced 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 replaced 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.

Change of sales units

- o None.

Information on change of amount per unit

- o None.

Information on change of price

- o None.

Information on change of EDQM storage/shipping conditions

Based on new stability information, storage and shipping conditions has been changed for **Batch 6** for the following reference standard:

- o CEFOXITIN SODIUM CRS (C0688000) **Batch 6** is stored at -20°C (previous batch was +5°C) and shipped at ambient temperature (same as previous batch).

Based on new stability information, storage and shipping conditions has been changed for **Batch 5** for the following reference standard:

- o BETACAROTENE CRS (Y0002050) **Batch 5** is stored at +5°C (previous batch was -20°C) and shipped at ambient temperature (previous batch was -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](#).