

EDQM reference standards monthly newsletter – July 2025

*6 new Ph. Eur. reference standards and
19 replacement batches released in July 2025*



Contents

New and replacement batches of Ph. Eur. reference standards	2
Distribution quota	3
Information on reference standards removed from catalogue	3
Information on reference standards with a future removal from catalogue	5
Change of sales units	5
Information on change of amount per unit	5
Information on change of price	6
Information on change of EDQM storage/shipping conditions.....	6
Information on International Chemical Reference Substances (ICRS) and International Standards for Antibiotics (ISA).....	6
Gradual rollout of a new primary label for European Pharmacopoeia reference standards	7

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:

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

Catalogue code	Name	Unit quantity	Price
Y0002528	CARBOPROST TROMETAMOL FOR ASSAY CRS	40 MG	300 EUR
Y0002518	EPIEDIUM LEAF FOR SYSTEM SUITABILITY CRS	520 MG	79 EUR
Y0002503	MONOCLONAL ANTIBODY FOR SYSTEM PERFORMANCE CRS	100 MG	79 EUR
Y0002537	FLUTICASON PROPRIONATE FOR SYSTEM SUITABILITY A CRS	0.2 MG	79 EUR
Y0002517	ICARIIN CRS	25 MG	79 EUR
Y0002519	PALONOSETRON IMPURITY A CRS	0.002 MG	100 EUR

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

Catalogue code	Name	Batch	Unit quantity	Price
Y0000842	ACEMETACIN IMPURITY MIXTURE CRS	2	0.06 MG	79 EUR
Y0002129	CHLORTALIDONE FOR SYSTEM SUITABILITY CRS	2	1.017 MG	79 EUR
Y0001782	DIENOGEST FOR SYSTEM SUITABILITY CRS	2	10 MG	79 EUR
Y0002073	BETACAROTENE FOR SYSTEM SUITABILITY CRS	2	10 MG	79 EUR
Y0001662	VALACICLOVIR IMPURITY P CRS	2	5 MG	79 EUR
Y0001195	STRYCHNINE CRS	2	30 MG	79 EUR
C2285000	CLOBETASONE BUTYRATE CRS	2	20 MG	79 EUR
Y0000350	OXELADIN HYDROGEN CITRATE CRS	2	40 MG	79 EUR
Y0002313	DOMPERIDONE IMPURITY MIXTURE CRS	3	0.04 MG	79 EUR
Y0001397	VORICONAZOLE IMPURITY E CRS	3	60 MG	79 EUR
Y0001085	LAMOTRIGINE FOR SYSTEM SUITABILITY CRS	3	10 MG	79 EUR
S1250000	STANZOLOL CRS	3	50 MG	79 EUR
Y0001984	CODEINE FOR SYSTEM SUITABILITY CRS - * NARC (CODEINE MONOHYDRATE, THEBAINE, NORCODEINE)	4	10 MG	79 EUR
Y0001436	MONTELUKAST DICYCLOHEXYLAMINE CRS	4	150 MG	79 EUR
T2500100	TRIMYRISTIN CRS	4	1000 MG	79 EUR
A0350000	ALLOPURINOL CRS	5	100 MG	79 EUR
Y0001422	VALPROIC ACID FOR SYSTEM SUITABILITY CRS	5	10 MG	79 EUR
C2170000	CILASTATIN SODIUM CRS	6	25 MG	79 EUR
D2975000	DOXORUBICIN HYDROCHLORIDE CRS	8	150 MG	79 EUR

Distribution quota

Information on distribution quota for IMMUNOGLOBULIN (ANTI-A, ANTI-B ANTIBODIES TEST NEGATIVE CONTROL) BRP (Y0001689)

Due to premature depletion of stocks of the IMMUNOGLOBULIN (ANTI-A, ANTI-B ANTIBODIES TEST NEGATIVE CONTROL) BRP (CAT. # Y0001689), we wish to inform users that a tight distribution quota has been established.

This BRP will be distributed to plasma-derived therapeutic product manufacturers and official medicines control laboratories only, with a maximum of 1 unit per quarter. This quota may be adjusted according to availability.

This exceptional measure will remain in place until the next batch of this BRP is established, which is expected by the end of the third quarter 2025.

Distribution of the IMMUNOGLOBULIN FOR ANTI-A, ANTI-B ANTIBODIES LIMIT TEST BRP (CAT. # Y0001153) and the IMMUNOGLOBULIN (ANTI-A, ANTI-B ANTIBODIES TEST POSITIVE CONTROL) BRP (CAT. # Y0001688) is not affected by this measure.

We apologise for any inconvenience caused and thank you for your understanding.

Information on reference standards removed from catalogue

Supplement 11.6

Following the implementation of **Supplement 11.6**, the following standards were officially withdrawn (or replaced) on **1 January 2025**.

Catalogue code	Name	Comments
Y0000289	POLYSORBATE 20 - REFERENCE SPECTRUM Will be replaced by a CRS	These standards will nevertheless remain available for sale, subject to sufficient stock, until 1 July 2025 . Likewise, they will remain in the catalogue for a period of 12 months (i.e. until 1 January 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.
Y0000290	POLYSORBATE 40 - REFERENCE SPECTRUM Will be replaced by a CRS	
Y0000291	POLYSORBATE 60 - REFERENCE SPECTRUM Will be replaced by a CRS	
P0309020	PEFLOXACIN IMPURITY B	
P0309030	PEFLOXACIN IMPURITY C	
N1230010	NORFLOXACIN IMPURITY A	
Y0002319	ATORVASTATIN FOR PEAK IDENTIFICATION A CRS	
Y0002327	CIPROFIBRATE FOR SYSTEM SUITABILITY A CRS will be replaced by CIPROFIBRATE FOR SYSTEM SUITABILITY B CRS (Y0002450)	

Catalogue code	Name	Comments
Y0002197	DEFERASIROX FOR SYSTEM SUITABILITY will be replaced by DEFERASIROX FOR SYSTEM SUITABILITY A (Y0002456)	
I0600000	ISOPRENALINE SULFATE	
P1255100	PHENYLMERCURIC BORATE - REFERENCE SPECTRUM	
Y0001463	ACTAEA RACEMOSA HRS	
Y0001958	COLCHICINE FOR SYSTEM SUITABILITY A will be replaced by COLCHICINE FOR SYSTEM SUITABILITY B (Y0002460)	

Supplement 11.7

Following the implementation of **Supplement 11.7**, the following standards were officially withdrawn (or replaced) on **1 April 2025**.

Catalogue code	Name	Comments
Y0000130	AMIODARONE IMPURITY E	These standards will nevertheless remain available for sale, subject to sufficient stock, until 1 October 2025 . Likewise, they will remain in the catalogue for a period of 12 months (i.e. until 1 April 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.
F0180000	FLUDROCORTISONE ACETATE will be replaced by FLUDROCORTISONE ACETATE FOR ID AND ASSAY	

Supplement 11.8

Following the implementation of **Supplement 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

Supplement 12.1

Following the implementation of **Supplement 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 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	

Change of sales units

- None.

Information on change of amount per unit

- OXELADIN HYDROGEN CITRATE CRS (Y0000350) **batch 2** contains 50 mg per unit (40 mg previously)
- CLOBETASONE BUTYRATE CRS (C2285000) **batch 2** contains 20 mg per unit (50 mg previously)
- STRYCHNINE CRS (Y0001195) **batch 2** contains 30 mg per unit (40 mg previously)
- VORICONAZOLE IMPURITY E CRS (Y0001397) **batch 3** contains 60 mg per unit (50 mg previously)
- GLUCOSAMINE HYDROCHLORIDE CRS (Y0001406) **batch 1.1** contains 20 mg per unit (15 mg previously)

- CHLORTALIDONE FOR SYSTEM SUITABILITY CRS (Y0002129) **batch 2** contains 1.017 mg per unit (1.02 mg previously)

Information on change of price

- None.

Information on change of EDQM storage/shipping conditions

Based on new stability information, storage and shipping conditions has been changed on **15 August 2025** for the following reference standard:

- LONICERA JAPONICA FLOWER FOR PEAK IDENTIFICATION HRS (Y0002396) **batch 1** is stored at +5°C (previously at ambient temperature) and remains shipped at ambient temperature.
- WHITE MULBERRY LEAF FOR SYSTEM SUITABILITY HRS (Y0002499) **batch 1** is stored at +5°C (previously at ambient temperature) and remains shipped at ambient temperature.
- AUSTRALIAN DODDER SEED FOR SYSTEM SUITABILITY HRS (Y0002480) **batch 1** is stored at +5°C (previously at ambient temperature) and remains shipped at ambient temperature.
- CALIFORNIA POPPY FOR PEAK IDENTIFICATION HRS (Y0002477) **batch 1** is stored at +5°C (previously at ambient temperature) and remains shipped at ambient temperature.
- CANNABIS FLOWER FOR SYSTEM SUITABILITY HRS - * NARC (Y0002440) **batch 1** is stored at +5°C (previously at ambient temperature) and remains shipped at ambient temperature.
- CHRYSANTHEMUM FLOWER FOR SYSTEM SUITABILITY HRS (Y0002395) **batch 1** is stored at +5°C (previously at ambient temperature) and remains shipped at ambient temperature.
- PULSATILLA ROOT FOR SYSTEM SUITABILITY HRS (Y0002345) **batch 1** is stored at +5°C (previously at ambient temperature) and remains shipped at ambient temperature.
- SAW PALMETTO EXTRACT HRS (Y0001483) **batch 2** is stored at +5°C (previously at ambient temperature) and remains shipped at ambient temperature.

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:

- o via the [WebStore](#);
- o 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:

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

Consult the [HelpDesk User Manual](#) for more information on how to use the EDQM [HelpDesk](#).