EDQM reference standards monthly newsletter – May 2025

2 new Ph. Eur. reference standards and 15 replacement batches released in May 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
Y0002510	L-MALIC ACID CRS	15 MG	79 EUR
Y0002514	PALONOSETRON FOR SYSTEM SUITABILITY CRS	15 MG	100 EUR

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

Catalogue code	Name	Batch	Unit quantity	Price
Y0001651	CILASTATIN FOR SYSTEM SUITABILITY 1 CRS	2	5 MG	79 EUR
Y0001690	TIMOLOL IMPURITY F CRS	2	15 MG	79 EUR
Y0001612	ESCULIN CRS	2	25 MG	79 EUR
Y0002274	FLUTICASONE FUROATE CRS	2	70 MG	79 EUR
Y0001903	PHOSPHATIDYLETHANOLAMINE FROM EGG YOLK CRS	2	200 MG	79 EUR
Y0000485	MYO-INOSITOL CRS	2	2020 MG	79 EUR
Y0000654	LEFLUNOMIDE CRS	2	100 MG	79 EUR
Y0000902	RACECADOTRIL FOR PEAK IDENTIFICATION CRS	3	5 MG	79 EUR
Y0001439	DILTIAZEM IMPURITY F CRS	3	15 MG	79 EUR
Y0001182	CAPTOPRIL FOR SYSTEM SUITABILITY CRS	3	20 MG	79 EUR
Y0001394	FUSIDIC ACID FOR PEAK IDENTIFICATION CRS	3	15 MG	79 EUR
S2190000	SULPIRIDE CRS	4	100 MG	79 EUR
C0682300	CEFAMANDOLE NAFATE CRS	4	125 MG	79 EUR
Y0002328	CHOLECALCIFEROL IMPURITY A CRS	4	0.06 MG	79 EUR
R0300000	RETINOL ACETATE CRS	8	500 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 second 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)	
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	

Catalogue code	Name	Comments
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 standard 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	

Information on reference standards with a future removal from catalogue

Supplement 11.8

Following the implementation of Supplement 11.8, the following standard will be officially withdrawn (or replaced) from 1 July 2025.

Catalogue code	Name	Comments
F0188500	FLUMETASONE PIVALATE	These standards will nevertheless remain available for sale, subject to 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.
Y0000372	THIAMAZOLE IMPURITY A	

Change of sales units

- None.

Information on change of amount per unit

- FUSIDIC ACID FOR PEAK IDENTIFICATION CRS (Y0001394) batch 3 contains 15 mg per unit (5 mg previously)
- MYO-INOSITOL CRS (Y0000485) batch 2 contains 2020 mg per unit (1020 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 May 2025 for the following reference standard:

- SAXAGLIPTIN FOR SYSTEM SUITABILITY CRS (Y0002361) batch 1 is stored at -20°C (previously +5°C) and shipped at -20°C (previously at ambient temperature).

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 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.