EDQM reference standards monthly newsletter – December 2024

3 new Ph. Eur. reference standards and 15 replacement batches released in December 2024

Contents

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
Y0002493	Memantine impurity B CRS	0.036 MG	79 EUR
Y0002494	Flumetasone pivalate for ID and assay CRS	110 MG	79 EUR
Y0002489	Memantine hydrochloride CRS	10 MG	79 EUR

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

Catalogue code	Name	Batch	Unit quantity	Price
Y0001954	N-acyl-phosphatidylethanolamine from soya bean CRS	2	40 MG	79 EUR
Y0002319	Atorvastatin for peak identification A CRS	2	15 MG	79 EUR
Y0002143	Sennoside B CRS	2	15 MG	79 EUR
Y0001411	Fusidic acid CRS	2	15 MG	79 EUR
Y0000670	Nonivamide CRS	2	20 MG	79 EUR
Y0000444	Flunixin impurity B CRS	3	15 MG	79 EUR
Y0002354	Everolimus for system suitability A CRS	3	10 MG	300 EUR
Y0001489	2-(Dimethylamino)ethyl methacrylate CRS	3	150 MG	79 EUR
Y0001527	Aescin for LC assay HRS	3	150 MG	79 EUR
Y0002242	Aciclovir for impurity C identification CRS	4	0.3 MG	79 EUR
Y0000297	Mesalazine CRS	4	80 MG	79 EUR
P3350000	Proline CRS	4	60 MG	79 EUR
A1225000	Alfadex CRS	4	160 MG	79 EUR
B0477000	Benserazide hydrochloride CRS	4	50 MG	79 EUR
K2000015	Ketoprofen impurity C CRS	5	15 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 first 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 11.5

Following the implementation of Supplement 11.5, the following standard was officially withdrawn (or replaced) on 1 July 2024.

Catalogue code	Name	Comments
C2320000	Clomifene citrate CRS	This standard will remain in the catalogue for a period of 12 months (i.e. until 1 July 2025) 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 11.6

Following the implementation of Supplement 11.6, the following standards will be officially withdrawn (or replaced) from 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	

Catalogue code	Name	Comments
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	
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 will be officially withdrawn (or replaced) from 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	

Change of sales units

None

Information on change of amount per unit

- Alfadex CRS (A1225000) batch 4 contains 160 mg per unit (150 mg previously)
- Nonivamide CRS (Y0000670) batch 2 contains 20 mg per unit (10 mg previously)
- 2-(Dimethylamino)ethyl methacrylate CRS (Y0001489) batch 3 contains 150 mg per unit (50 mg previously)

- Fusidic acid CRS (Y0001411) batch 2: contains 15 mg per unit (10 mg previously)
- Mesalazine CRS (Y0000297) batch 4: contains 80 mg per unit (50 mg previously)
- Atorvastatin for peak identification A CRS (Y0002319) batch 2: contains 15 mg per unit (10 mg previously)
- Flunixin impurity B CRS (Y0000444) batch 3: contains 15 mg per unit (10 mg previously)

Information on change of price

None

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 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.