


How can I find out the expiry date of an EDQM reference standard?

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Answer:

No expiry date is assigned to EDQM reference standards, but they are monitored regularly. Users must ensure that the EDQM reference standard is valid at the time of use by checking the batch validity statement (BVS) available from the [Ph. Eur. reference standards database](#). We recommend that users purchase only a sufficient amount for immediate use.

As a general rule, the previous batch is still valid for 6 months once a new batch has been officially implemented. Nevertheless, only the BVS should be used to check if the batch is valid at the time of use, as a shorter (or even no) validity period may be applied to a replaced batch, for example in case of a quality issue.

In order to help users to fulfil their regulatory requirements, the EDQM has implemented a new policy since the publishing of Supplement 10.2 (01/07/2020).

A number of users had informed us that regulatory requirements in their country permit the use of withdrawn reference standards (and therefore the corresponding monographs), even after their official withdrawal date. To help these users, the EDQM has modified its withdrawal policy.

Therefore, stocks permitting, sale of these reference standards will continue for 6 months after the official withdrawal date. Similarly, they will remain in the catalogue for a period of 12 months after this date to allow users to print the BVS and/or finalise the necessary procedures for controlled substances.

Example:

Fluoxetine hydrochloride CRS (F0253000) is used in monograph 1104.

The revised monograph entered into force on 01/01/2021.

Reference standard F0253000 will be available for purchase until 01/07/2021 (01/01/2021 + 6 months) and will feature in the catalogue until 01/01/2022 (01/01/2021 +1 year).

Please note that although it will still be listed in the catalogue until 01/01/2022, it will not be possible to order the reference standard after 01/07/2021.

This standard will thus have an end of validity on 02/01/2022. At this date, it will no longer be displayed in the catalogue and therefore can no longer be used.

All reference standards affected by this change are mentioned in the EDQM Newsletter and more comprehensive information is provided in the detailed view of the online catalogue.