

Dear Sir/Madam,

I am writing to inform you of recent challenges experienced by importers of Reference Standards and Analytical Reference Materials (ARMs), including PAI, from the United States Pharmacopeial Convention (USP) when completing the Bill of Entry (BOE) Filing. USP Reference Standards and ARMs are intended for analytical purposes only. As these products are intended for test and assay use only, they are not for use in humans and animals as drugs. This fact is reinforced in the Central Drug Standards Control Organisation's Circular titled "Clarification regarding Reference Standards – reg," dated December 4, 2020. The Circular states that USP Reference Standards are not to be used as drugs. Because Reference Standards, along with PAI and ARMs, are not drugs, they do not bear the same product information as drugs. Specifically, these USP products generally do not bear manufacturing dates, expiry dates, or best before dates.

Due to current system requirements under SWIFT 2.0 implemented by Indian Customs on the ICEGATE portal, it has become mandatory to provide a manufacturing date, expiry date and best before date at the time of BOE initiation. However, as noted above, this information is not generally provided by USP for USP Reference Standards and ARMs. Therefore, we are providing this letter regarding USP Reference Standards and ARMs to provide an explanation of the information that we have recommended that importers enter for the purpose of completing the BOE filing. Please note that our recommended "manufacturing dates," "expiry dates," and "best before dates" are being provided to importers solely for the purpose of the BOE filing and should not be considered official product information.

With respect to expiry dates and best before dates, USP Reference Standards and ARMs do not generally carry expiry dates or best before dates in a conventional manner. Instead, these products are generally assigned Valid Use Dates. If the lot is listed as being the "current lot," it is valid and suitable for use. Once a current lot is depleted, it becomes the "previous lot" and a valid use date is assigned, which is typically 3-12 months from the date of depletion. It is the responsibility of the user to ascertain whether the product is a "Current Lot" or a "Previous Lot" within the valid use date. The USP Catalog and the online USP store are updated daily. In light of the foregoing, we have recommended that importers of USP Reference Standards and ARMs that do not bear expiry dates or best before dates enter an expiry date and best before date of 31 December 2099, solely the purpose of the BoE filing.

For the manufacturing date, which is generally not available to purchasers of USP Reference Standards or ARMs, we are recommending that importers enter, as applicable:

1. The date listed or the "certificate issue date" listed on the bottom right-hand corner of the product certificate for USP Reference Standards.
2. The date listed on the far-left side of the version history for ARMs (including PAI).

Like the expiry date and best before date that we recommend providing in the BOE filing, the recommended manufacturing dates are provided solely for the purpose of the BOE filing.

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Thank you for your understanding in this matter.

Sincerely,

DocuSigned by:

*Kenneth B. Alexander*

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