Ordering Instruction for exporting USP DEA Controlled Substance and List I Chemical Reference Standards

Your quotation (proforma invoice) contains one or more standards that are controlled in the U.S, therefore we are required to obtain US DEA approval to export. To process your order the following documents are required to be submitted:

Required documents:

- Import permit or letter of no objection valid for at least three (3) months at the time of order submission to USP
- Justification of End-Use and No-Re-Export Statement issued & signed by the end user, printed on End User's company letterhead
- English translation for all documents which are not written in English
- Purchase order (PO) for credit term Customers, prepayment for immediate/cash advance payment term Customers

Please refer to below matrix on further details and clarification on how these documents can be submitted to USP:

1. Select if the ordered item(s) is(are) CONTROLLED IN YOUR (IMPORTING) COUNTRY or NOT CONTROLLED IN YOUR (IMPORTING) COUNTRY.
2. Select if your ordered item(s) is(are) Class I-V substances, Ephedrines/Pseudoephedrines/Phenylpropanolamines or other list I chemical items, follow the document requirements and acceptable submission methods.

A	B	C	D	E	F
CONTROLLED IN YOUR (IMPORTING) COUNTRY			*NOT CONTROLLED IN YOUR (IMPORTING) COUNTRY*		
DEA Drug Class: CI, CII, CIII, CIV, CV	**List Chemicals: Ephedrines / Pseudoephedrines / Phenylpropanolamines**	**All other List Chemicals**	**DEA Drug Class: CI, CII, CIII, CIV, CV**	**List Chemicals: Ephedrines / Pseudoephedrines / Phenylpropanolamines**	**All other List Chemicals**
Import permit valid at least three (3) months at the time of order submission to USP issued by the competent authority of the importer country *(original sent by courier if issued on paper by the competent authority)*	**Import permit** valid at least three (3) months at the time of order submission to USP issued by the competent authority of the importer country *(**electronic copy)*	**Import permit** valid at least three (3) months at the time of order submission to USP issued by the competent authority of the importer country *(**electronic copy)*	**Letter of No Objection** valid at least three (3) months at the time of order submission to USP issued by the competent authority of the importer country *(electronic copy)*	**Letter of No Objection** valid at least three (3) months at the time of order submission to USP issued by the competent authority of the importer country *(electronic copy)*	******End User statement** that the item is not regulated in the importing country *(electronic copy)*
Justification of End-Use and No-Re-Export Statement issued & signed by the End-User, printed on End User company letterhead	**Justification of End-Use and No-Re-Export Statement** issued & signed by the End-User, printed on End User company letterhead *(electronic copy)*	**Justification of End-Use and No-Re-Export Statement** issued & signed by the End-User, printed on End User company letterhead *(electronic copy)*	**Justification of End-Use and No-Re-Export Statement** issued & signed by the End-User, printed on End User company letterhead *(electronic copy)*	**Justification of End-Use and No-Re-Export Statement** issued & signed by the End-User, printed on End User company letterhead *(electronic copy)*	**Justification of End-Use and No-Re-Export Statement** issued & signed by the End-User, printed on End User company letterhead *(electronic copy)*
English translation for all documents which are not English	**English translation** for all documents which are not English *(electronic copy)*	**English translation** for all documents which are not English *(electronic copy)*	**English translation** for all documents which are not English *(electronic copy)*	**English translation** for all documents which are not English *(electronic copy)*	**English translation** for all documents which are not English *(electronic copy)*
*****Purchase Order (PO)/Prepayment**	*****Purchase Order (PO)/Prepayment** *(electronic copy)*	*****Purchase Order (PO)/Prepayment** *(electronic copy)*	*****Purchase Order (PO)/Prepayment** *(electronic copy)*	*****Purchase Order (PO)/Prepayment** *(electronic copy)*	*****Purchase Order (PO)/Prepayment** *(electronic copy)*

* For DEA Drug Class: CI, CII, CIII, CIV, CV, which are controlled substances both in the US and in the importing country, if needed to be couriered, we ask you to send all needed documents for the submission together for prompt processing.
** The electronic copy is a document sent via email. If it is required that original import permit must be returned with shipment for customs clearing purposes in the importing country, please send us the original import permit by courier.
DEFINITION OF ELECTRONIC COPY: Electronic copy is a clear color scanned PDF document sent via email (not a picture). Please note that we can always ask for the original document.
*** Purchase Order (PO) is only required for credit term Customers.
**** The End User declaration that the ordered substance is not controlled in the importing country can be combined with the Justification of End-Use and No-Re-Export Statement as one document or confirmed via email

All documents to be submitted as originals should be sent to the attention of USP Customer Service to the below mailing address:

United States Pharmacopeial Convention
7135 English Muffin Way
Frederick, MD 21704
USA
Tel: 301 881 0666

Upon receipt of all necessary and correct documentation, we will submit applications to US DEA for authorizations to export. Please note that this process will take a minimum of (8) eight weeks.

Important Notes:

- Download USP reference standard catalogue for detailed item information such as description, current lot, HS code, country of origin, CAS#, packaging size, base controlled substance name, base control drug percent and other information necessary to expedite exportation of the controlled substance and list I chemical products at: https://www.usp.org/reference-standards/reference-standards-catalog

- Please use the following information as the Exporter when you apply for your import permit:

  United States Pharmacopeial Convention
  7135 English Muffin Way
  Frederick, MD 21704
  USA

  Our US competent authority can issue permit to export only if exporter's name and address is identical to our DEA exporter registration certificate provided above. Import permits with incorrect information will not be accepted.

- U.S. DEA recognizes the appropriate competent national authorities under:
  - article 18 of the Single Convention on Narcotic Drugs of 1961;
  - article 16 of the Convention on Psychotropic Substances of 1971;
  - article 12 of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988.

  Please contact your local authority to find the correct competent authority.

- Review all information on your quotation (USP Proforma invoice) carefully, including ordered items and quantity, Bill To / Ship To details, PO reference, contact name and email address, and let us know if there's anything we need to revise. Once your order is processed and we apply for our permit to export, we will not be able to make any changes to the invoices or corresponding shipping documents.

- All orders are final, and we are unable to change any information once the order has been processed. We are unable to accept any return after the order has shipped.

- US DEA regulated items are shipped outside of the United States by AIR FREIGHT/DOOR TO AIRPORT or FedEx Air (door to door) Service. Please check which USP shipping method complies with importing regulations in your country.

- There is an additional fee of US$25.00 to each unit price of USP DEA controlled substance and list chemical reference standard shipping outside of the United States.

- For your information, please review our terms and conditions of Sale at: https://www.usp.org/sites/default/files/usp/document/help/terms-of-sale.pdf

Instruction for preparing Justification of End-Use and No-Re-Export Statement

Justification of End-Use and No-Re-Export Statement required by USP for all US controlled substance and list I chemical reference standards ordered quantities shipping internationally. It must be issued and signed by the End User and should be printed on End User's company letterhead.

It is a combined statement, which includes the no-re-export declaration and the justification of end use. The Justification of end use must include specific amount of the USP controlled substance/list I chemical reference standard required for each test and/or purpose. The total justification of end-use quantity should equal to the amount being purchased.

Here is an example of the breakdown table for a controlled substance item with package size 400mg ordering 10 vials:

(Insert name of USP controlled substance/list chemical reference standard)

Name of Test	Parameter	Quantities/Amount
Evaluation Process	Blend uniformity, Blend Assay, Related Substance Drug product dissolution media	1,800.00 mg
Method Verification	Assay, Related Substance, Identification, Batch Analysis	1,800.00 mg
Process Evaluation	Blend uniformity, Assay Content Uniformity, Related Substance Drug product dissolution media	400.00 mg
Total		4,000mg

****In case of multiple reference standards on the order, you can issue a separate statement per each item or you may insert multiple breakdown tables per item into the same document.***

Justification of End-Use and No-Re-Export Statement – International Controlled Substances and List Chemicals

The information contained on this document must be completed and recorded on End-User's company letterhead.

(Insert date DD/MM/YYYY) :

To Whom it May Concern:

The standard(s) below will be imported by ***(Insert Importing Company Name)*** for ***(Insert End User Company Name)*** and are required only for ***(Insert What End User is using It (Them) For)*** within ***(Insert End User Country)*** and will not be re-exported.

Justification of Use:

(Insert name of USP controlled substance/list chemical reference standard)

Name of Test	Parameter	Quantities/Amount
Total Amount		

Signed by:

(Insert Name and Title of authorized company representative of the End User)

Signature