

APPENDIX – 4 I

**(Please see Para 4.18 to 4.21 of HBP)**

Register for accounting of consumption and stocks of duty free imported or domestically procured raw materials, components etc. allowed under advance authorisation for pharmaceutical product manufactured through Non Infringing (NI) process.

| Inputs allowed in the authorisation |                                |                    |          | Product(s) exported under the authorisation |          |   |   | Balance inputs, if any (4 -8) | In case of balance inputs as in column 9 |    |    | Remarks |
|-------------------------------------|--------------------------------|--------------------|----------|---|----------|---|---|-------------------------------|--|----|----|---------|
| Sl No.                              | Authorisation No (s) with date | Name of the Inputs | Quantity | Name of the Product                         | Quantity | Inputs Actually consumed for the exported product** |   |                               |  |    |    |         |
|                                     |                                |                    |          |   |          | Inputs  | Quantity (Including actual wastage incurred ) |                               |  |    |    |         |
| 1                                   | 2                              | 3                  | 4        | 5   | 6        | 7   | 8   | 9                             | 10                                       | 11 | 12 | 13      |
|                                     |                                |                    |          |   |          |   |   |                               |  |    |    |         |

\*Applicable only in case either partial import or “NIL” import has been effected.

\*\*In case of post export replenishment, details of inputs used (whether duty paid or not) in the exported product has to be furnished.

We declare that the aforesaid particulars are correct.

Place:

Date:

Signature of the authorisation holder

Name in block letters: \_\_\_\_\_

Full official address: \_\_\_\_\_

Full Residential address: \_\_\_\_\_

Official Seal / Stamp

Telephone No.: \_\_\_\_\_

E-mail: \_\_\_\_\_

**Note:**

1. Please mention N.A. wherever the information required in the table is not applicable.
2. For columns 10 & 12 of the table, please furnish the copy of the documentary evidence.

**FORMAT OF CHARTERED ENGINEER (Chemical) / CUSTOMS CERTIFICATE**

I hereby confirm that I have examined the production details and the records of M/s \_\_\_\_\_ (Name of the authorisation holder) and verified the details furnished in Appendix 4-I format. I hereby certify the following details of consumption of inputs for the pharmaceutical product, manufactured through Non Infringing (NI) process, against their advance authorization no. ----- dated ----- .

1. Name of the Advance Authorisation holder:
2. Address of the manufacturing unit:
3. Name of the exported product:
4. Type of exports: Physical / Deemed / Both (strike out whichever is not applicable).
5. Period for which production details verified:
6. Quantity exported against the authorization:
7. Details of inputs consumed in per unit of exported product:

| Sl. No. | Name of the Input(s) used | Quantity consumed |
|---------|---------------------------|-------------------|
| 1       |                           |                   |
| 2       |                           |                   |

Date:

Place:

Office seal/Stamp:

Name:

Designation:

Telephone No. (O):

E-mail address (if any):

Postal Address:

Note:

1. This certificate shall be required only when the product manufactured and exported is a pharmaceutical product manufactured through Non-Infringing (NI) process. This certificate is to be signed by an official not below the rank of Superintendent of Customs, under whose jurisdiction the manufacturing unit of the Advance Authorisation holder is located).
2. As per the policy provision, solvent(s) shall be allowed maximum upto 25% of the requirement of solvents indicated in the ANDA / DMF. However, in cases where recovery is not possible and the solvent gets poisoned, full quantity of solvent as per ANDA / DMF shall be allowed. Customs Authority shall verify and certify the actual requirement of solvents accordingly for the purpose of Sl. No. 7 above.