APPENDIX 32 C

FORMAT OF CHARTERED ENGINEER (CHEMICAL) CERTIFICATE

(Please see para 4.7A of HBP v.1)

(For Pharmaceutical Product manufactured through Non-Infringing process)

1. I am a Chartered Engineer (Chemical) with Registration No. _____ dated _____. This Certificate is being furnished as per the requirement of paragraph 4.7A of Handbook of Procedure, Vol. 1.

2. I hereby certify that the approval communication dated _____ of *the Food & Drug Administration / concerned regulatory authority of the country of import* _____*(*name of country) *pertains to the Drug Master File (DMF) reference No.*_____, meant for the export product for which the advance authorisation application is being filed*.*

3. I have examined the details of requirements of inputs of the applicant M/s _____, _____(Name and address of the manufacturer exporter) with regard to their technical description / specification and the quantity against each input from the *Abbreviated New Drug Application (ANDA) / Drug Master File (DMF) of the applicant, as given at Sl. No. 2 above and as approved by the Food & Drug Administration / Concerned regulatory authority of the country of import. I have also verified that the details of the export product and the inputs sought thereof in their application* in 'Aayaat Niryaat Form (ANF 4 J)' are as per ANDA / DMF. I have also examined the proper norms of consumption and after technical scrutiny of relevant designs and drawings of the export product, I hereby certify that they are correct in all respects and are actually required for the execution of the export product, for which the application is made.

4. I hereby certify the export product and the requirement of inputs thereof as follows:

(a) Details of product(s) to be exported / supplied under the Authorisation:

Sl. No.	***Product Description***	***Technical Characteristics / Quality / Specification***	***ITC (HS) Code***	***Quantity (Along with the Unit of Measurement)***

(b) Details of inputs required as per *ANDA / DMF of the applicant and that* ***as per SION or Adhoc Norms****:

Sl. No	***Input Description***	***Technical Characteristics / Quality / Specification of the Inputs***	***ITC (HS) Code***	***Quantity (Along with the Unit of Measurement)***	***Quantity allowed as per SION or Adhoc Norms****

** State "NIL" in case the SION or the adhoc norm for the said export product is not available.*

5. *I am issuing this certificate having verified the approval of the concerned department / authority of the regulated overseas market and the details of each input and its quantity as given in ANDA / DMF of the applicant to that declared in the Aayaat Niryaat Form (ANF 4 J) and found them to be correct.*

6. In the event that any of the statements / facts certified above by the undersigned, is found to be incorrect, I am li*able* for penal action under the Foreign Trade (Development & Regulation) Act, 1992 (as amended), Rules and Orders framed there under and the provisions of any other Act, in force.

Date:	Signature of Chartered Engineer (Chemical)
Place:	Name:
Seal of Chartered Engineer:	E-mail:
	Tel. No. (O):
	Official Address:
	Residential Address:
	Registration Number:
	Name & Address of the Institution with which registered:

Note :

1. Unless and otherwise provided for, solvent(s) shall be allowed maximum upto 25% of the requirement of solvents indicated in the ANDA / DMF for the purpose of advance authorisation. However, in cases where recovery is not possible and the solvent gets poisoned, full quantity of solvent as per ANDA / DMF shall be allowed. Chartered Engineer shall verify and certify the same accordingly for the details of solvents required as in Table 4(b) above.
2. In case of deemed exports, this certificate shall be based on details given in ANDA of the recipient unit and DMF of supplying unit (deemed exporter).