## 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)

I	-		product and the requirement of in the been exported / supplied under the supplied under t	•	follows:  Quantity  (Along with the Unit of  Measurement)				
I	-		·	Authorisation:					
I	-		·	•	follows:				
a	I hereby certify the export product and the requirement of inputs thereof as follows:								
	application is made.								
	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								
	Form (ANF 4 J)' are as per ANDA / DMF. I have also examined the proper norms of consumption and afte								
	that the details of the export product and the inputs sought thereof in their application in 'Aayaat Niryaa								
F	Food & Drug Administration / Concerned regulatory authority of the country of import. I have also verified								
(	(ANDA) / Drug Master File (DMF) of the applicant, as given at SI. No. 2 above and as approved by the								
d	description / specification and the quantity against each input from the Abbreviated New Drug Application								
I	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								
а	authorisatio	on application is	being filed.						
٨	Master File (DMF) reference No, meant for the export product for which the advance								
	concerned regulatory authority of the country of import(name of country) pertains to the Drug								
ı	hereby c	ertify that the	approval communication dated	of the	Food & Drug Administration				
	arriiorioa c	is per the regain		abook of 1 foces	lure, vol. 1.				
fı	urnished a	s ner the requir	ement of paragraph 4.7A of Han	dhook of Proced					

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

SI. 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*

<sup>\*</sup> 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 liable 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:

- 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).