ANNEXURE-1

VENDOR QUESTIONNAIRE FOR RAW & CAPSULE SHELL

Company Overview

Name of Vendor :	
Type of Business :	Manufacturer / Distributor / Dealer / Agent
Factory Address :	
Office Address :	
Contact information :	**Mobile:** **Telephone:** **E-mail:** **Fax:**
Establishment Year :	

Questionnaires Overview

Sl. No.	Questionnaires	Observation	
1	How many plants do you have to manufacture Raw Materials? (Please enclosed the details with address and establishment of plants)		
2	From which plant you willing to supply the material to us? **Name:** **Address:**		
3	Is more than one product manufactured in the same manufacturing facility? If yes, please attach the list of product(s) manufactured in the same premises.	Yes	No
4	What is the total manufacturing capacity of your plant? (every product) Enclosed attachment with details	Yes	No
5	Indicate Range of Your Products (Enclosed attachment with details)	Yes	No
	Active Pharmaceutical Ingredient (API) Pharmaceutical excipients Packaging materials Others Product		

6	Is there any written procedure for manufacturing the product?		
Sl. No.	**Questionnaires**	**Observation**	
7	What percentage of the output are for Pharmaceuticals customers?		%
8	What is the typical batch/ lot size?		
9	Does batch identity allow traceability of the followings?	Yes	No
	Input Material	Yes	No
	In-process check	Yes	No
	Final product checking	Yes	No
10	Is written record maintained for each batch giving a complete record of the manufacturing history?	Yes	No
11	What is the retention period of Quality Records?		
12	Is your manufacturing premises inspected by an internationally accepted Regulatory Authority or any other independent quality certification body?	Yes	No
	If yes, please quote the authority name, license and date. (if any) **Authority Name:** **License No.:** **Date:**		
13	Do you have any quality complying facilities for controlling quality of bought out raw materials and finished products?	Yes	No
14	Is your product tested by any agency? If yes enclosed attachment with details.	Yes	No
15	Is your process validated?	Yes	No
16	Are manufacturing and quality control equipment calibrated regularly?	Yes	No
17	Are rejected materials clearly identified?	Yes	No
18	Do you have any written procedure for disposal of rejected materials and reprocessing of intermediate or finished products?	Yes	No
19	Do you retain sample of each batch?	Yes	No
	If yes, for how long?		
20	Do you have any internal quality audit system?	Yes	No
21	Would you be willing to provide analytical procedure of supplied material? If yes, please attach the documents.	Yes	No
22	Do you have the stability study of the supplied material following ICH guideline? If yes, please attach the documents.	Yes	No
23	Would you be willing to provide open part of DMF? If yes, please attach the documents.	Yes	No
24	What is the annual turnover of your company in terms of $?		
25	What is the minimum packing quantity?		
26	What is the maximum packing quantity?		
27	What type of material do you use for packing?		

28	What is the minimum order/ lot size?		
Sl. No.	**Questionnaires**	**Observation**	
29	What is the lead-time required?		
30	Indicate Range of Your Products		
	Active Pharmaceutical Ingredient (API)	Yes	No
	Pharmaceutical Excipients	Yes	No
	Capsule Shells	Yes	No
	Others	Yes	No
	List of Product is Enclosed	Yes	No

Valuable Customers

Name of the Customer	Address	Supplied Product	Supplied Year	Value in $

Contact Technical Person

	Head of Quality	Plant/Production Manager
Name		
Designation		
Date of Joining		
Year of experience		
Contact address		
Contact Phone no		
Fax No		
E-mail address		

I certify that the information supplied herein is correct and the following documents are enclosed.

Name	Designation	Signature	Date

Attachment

- Company brochure
- COA of material
- Materials Safety Data Sheet (MSDS)
- Stability Data as per ICH guideline
- Sample of the Material
- Analytical Procedure
- Drug master file (open part)
- Working standard with COA

ANNEXURE-2

VENDOR QUESTIONNAIRE FOR PACKAGING MATERIALS

Company Overview

Name of Vendor :	
Type of Business :	Manufacturer / Distributor / Dealer / Agent
Factory Address :	
Office Address :	
Contact information :	**Mobile:** **Telephone:** **E-mail:** **Fax:**
Establishment Year :	

Questionnaires Overview

Sl. No.	Questionnaires	Observation	
1	Is more than one product manufactured in the same manufacturing facility? If yes, please attach the list of product(s) manufactured in the same premises.	Yes	No
2	What is the total manufacturing capacity of your plant? (every product)	Yes	No
3	What percentage of the output are for Pharmaceuticals customers?		
4	What is the typical batch/ lot size?		
5	Does batch identity allow traceability of the followings?	Yes	No
	Input Material	Yes	No
	In-process check	Yes	No
	Final product checking	Yes	No

Sl. No.	Questionnaires	Observation	
6	Is written record maintained for each batch giving a complete record of the manufacturing history?	Yes	No
7	What is the retention period of Quality Records?		
8	Is your manufacturing premises inspected by independent quality certification body or any other company?	Yes	No
	If yes, please quote the name & address of the inspection team and date. **Name:** **Address:**		
9	Do you have any quality complying facilities for controlling quality of bought out raw materials and finished products?	Yes	No
10	Are rejected materials clearly identified?	Yes	No
11	Is there any written disposal record of rejected materials?	Yes	No
12	Do you retain sample of each batch?	Yes	No
	If yes, for how long?		
13	Do you have any internal quality checking system?	Yes	No
14	What is the annual turnover of your company in terms of Tk.?		
15	What is the minimum packing quantity?		
16	What is the maximum packing quantity?		
17	What type of material do you use for packing?		
18	What is the minimum order/ lot size?		
19	What is the lead-time required?		
20	Indicate Range of Your Products		
	Packaging Materials	Yes	No
	Others	Yes	No
	List of Product is Enclosed	Yes	No

Valuable Customers

Name of the Customer	Address	Supplied Product	Supplied Year	Value in $

Contact Technical Person

	Head of Quality	Plant/Production Manager
Name		
Designation		
Date of Joining		
Year of experience		
Contact address		
Contact Phone no		
Fax No		
E-mail address		

I certify that the information supplied here in is correct.

Name	Designation	Signature	Date