No	Responsibilities	<Supplier>	<Customer>
1.0	**Compliance**		
1.1	Conform to the Joint IPEC-PQG GMP Guide and/or other quality criteria and systems as defined in Section D of this Agreement.	X	
1.2	Mutually agree upon specifications for the Excipients which are the subject of this Agreement. Specifications in place at the time of this Agreement are attached or referenced herein. *Note: Attachment of specifications is optional.*	X	X
1.3	Changes to the specifications shall be mutually agreed upon and communicated in writing between the parties to this Agreement, except for compendial changes which can be implemented without mutual agreement. Compendial changes shall be implemented by the compendial implementation date.	X	X
1.4	Ensure that the specifications for compendial Excipients are in compliance with the current compendia.	X	
1.5	Manufacture Excipients that conform to the mutually agreed upon specifications.	X	
1.6	Ensure the Excipient is appropriate for its intended use.		X
1.7	Upon request, disclose information to the Customer regarding any recent regulatory agency inspections and adverse findings pertaining to the Excipients.	X	
1.8	Notify promptly if, in the course of a regulatory inspection, findings are made related to the quality or safety of the Excipients already supplied.	X	
1.9	Supplier shall have a qualification, and approval process for management of third parties that includes periodic re-evaluation. Supplier shall retain related records.	X	
2.0	**Manufacturing, Packaging and Labelling**		
2.1	Document that manufacturing and packaging processes are reproducible and capable of meeting Excipient specifications.	X	
2.2	Demonstrate the commissioning of systems and equipment that may affect excipient quality, used in the manufacture and control of the Excipient.	X	
2.3	Demonstrate that cleaning procedures are appropriate and their effectiveness has been demonstrated.	X	
2.4	Samples will be retained for a period of ____ years from _____ (*specify*).	X	
2.5	Agree upon special labelling requirements as applicable	X	X
2.6	Agree upon special tamper evidence features in packaging unit and transport unit as applicable.	X	X
3.0	**Documentation and Records**		
3.1	Certificate of Analysis will be supplied with each batch.	X	
3.2	Certificate of Analysis (including electronically generated certificates) will be prepared either according to the current *Certificate of Analysis Guide for Pharmaceutical Excipients* or an agreed upon alternative that is defined in this Agreement. *Note: Define alternative in Section D or specify information to be included in CoA. An example CoA may be attached.*	X	

No	Responsibilities	<Supplier>	<Customer>
3.3	Agree upon special Certificate of Analysis requirements as applicable.	X	X
3.4	If applicable, electronic signatures may be used according to documented procedures if they provide a degree of control equivalent to that given by a handwritten signature.	X	
3.5	Records required by the agreed upon quality system will be maintained for a period of ____ years from _____ (*specify*).	X	
4.0	**Storage and Distribution**		
4.1	When applicable, maintain and supply upon request documentation that supports the recommended storage and special transport conditions.	X	
4.2	Maintain and supply upon request documentation that supports re-test or expiry dates *(for example, stability data)*.	X	
4.3	Ensure that Excipients are stored and shipped in accordance with Excipient manufacturer's recommended conditions.	X	X
4.4	Where applicable, agree upon requirements for reusable shipping containers.	X	X
4.5	Perform incoming quality control testing within a reasonable timeframe after receipt of the Excipient. *Note: Parties may choose to define this timeline for example within this Agreement or a supply agreement.*		X
5.0	**Change Control** *Note: Refer to the IPEC Significant Change Guide for Pharmaceutical Excipients (specifically section on "Notification Requirements").*		
5.1	Changes shall be evaluated.	X	
5.2	Supplier shall provide adequate notice based on the type of change.	X	
	Example: Customer shall provide written feedback to Supplier within a defined timeframe. The parties shall agree upon further action based upon that feedback. If no Customer feedback is received in this timeframe the change is assumed accepted. *(Note: For the Excipient users it is crucial not to receive material produced after a change before the impact of the change on their finished product has been assessed. Therefore, it is in the interest of the Customer to accept changes prior to delivery of Excipient affected by the change. For the Supplier it can be important to receive prompt feedback from the Customer to continue their operations. Depending on their business relationship the parties might include particular provisions in the quality agreement to address this. The parties should consider the requirement of Customer feedback, the implications of Customer feedback received or missing and required actions of the Supplier.)*		
5.3	Provide up to date instructions detailing how to submit notification of a change (e.g., generic email address).		X
6.0	**Deviations and Out of Specification Results**		

No	Responsibilities	<Supplier>	<Customer>
6.1	Deviations and out of specification results occurring during GMP activities (e.g., manufacture and testing of Excipients) shall be investigated by Supplier according to Supplier's documented procedures. Supplier shall document the investigation and implement appropriate corrective and preventive actions, in accordance with current Excipient GMP as listed in Section D of the agreement. Impact to other batches shall be checked, where applicable.	X	
6.2	Impacted Excipients may only be released and shipped to Customer after investigation has been finalized and demonstrated Excipient's compliance to its agreed specification.	X	
6.3	*Where applicable, agree on reworking and reprocessing.*	X	X
7.0	**Non-Conformances Detected by Supplier after Customer Receipt**		
7.1	When Supplier becomes aware that any batch of Excipient already shipped to Customer fails to conform to its specification or is considered to have negative impact on quality, Supplier shall notify Customer without unreasonable delay. (E.g., Excipient is in specification, but packaging container sheds foreign particles). Additionally, an investigation report shall be provided to Customer as soon as possible.	X	
8.0	**Complaints**		
8.1	Customer shall inform Supplier of any complaint by written notice indicating at least the affected Excipient (name, article code, volume and batch number) and the complaint subject as soon as detected or confirmed. Notification can only be made within the Excipient's shelf life or retest date. Defects discovered during receipt of Excipient shall be recorded on the proof of delivery.		X
8.2	Supplier shall investigate and document any complaint from Customer according to a written procedure. This may include a root cause analysis and definition of corrective and preventive actions. Impact on other batches shall be checked, where applicable. A rapid initial response and a final report shall be provided to Customer as soon as possible. *Note: Parties may want to specify timeframes.*	X	
8.3	The parties shall cooperate in the exchange of information, samples and other means of evidence required to effectively conduct an investigation.	X	X
9.0	**Recalls**		
9.1	In the case of a recall of the Excipients, Supplier shall inform Customer without unreasonable delay.	X	
9.2	There shall be a written recall procedure.	X	X
9.3	Customer shall notify Supplier as soon as possible of any finished product recall which has been investigated or is under investigation and has potential to be related to the quality of the Excipients.		X
9.4	Customer is responsible for final decision and coordination of the recall of his finished product(s).		X

No	Responsibilities	<Supplier>	<Customer>
9.5	The parties shall cooperate in the exchange of information required to effectively conduct a recall activity or recall investigation.	X	X
10.0	**Returned Excipients**		
10.1	To prevent mix up with released Excipients, returned Excipients shall be identified as such by Supplier and handled, stored, tested or disposed according to written procedures.	X	
11.0	**Auditing**		
11.1	Have the right to audit Supplier's facilities, systems and documentation, as they relate to the manufacture of Excipients, at mutually agreed upon time. *Note:* *Consideration should be given to 3rd party certification schemes with an option to obtain the 3rd party certification audit report.* *Available certificates may include: EXCiPACT™, NSF/IPEC/ANSI Standard 363* *Note: Conditions, restrictions, and requirements (e.g. confidentiality agreement, auditing frequency) can be added.*		X
11.2	Have the right to perform non-routine (e.g. for-cause) audits of Supplier facilities, systems and documentation at short notice at mutually agreed upon times in the event of critical or major issues. *Note: Conditions, restrictions, and requirements (e.g. confidentiality agreement, auditing frequency) can be added.*		X
11.3	Customer shall issue a confidential written audit report including audit observations to the Supplier within X days. *Note: Parties should mutually agree upon timeline to define "X".*		X
11.4	Supplier shall issue responses in writing to the Customer within X days to all observations. Where the auditee commits to a corrective action, a description and timeframe for completion will be included in the written response. *Note: Parties should mutually agree upon timeline to define "X".*	X	