This Manufacturer’s Quality Statement is a subset of the manufacturer’s quality commitments and responsibilities from the QA and is not meant to repeat the QA in total. It is a tool used to provide specific information for which the manufacturer is solely responsible.

For such products covered by this Quality Agreement (the “Excipients”), <Manufacturer Name> agrees that it will:

|  |  |
| --- | --- |
| **1.0** | **Compliance** |
| 1.1 | Conform to the Joint IPEC-PQG GMP Guide. |
| 1.2 | Establish specifications for the Excipients. |
| 1.3 | Communicate changes to the established specifications to Distributor in writing, except for compendial changes which can be implemented without notification. |
| 1.4 | Ensure that the specifications for compendial Excipients are in compliance with the current compendia. |
| 1.5 | Have systems in place designed to manufacture Excipients that conform to the established specifications. |
| 1.6 | Notify Distributor promptly if, in the course of a regulatory inspection, findings are made related to the quality or safety of the Excipients already supplied to Distributor. |
| 1.7 | Have a qualification, and approval process for management of third parties that includes periodic re-evaluation. Related records are retained. |
| **2.0** | **Manufacturing, Packaging and Labelling** |
| 2.1 | Document that manufacturing and packaging processes are reproducible and capable of meeting Excipient specifications. |
| 2.2 | Demonstrate the commissioning of systems and equipment that may impact excipient quality used in the manufacture and control of the Excipient. |
| 2.3 | Demonstrate that cleaning procedures are appropriate and effective. |
| 2.4 | Retain samples for a period of \_\_\_\_ years from \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*specify*). |
| **3.0** | **Documentation and Records** |
| 3.1 | Supply a Certificate of Analysis with each batch of Excipient to Distributor. |
| 3.2 | Prepare Certificates of Analysis (including electronically generated certificates) according to the current *Certificate of Analysis Guide for Pharmaceutical Excipients*. |
| 3.3 | Maintain records required by the agreed stated quality system for a period of \_\_\_\_ years from \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*specify*). |
| **4.0** | **Storage and Distribution** |
| 4.1 | Maintain and supply to Distributor documentation that supports the recommended storage and transport conditions. |
| 4.2 | Maintain and supply to Distributor documentation that supports re-test or expiry dates *(for example, stability data)*. |
| **5.0** | **Change Control** |
| 5.1 | Evaluate changes and communicate to Distributor following the IPEC *Significant Change Guide*.  |
| **6.0** | **Deviations and Out of Specification Results** |
| 6.1 | Investigate deviations and out of specification results occurring during GMP activities (e.g., manufacture and testing of Excipients) according to <Manufacturer Name’s> documented procedures.The investigation will be documented and corrective and preventive actions will be implemented as appropriate, in accordance with current Excipient GMPs.Impact to other batches will be checked, where applicable. |
| 6.2 | Release and ship impacted Excipients only after investigation has been finalized and Excipient's compliance to its agreed specification has been demonstrated. |
| *6.3* | *Where applicable inform Distributor of reworking and reprocessing practices.* |
| **7.0** | **Non-Conformances Detected by Manufacturer after Distributor Receipt** |
| 7.1 | Notify Distributor without unreasonable delay when <Manufacturer Name> becomes aware that any batch of Excipient already shipped to Distributor fails to conform to its specification or is considered to have negative impact on quality. |
| **8.0** | **Complaints** |
| 8.1 | Have a written procedure to investigate and document quality related complaints. |
| **9.0** | **Recalls** |
| 9.1 | In the case of a recall of the Excipients, inform Distributor without unreasonable delay. |
| 9.2 | Have a written recall procedure. |
| 10.0 | **Returned Excipients** |
| 10.1 | Have a written procedure for handling returned goods. |
| 11.0 | **Auditing** |
| 11.1 | Allow an audit of <Manufacturer Name> facilities, systems and documentation, as they relate to the manufacture of Excipients, at mutually agreed upon times and in compliance with <Manufacturer Name’s> confidentiality, security and operational procedures.*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.* |

Issued by <Manufacturer Name>

Herewith <Manufacturer Name> allows their distributor <Distributor Name> to share this Manufacturer’s Quality Statement with the excipient customer or regulator.

Signatory’s Name and Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Acknowledged by <Distributor Name>

Herewith <Distributor Name> confirms receipt of this Manufacturer’s Quality Statement for the purpose of sharing with the excipient customer or regulator.

Signatory’s Name and Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_