

Manufacturer's Quality Statement

Attachment to Quality Agreement (QA) between the manufacturer and the distributor

Note: It is recommended to apply version control according to company standards and to use Manufacturer's company letterhead.

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 _____ (<i>specify</i>).
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 <i>Certificate of Analysis Guide for Pharmaceutical Excipients</i> .
3.3	Maintain records required by the agreed stated quality system for a period of ____ years from _____ (<i>specify</i>).
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 (<i>for example, stability data</i>).
5.0	Change Control
5.1	Evaluate changes and communicate to Distributor following the IPEC <i>Significant Change Guide</i> .
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	<i>Where applicable inform Distributor of reworking and reprocessing practices.</i>

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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. <i>Note:</i> <i>Consideration should be given to 3rd party certification schemes with an option to obtain the 3rd party certification audit report.</i> <i>Available certificates may include: EXCiPACT™, NSF/IPEC/ANSI Standard 363</i> <i>Note: Conditions, restrictions, and requirements (e.g. confidentiality agreement, auditing frequency) can be added.</i>

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 to share with the excipient customer or regulator.

Signatory's Name and Title: _____

Signature: _____

Date: _____