Quality Requirements for the Supply with Pharmaceutical Excipients

BERLIN-CHEMIE MENARINI

- The excipient has to be produced, packaged, labelled, and QC-tested with processes suitable for the intended pharmaceutical use, in accordance to the specifications defined in the referenced pharmacopoeial monograph(s) and/or those specifically claimed, and in compliance with suitable Good Manufacturing Practices for pharmaceutical excipients.

- Storage, handling, and distribution of the excipient has to be done in accordance to the storage and transportation conditions recommended by the supplier and in compliance with suitable Good Manufacturing Practices for pharmaceutical excipients in order to maintain the quality characteristics of the excipient, to exclude the possibility of deterioration, contamination, or mix-ups with any other material, and to ensure that test results remain applicable to the delivered excipient.

- Customer has to be informed in writing in case that the applied Good Manufacturing Practices are not those defined in the preferred standards (EU, ICH Q7, IPEC or WHO, current versions always) but are according to alternate standards (e. g. ISO 22716, HACCP, ISO 9001) and has to informed what alternate standard(s) are applied.

- The certificate of analysis has to be signed by a designated person with appropriate qualifications and experience whereas this signature assures that the batch has been checked for compliance with the specification.

- Any change that affects the manufacture, testing and/or distribution of the excipient has to be evaluated and communicated according to the principles set forth in the most recent "IPEC Significant Change Guide for Pharmaceutical Excipients". For those changes regarded as significant and therefore requiring a notification to the customer, the notification has to be done in writing and within a reasonable time prior to implementation, to allow customer to evaluate the impact of the change on customer's products.

- All non-conformances have to be investigated, including a risk analysis for other lots and the impact to other test results. Customer has to be informed in writing without unreasonable delay if an investigation reveals that there is an impact to excipients received by the customer. In the case of a recall of the excipient, customer has to be informed in writing and without unreasonable delay of the planned recall.

- Quality complaints have to be responded in a timely manner and in writing including the conclusions driven by the investigation performed and corrective/preventive actions defined. In case the investigation could not be finalized within 20 business days, an interim report has to be provided to customer.

- Every pharmaceutical raw materials order made by Berlin-Chemie AG is subject to these quality requirements. When accepting the order, the supplier agrees to the requirements of these contents and recognises them as binding.

authorized /

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