EXCiPACT Certificates
Standard applied and Scope of Activities

The information detailed within this document was correct at the time of publication.

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EXCiPACT Certificates: scope and standard applied

1. INTRODUCTION

It is important that any EXCiPACT Certificate details the activities performed by the excipient supplier which have been subject to an EXCiPACT audit. In ISO terms these activities are called the "certificate scope". Often this will be quite a general and simple statement, for example, "manufacture and supply of excipients intended for use in oral applications".

Equally it is vital that the EXCiPACT Certificate clearly states the EXCiPACT standard that has been audited, for example GMP, GDP or GWP.

This document explains what excipient suppliers should request EXCiPACT registered Certifying Bodies place in the Certificate to ensure the details are clearly communicated to the excipient users. As the Certificate is usually text based this should mean the certificate template used by each Certification Body does not need to be modified for each individual excipient supplier.

2. STANDARD APPLIED

The Certificate should state the EXCiPACT standard(s) used during the certification audit. This would typically be:

- EXCiPACT GMP
- EXCiPACT GDP
- EXCIPACT GWP
- EXCiPACT GMP – China Annex
- EXCiPACT GMP-PAMS
- Or some combination where the supplier performs manufacturing, distribution and warehousing activities.

3. CERTIFICATE SCOPE

The scope should state the activities performed. Usually, the Certifying Body will have some rules about what can appear in this section of the certificate and there may be limits on the amount of text that can be included. Key will be to make clear the activities performed which have been audited to the stated EXCiPACT standard.

In the case of PAMs, the scope should mention pharmaceutical auxiliary materials.

Examples of the certificate scope which meet these requirements include:

<Excipient supplier name, address> has been assessed and certified as meeting the requirements of:
EXCiPACT GWP 2021
For the following activities:
Ambient warehousing and distribution of pharmaceutical excipients.

<Excipient supplier name, address> has been assessed and certified as meeting the requirements of:
EXCiPACT GMP 2021 - PAMS
For the following activities:
Manufacture and distribution of pharmaceutical auxiliary materials.

4. DATE FORMAT

Date formats should be unambiguous, thus pure numeric formats which end with the year should be avoided due to the confusion over the placement of day and month. Japanese standard numeric format is unambiguous (YYY/MM/DD). Otherwise, an alphabetic version of the month should be used.

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5. REASON FOR REVISION

No changes to original, other than placed into an approved template and assigned a document number.

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