

**SPECIFIC REGULATIONS FOR THE
CERTIFICATION OF
PHARMACEUTICAL EXCIPIENT
SUPPLIERS ACCORDING TO
EXCiPACT™ SCHEME**

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AENOR

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1 OBJECTIVE

According to section 1.2 of the General Regulations for Certificates of Conformity (hereinafter General Regulations), these regulations describe the specific evaluation system to ensure AENOR's compliance with the EXCiPACT™ standards for the certification of excipients.

2 REFERENCE DOCUMENTS

- EXCiPACT™ Standards:2017
- General Rules for the Certification Commission
- General Rules for the Certificates of Conformity

The current editions of the above mentioned standards and other applicable standards can be found at www.excipact.org, and the current versions of the above mentioned general rules can be found at the AENOR intranet (NEXO), as well as the AENOR website (www.aenor.com).

3 SCOPE

This document is applicable to the activities carried out by AENOR to perform the certification of pharmaceutical excipient suppliers according to the EXCiPACT™ system.

4 MANAGEMENT BODY

AENOR Statutes and General Regulations entrust the management of this particular certification to AENOR technical services.

As required by the interested parties, AENOR will provide the names of its members involved in the decision-making, complaints resolution, impartiality review and policy implementation stages of the certification process.

5 CERTIFICATION PROCESS

5.1. Applying for EXCiPACT™ certification

The applicant for EXCiPACT™ certification will complete the application form in the EXCiPACT™ section, or will provide AENOR with this required information through any other form of communication (email, phone, etc.).

It is also worth mentioning that organizations that wish to apply for EXCiPACT™ certification shall hold an ISO 9001 certificate. For organizations not holding an ISO 9001 certificate it is also possible to apply directly to ISO 9001 and EXCiPACT™ or NSF/IPEC/ANSI 363-2014. Since NSF/IPEC/ANSI 363-2014 is a quality standard which is equivalent to ISO 9001 plus the EXCiPACT™ standard, the EXCiPACT™ organisation accredits AENOR so that it can offer certification to NSF/IPEC/ANSI 363-2014 as well.

Note regarding multi-site sampling: The Certification Bodies shall audit all sites at initial certification, surveillance and recertification to the GMP/GDP requirements. Multi-site sampling does not apply for EXCiPACT GMP/GDP.

5.2 Reception and processing of application

Once the application is received, it will be processed by AENOR's technical certification services.

AENOR will define the length of audits and assigned visits, along with the necessary number of overall and on-site days.

AENOR will also designate the members of the auditing team, who will meet the qualification requirements established in the document EXCiPACT™ Auditor Certification Scheme. In particular, the members of the auditing team must be approved by EXCiPACT™. The EXCiPACT™ Registered Auditors list can be found at www.excipact.org.

Once the offer is prepared, it will be sent to the client. Acceptance of the offer implies acceptance of all the conditions set forth therein and is for all intents and purposes a contractual document between the signatories.

5.3 Initial audit

The initial audit is a complete audit, as it includes all applicable requirements. It will be conducted in two stages.

a) Stage 1

The Stage 1 is performed to assess the clients Quality Management System (QMS) and discuss preparation for the Stage 2. The Stage 1 audit can be used to determine the duration of the Stage 2 audit, and will be conducted always at client's facilities.

b) Stage 2

The Stage 2 is to evaluate implementation and effectiveness of the management system and includes:

- Information and evidence of conformity to EXCiPACT™ GMPs/GDPs,
- Links between normative requirements, policy, performance objectives, and targets consistent with the expectations of EXCiPACT™ GMPs/GDPs, any regulatory requirements, responsibilities, competence of personnel, operations, procedures, performance data, and internal audit findings and conclusions.

In determining the interval between stage 1 and stage 2, considerations shall be given to the needs of the client to resolve areas of concern identified during stage 1. AENOR may also need to revise its arrangements for stage 2. If any significant changes which would impact in the management system occur, AENOR could consider the need to repeat all or part of stage 1. The client will be informed that the results of stage 1 may lead to postponement or cancellation of stage 2.

5.3.1 Audit planning

The lead auditor will agree with the client on the audit scope, dates and location for the audit, taking its duration into account, and will plan the audit following AENOR's internal procedures.

AENOR will send the client an audit plan at least fifteen days before the beginning of the audit.

5.3.2 Audit and audit report

As indicated in the audit plan, the auditing team will evaluate compliance with all applicable requirements established in EXCiPACT™ standards.

After performing the stage 2, an audit report and an evaluation report will be written according to AENOR's specific procedures and instructions.

In addition, the requirements set in Excipact Standards:2017 will be taken into account. Thus, the audit report will be issued in English and the client will be permitted to share copies of the complete audit report with their customers.

Audit findings not compliant with the EXCiPACT™ Standards, will be classified as: Life Threatening, Critical, Major, or Minor.

- a) **Life Threatening:** A nonconformity or other situation which has produced a product that is harmful to the human or veterinary patient, or one which poses a very high risk of producing product that is harmful to the human or veterinary patient.
- b) **Critical:** The excipient poses a significant risk to patient safety. Remediation before further excipient is produced would be indicated and/or a recall should be considered.
- c) **Major:** Evidence indicates that the Quality Management System is not effectively developed or implemented. For instance, the system is poorly designed or not followed; or multiple or repetitive minor nonconformities in the same aspect of the quality management system, and or evidence that the product consistently fails to meet the requirements for use as an excipient.
- d) **Minor:** A departure from the standard that is neither a critical nor major. Action to rectify the finding is indicated.

In the case that there are any major and/or minor non conformities, the organization will have a period of 30 calendar days to provide AENOR with a Corrective and Preventive Action Plan (CAPA) that resolves these issues.

5.4 Evaluation and decision-making process

The initial audit report and CAPA, if necessary, will be evaluated by AENOR. For certification to be granted, the corrective and preventive actions must sufficiently resolve the non conformities detected and must be correctly implemented.

For EXCiPACT™ Certification the acceptance criteria to issue a certificate are:

1. No items rated as Life Threatening
2. No items rated as Critical.
3. No items rated as Major without CAPA

AENOR will notify EXCiPACT™ without delay of any Life Threatening non-conformities identified in any audit providing details of the client and the situation identified. By written contract with the client, AENOR will require the client to notify the relevant regulatory authorities of the Life

Threatening findings without delay in all the countries in which the excipient is knowingly supplied.

AENOR may decide to issue or deny certification and may carry out a special audit (before or after certification) in order to confirm the implementation of corrective and preventive actions.

AENOR will send a letter to the client on the decision taken regarding their application, along with reasons for the decision.

5.5 Issuance of EXCiPACT™ certificates

Once granted AENOR will inform EXCiPACT™ regarding the certification.

AENOR will release the certificate once EXCiPACT™ confirms that the client has paid the certification fee.

The certificate will be prepared according Excipact Standards: 2017. Thus, the certificate according to the EXCiPACT™ requirements will not be valid without a current ISO 9001 Certificate.

In addition, AENOR will inform EXCiPACT™ regarding the certification. EXCiPACT™ will publish on the EXCiPACT™ website the name of the company and the certification details, which can be accessed at www.excipact.org.

EXCiPACT™ certificates are valid for three years subject to a successful annual surveillance audit.

In no case does the certificate exempt the corresponding company from any guarantees or liabilities it has under current legislation.

The certificate, or any other document obtained during the certification process, may not be used for other purposes than those for which they were intended, including falsification or unauthorised use.

The AENOR certificates EXCiPACT™ as well as the AENOR audit reports will be validated and authenticated on request by the client or any other interested party. This request will be sent to the Centralized Operations Dept. of AENOR.

5.6 Reference to certification and use of marks

Certified organizations are entitled to use the Certified Excipient Mark on letter, headings, business cards, brochures, advertisements and other promotional material including vehicles. The mark may also be used on outer packaging, trade samples and flags.

The Certified Excipient Mark may be reproduced in any size but shall not be displayed where the resulting printed definition becomes unclear or the text (including a unique number whose prefix identifies AENOR) becomes unreadable to the naked eye.

The Mark must be reproduced in its entirety, including surrounding outline

The mark may be reproduced in any colour.

The Certified Excipient Mark must not be used on, or closely associated with, products in such a way as to imply that the product itself is certified.

The client will be required by contract to use the mark as required by EXCiPACT™.

The Mark may only be applied to the Certificate of Analysis where the Mark is displayed as part of the document letterhead and does not convey the impression that the certification includes verification of Excipient quality.

It is not allowed reference to certification to imply certification of the excipient.

AENOR exercises control of ownership and takes action to deal with incorrect references to certification status or misleading use of certification documents, marks, or audit reports. AENOR will notify the excipient certification programme owner of any such incidents.

6 MAINTAINING CERTIFICATION

As a requirement to maintain the certificate, companies applying for EXCiPACT™ certification must demonstrate compliance. This will be checked by an annual surveillance audits.

6.1 Surveillance audits

While the certificate is valid (three years), AENOR services will annually carry out surveillance audits with the same scope and system used in the initial audit, with the aim of checking that the conditions permitting certification are still met. The audit should be scheduled to occur between the 46th and 58th week after the initial certification or recertification audit. AENOR will inform EXCiPACT™ if any audit is overdue by more than 6 weeks against the anniversary date.

In the case that there are non conformities, the audited company will have a period of 30 calendar days to provide AENOR with a CAPA to resolve the issues.

6.2 Evaluation and decision process

The surveillance audit report and corresponding corrective and preventive actions will be evaluated by AENOR. They can decide to maintain certification or call for a special audit to check the implementation of corrective and preventive actions, along with any of the sanctions indicated in chapter 10 of the General Rules.

For maintaining certification, the surveillance audit shall have:

1. No items rated as Life Threatening and/or Critical.
2. No items rated as Major unless the deficiency has been remediated or an interim control is in-place i.e. CAPA accepted by the AENOR and verified.
3. No items rated as Minor from a prior audit that have either not been corrected or for which an acceptable CAPA plan has not been developed.

AENOR will notify EXCiPACT™ without delay of any Life Threatening non-conformities identified in any audit providing details of the client and the situation identified. By written contract with the client, AENOR will require the client to notify the relevant regulatory authorities of the Life Threatening findings without delay in all the countries in which the excipient is knowingly supplied.

AENOR will send a letter to the company regarding its decision on maintaining the certificate, along with reasons for the decision.

7 SPECIAL AUDITS

As a consequence of non conformities detected during initial, surveillance or recertification audits AENOR may decide to perform a special audit, preferably within six months of the latest audit, with the aim of ensuring that all non conformities have been properly resolved. It will be performed in the same manner as the initial or surveillance audits, and the corresponding audit plan will define the scope of the audit.

8 RECERTIFICATION

A recertification audit will be performed to ensure that conditions at the time of issuance have been maintained and that renewal is a viable option. Recertification audit is a complete audit (it includes all applicable requirements) and shall occur at intervals of not more than three years after initial certification or last recertification.

If the company does not wish to renew the certificate, they must give written notice of the same at least three months before the certificate's expiration date.

AENOR will inform EXCiPACT™ if any audit is overdue by more than 6 weeks against the anniversary date.

Certificates will not be renewed if a major defect exists that shows no sign of being resolved.

AENOR will notify EXCiPACT™ without delay of any Life Threatening non-conformities identified in any audit providing details of the client and the situation identified. By written contract with the client, AENOR will require the client to notify the relevant regulatory authorities of the Life Threatening findings without delay in all the countries in which the excipient is knowingly supplied.

AENOR will send a letter to the company about the outcome of their certificate renewal process, along with reasons for the decision. In the case of renewal, a new three-year certificate will be issued.

9 DIRECTORY OF CERTIFIED CLIENTS

EXCiPACT™ will maintain a directory of valid certifications, including the name, standard, scope and geographical location, for each certified auditee.

10 NOTICE OF CHANGES BY AENOR

Upon notification from EXCiPACT™ of any revision to the standard, an implementation plan will be developed by AENOR including:

- A description of the change to the certification programme;
- Potential impact of the change to the clients
- Timeframe within which the clients are to implement the change
- Verification schedule that the change by clients has been completed.

11 SANTIONS AND MEASURES

The provisions stated in the General Rules for Certificates of Conformity will be followed.

AENOR will suspend certification in cases when, for example:

- There have been persistent or serious failures to meet certification requirements.
- A regulatory authority inspection has found significant deviation from GMP/GDP requirements that meets the definition of critical finding

In either of two cases AENOR will notify EXCiPACT™ immediately of the situation and the reasons for the suspension.

Under suspension, the auditee shall refrain from promoting certification.

AENOR will notify EXCiPACT™ of the auditee suspension.

In case of withdrawal of a certificate, the client is obliged to return the certificate to AENOR.

12 COMPLAINTS AND APPEALS

12.1. Complaints

This section describes the procedure followed for the management of any complaints that may be lodged with AENOR, by any client or any other interested party (i.e. consumer associations, Public Administration...).

The complaints are initially received by the personnel at any AENOR site who will inform without delay to the Quality Department (TQD).

The receiver or TQD will communicate the complaint received both to the site responsible for dealing with it and to the site from where it was originated. The TQD shall provide an initial response to the complainant within two weeks of receiving the complaint, including the deadline to follow up on the complaint.

The cause analysis and corrective actions, as applicable, are carried out and registered with the collaboration of TQD and the site personnel involved.

The TQD shall keep informed the complainant and will answer within three months of receiving the complaint.

All records will be kept for at least 7 years. TQD will control, monitoring and closing all complaints, including any corrective and improvement actions.

If the complainant disagrees with the decision taken, he/she can address a reasoned writing to the AENOR General Manager, who will give a definitive answer.

Finally, as required by the complainant, the names of the AENOR personnel involved in the complaint resolution process will be provided.

12.2 Appeals

AENOR will follow the provisions in the General Rules for the Certification Commission, to deal with the appeals received for the EXCiPACT™ certification process. This document will be provided on request.

Where the appeal cannot be resolved to the satisfaction of the client, the appeal shall be escalated to EXCiPACT™.

Formal notice shall be given to the petitioner at the closure for the appeal by AENOR. If not satisfied, the petitioner can appeal to EXCiPACT™ whose decision is final.

AENOR, together with the appellant, shall determine the extent to which the appeal and resolution is made public. If not satisfied with the appeal resolution process or decision, the appellant can raise the matter to EXCiPACT™ whose decision is final.

EXCiPACT™ shall be notified of all appeals received from the clients concerning the EXCiPACT™ certification scheme, and their customers.

In exceptional cases, EXCiPACT™ may require AENOR to cease providing services to the auditee.

13 AENOR ACCREDITATION

In the case of suspension or withdrawal of AENOR's accreditation to perform EXCiPACT™ audits, the certificates of affected clients will be suspended *ipso facto* six months from the date of suspension or withdrawal of AENOR's accreditation.

In this case, certified clients will be informed by AENOR within 30 days of suspension or withdrawal of AENOR's accreditation. The clients must find another EXCiPACT™ certification body within the next six months in order to keep their certificate valid.