Quality System & GMP Certificates

质量体系与 GMP 证书

Certificates, licences, registrations, manufacturing sites and the audit pathway.
证书、许可证、注册、生产场地与审计通道。

TEMPLATE / 模板. This document is a formatted template prepared for the Unibest excipient range. Fields marked **[to be confirmed]** must be completed from the manufacturing site's stamped originals, and every declaration or certificate must be issued and signed by the manufacturing site before this pack is sent to a customer.
模板说明。本文件为 Unibest 辅料产品线的标准格式模板。标注 **[待确认]** 的字段须由生产场地盖章原件补齐；凡属声明或证书性质的文件， 必须由生产场地出具并签章后，方可对外提供。

Product 产品	Polyethylene Oxide (PEO) · Benzalkonium Chloride (BKC) · Trehalose Dihydrate, injectable grade 聚环氧乙烷 · 苯扎氯铵 · 海藻糖二水合物（注射级）
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1 Certificates, licences and registrations 证书、许可证与注册

Item 项目	Issuing body 出具机构	Reference no. 编号	Validity 有效期	Status 状态
Excipient GMP certificate (Excipact) 药用辅料 GMP 证书（Excipact）	SGS	**[to be confirmed]**	**[to be confirmed]**	Pending 待提供
Drug manufacturing licence 药品生产许可证	Provincial MPA 省级药品监督管理局	**[to be confirmed]**	**[to be confirmed]**	Pending 待提供
NMPA registration / platform filing NMPA 注册 / 登记平台登记	NMPA / CDE	**[to be confirmed]**	**[to be confirmed]**	Pending 待提供
ISO 9001 certificate ISO 9001 证书	**[to be confirmed]**	**[to be confirmed]**	**[to be confirmed]**	If held 如有
Business licence 营业执照	Administration for Market Regulation 市场监督管理局	**[to be confirmed]**	**[to be confirmed]**	Pending 待提供

Certificates are supplied as colour scans of the signed originals, with the validity period visible. Where a certificate is issued in Chinese, a notarised or company-certified English translation is supplied with it.
证书以签章原件彩色扫描件提供，须可见有效期。中文证书同时提供经公证或企业盖章的英文译本。

2 Manufacturing sites and scope 生产场地与范围

Product 产品	Site 生产场地	GMP status GMP 状态	Scope 覆盖范围
PEO 聚环氧乙烷	[to be confirmed] （中方工厂名称与地址）	Excipact GMP	聚合、干燥、粉碎、包装
BKC 苯扎氯铵	[to be confirmed]	NMPA registered	合成、配制（50% 溶液）、包装
Trehalose Dihydrate 海藻糖二水合物	[to be confirmed]	NMPA registered	精制、结晶、干燥、内包装

3 Quality management system 质量管理体系

Basis 体系依据	ICH Q7 · Excipact (NSF/IPEC-PQRI) · current ChP general chapters on excipients ICH Q7 · Excipact · 现行中国药典辅料通则
Batch traceability 批追溯	Batch production records and QC records retained and traceable from raw material to released batch. 批生产记录与检验记录完整保存，可从原料追溯至放行批次。
Change control 变更控制	Customer notification before implementation of any change affecting specification, method, site, process or packaging. 凡影响质量标准、方法、场地、工艺或包装的变更，实施前通知客户。
Deviation, OOS and complaints 偏差、OOS 与投诉	Documented investigation with root-cause analysis and CAPA; outcome shared with affected customers on request. 书面调查，含根本原因分析与纠正预防措施；结果可依客户要求共享。
Retention samples 留样	Retained for the shelf life of the batch, or as required by the applicable regulation. 留样保存至该批次有效期末，或按适用法规要求执行。
Subcontracting 委托生产	[to be confirmed] — any subcontracted step is disclosed and audited. 凡委托工序均予披露并接受审计。

4 Supplier qualification and audit 供应商审核与现场审计

Activity 事项	Lead time 周期	Note 说明
Written supplier questionnaire 书面供应商问卷	收到问卷后 5 个工作日内	Customer template accepted; completed and signed by the site QA. 可使用客户模板，由工厂 QA 填写并签章。
Confidentiality agreement 保密协议	2 – 5 个工作日	Either party's template, or a mutual CDA. 可用任一方模板，或签署双向保密协议。
On-site audit 现场审计	协商确定，通常 4 – 8 周	Welcomed. Agenda, participant list and site access arranged in advance. 欢迎审计。议程、参与人员与进厂安排提前协商。

Activity 事项	Lead time 周期	Note 说明
Remote / desktop audit 远程审计	1 – 2 周	Document review by video conference, with batch records shown live. 视频会议方式审核文件，可实时展示批记录。

Note on excipient audits 辅料审计说明

For excipients, a documented written supplier questionnaire is accepted in most cases in place of an on-site audit; site audits are mandatory mainly for active pharmaceutical ingredients. State your requirement and we will match it.
对辅料而言，多数情况下可用书面供应商问卷替代现场审计；现场审计主要为原料药的强制要求。请告知贵司要求，我们按此安排。

5 Declaration and sign-off 声明与签章

The information in this document is issued by the manufacturing site. Certificates are complete and unaltered; no page has been removed or modified.
本文件信息由生产场地出具。证书完整、未作修改，无删页或改动。

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