

Regulatory & Compendial Compliance

法规与药典符合性

DMF and filing status by market, compendial compliance statements and the regulatory support we provide.

各市场 DMF 与备案状态、药典符合性声明，以及我们提供的法规支持。

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.

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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 Regulatory filing status by market 各市场注册备案状态

Market 市场	Filing type 备案类型	Status 状态	Letter of access 授权信
China 中国	NMPA 辅料登记平台登记	[to be confirmed]	可出具
United States 美国	FDA DMF (辅料通常为 Type IV)	[to be confirmed]	可出具，用于客户 ANDA / NDA 引用
European Union 欧盟	辅料无 CEP；以药典符合性声明 + 供应商资料支持	[to be confirmed]	可按需出具合规声明
Japan 日本	MF 或药典符合性资料	[to be confirmed]	可出具
Korea 韩国	MF / 药典符合性资料	[to be confirmed]	可出具
Brazil 巴西	ANVISA 辅料资料支持	[to be confirmed]	可出具
India 印度	CDSCO 资料支持	[to be confirmed]	可出具

Regulatory expectations differ by market and by route of administration. Confirm the filing route with your regulatory affairs team before submission; we will supply the corresponding document set.

各市场的法规要求因给药途径而不同。提交前请与贵司注册部门确认申报路径，我们据此提供对应文件组合。

2 Compendial compliance statement 药典符合性声明

We confirm that the grades listed below are manufactured and released in accordance with the current editions of the pharmacopoeial monographs stated, and that the certificate of analysis for each batch reports the results obtained by the methods of those monographs.

兹确认：下列型号按所述药典正文的现行版本生产与放行，每批检验报告均按该药典方法出具结果。

Product 产品	USP-NF	EP / Ph. Eur.	JP	ChP
PEO	Complies 符合	Complies 符合	按需	Complies 符合
BKC	Complies 符合	Complies 符合	Complies 符合	Complies 符合
Trehalose Dihydrate	Complies 符合	Complies 符合	Complies 符合	Complies 符合
Editions applied 适用版本	[to be confirmed] (现行版本，如 USP-NF 2026、Ph. Eur. 12th Edition、ChP 2025)			
Statement reference 声明编号	[to be confirmed]			
Re-issue policy 换版政策	药典换版后 3 个月内完成符合性复核并重新出具声明			

3 Regulatory support we provide 我们提供的法规支持

Support 支持事项	Detail 说明
Letter of access 授权信	Issued to the customer or to the authority, for DMF or MF referencing. 向客户或监管机构出具，用于 DMF / MF 引用。
Regulatory questionnaire 法规问卷	Completion of customer templates, including excipient qualification questionnaires. 可填写客户模板，含辅料资质问卷。
Change notification 变更通知	Prior notice 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，事前通知。
Samples for verification 方法验证样品	Samples provided for customer method verification and comparability studies. 提供样品用于客户方法验证与可比性研究。
Statements 专项声明	GMO-free, Halal, Kosher, allergen, vegan, latex-free, REACH SVHC, Proposition 65 — see document 09. 无转基因、Halal、Kosher、过敏原、纯素、无乳胶、REACH SVHC、加州 65 号提案 —— 见文件 09。
Authorities 官方答复	Support for authority questions arising during review, through the customer's licensing route. 在客户申报路径下，协助答复审评过程中的官方提问。

Note 说明

Filing status, DMF numbers and letter-of-access availability are confirmed per product and per market by the manufacturing site. Where a filing does not yet exist, the timeline for opening one is confirmed in writing.

备案状态、DMF 编号与授权信可出具性由生产场地按产品与市场确认。尚未备案的，备案周期以书面形式确认。

Prepared by 编制	Name 姓名:	Signature 签名:	Date 日期:
Checked by 审核	Name 姓名:	Signature 签名:	Date 日期:
Approved by 批准 (QA)	Name 姓名:	Signature 签名:	Date 日期:

Signed by the manufacturing site 由生产场地签章 · Company chop required on the released version 正式版须加盖企业公章