Batch Consistency & Stability

批间一致性与稳定性

Consecutive batch results and the long-term / accelerated stability programme.
连续批次数据与长期、加速稳定性方案。

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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 Batch-to-batch consistency 批间一致性

Three consecutive commercial batches are reported as standard. Additional batches from the previous twelve months are available on request. Results are reported against the released specification, and the batch numbers are stated so that a reviewer can cross-check them against the corresponding certificates of analysis.
默认提供连续三个商业化批次的数据；如需更多批次，可提供近十二个月内的批记录摘要。 结果按正式质量标准报告，并标明批号，便于审评人员与对应 CoA 交叉核对。

Parameter 项目	Specification 限度	Batch 1	Batch 2	Batch 3
Appearance 性状	按质量标准			
Identification 鉴别	符合			
Dynamic viscosity 动力黏度	按型号			
Molecular weight 分子量	按型号			
Water content 水分	NMT [ ]%			
pH	按质量标准			
Assay 含量	NLT [ ]%			

Parameter 项目	Specification 限度	Batch 1	Batch 2	Batch 3
Microbial limits 微生物限度	按质量标准			
Product 产品	[to be confirmed]			
Grade 型号	[to be confirmed]			
Batch numbers 批号	[to be confirmed]			
Manufacturing site 生产场地	[to be confirmed]			
Conclusion 结论	[to be confirmed] （批间一致性评价：符合 / 不符合）			

2 Stability programme 稳定性研究方案

Study 研究	Condition 条件	Timepoints 取样点	Purpose 目的
Long term 长期	30 °C / 65% RH （或 25 °C / 60% RH）	0, 3, 6, 9, 12, 18, 24, 36 个月	Supports the retest period or shelf life 支持复验期或有效期
Accelerated 加速	40 °C / 75% RH	0, 1, 2, 3, 6 个月	Short-term excursions and change assessment 短期偏离评估与变更支持
Intermediate 中间	30 °C / 65% RH	0, 6, 9, 12 个月	Applied where significant change occurs at accelerated condition 加速条件下发生显著变化时启用
Stress 强制	高温、高湿、光照	按需	Support for method development and packaging assessment 支持方法开发与包材评估

Programme designed to ICH Q1A(R2) and evaluated to ICH Q1E. Container closure: the marketed pack, stored upright. 方案依据 ICH Q1A(R2) 设计，按 ICH Q1E 评估；样品以市售包装直立存放。

Stability summary table 稳定性数据汇总（模板）

Parameter 项目	Months 月							
Appearance 性状	0	3	6	9	12	18	24	36
Assay 含量	0	3	6	9	12	18	24	36
Water content 水分	0	3	6	9	12	18	24	36
pH	0	3	6	9	12	18	24	36
Viscosity 黏度	0	3	6	9	12	18	24	36
Microbial limits 微生物限度	0	3	6	9	12	18	24	36

Values are entered from the stability study reports of the specific grade. Data are reported at the study condition shown above the table (long term and accelerated are presented separately).
数据摘自具体型号的稳定性研究报告；长期与加速条件数据分别列表呈现。

3 Retest period and shelf life 复验期与有效期

PEO	**[to be confirmed]** （建议：以长期稳定性数据支持的复验期）
BKC powder 粉末	**[to be confirmed]**
BKC 50% solution 溶液	**[to be confirmed]**
Trehalose Dihydrate	**[to be confirmed]**
Extrapolation basis 外推依据	ICH Q1E ；如未经外推，以实测数据为准

Ongoing and commitment 持续稳定与承诺

At least one batch per year per grade is placed on the ongoing stability programme. Any out-of-specification result on stability triggers an investigation and, where relevant, notification to affected customers.
每个型号每年至少一批进入持续稳定性考察。稳定性结果超标时启动调查，并在必要时通知受影响客户。

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