

Polyethylene Oxide — Technical Data Sheet

聚环氧乙烷 —— 技术数据表

Grades, viscosity, applications, handling and regulatory support.

型号、黏度、应用、操作与法规支持。

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Product 产品	Polyethylene Oxide (PEO) 聚环氧乙烷
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1 Product profile 产品概况

Chemical name 化学名称	Polyethylene Oxide 聚环氧乙烷 · Macrogols, high molecular mass 高分子量聚乙二醇
CAS No.	25322-68-3
Function 功能	Thermoplastic polymer with a fast hydration rate; forms a hydrogel rapidly. Supports modified-release formulations, tablet binding and mucoadhesion. 热塑性高分子，水合速率快，可迅速形成水凝胶。适用于缓控释制剂、片剂黏合与黏膜黏附给药系统。
Appearance 性状	White to off-white, free-flowing powder 白色至类白色自由流动粉末
Solubility 溶解性	Freely soluble in water 易溶于水
Standards 质量标准	Current USP-NF · EP · ChP
Grades 规格	10 grades, 100,000 – 7,000,000 MW

2 Grades and grade matching 型号与对标

Grade 型号	MW 分子量	Viscosity (mPa·s) 黏度	Test solution 测定液	Dow	Sumitomo
PEO-10	100,000	12 – 50	30 g / (570 + 125) mL	WSR N-10	PEO-1

Grade 型号	MW 分子量	Viscosity (mPa·s) 黏度	Test solution 测定液	Dow	Sumitomo
PEO-20	200,000	65 – 115	30 g / (570 + 125) mL	WSR N-80	PEO-1
PEO-40	400,000	2,250 – 4,500	30 g / (570 + 125) mL	WSR N-3000	—
PEO-60	600,000	4,500 – 8,800	30 g / (570 + 125) mL	WSR-205	—
PEO-90	900,000	8,800 – 17,600	30 g / (570 + 125) mL	WSR-1105	—
PEO-100	1,000,000	400 – 800	12 g / (588 + 125) mL	WSR N-12K	PEO-3
PEO-200	2,000,000	2,000 – 4,000	12 g / (588 + 125) mL	WSR N-60K	PEO-8NF
PEO-400	4,000,000	1,650 – 5,500	6 g / (594 + 125) mL	WSR-301	PEO-15
PEO-500	5,000,000	5,500 – 7,500	6 g / (594 + 125) mL	WSR Coagulant	PEO-18
PEO-700	7,000,000	7,500 – 10,000	6 g / (594 + 125) mL	WSR-303	PEO-20NF

Solvent: carbon-dioxide-free water + isopropyl alcohol, expressed as (water + IPA) mL. Grade correspondence is indicative and based on molecular-weight and viscosity equivalence; confirm against your own dissolution profile before filing. 溶剂为无二氧化碳水 + 异丙醇；型号对应为指示性对照，正式变更前请以自有溶出曲线确认。

3 Applications 应用

Application 应用	Role of PEO PEO 的作用
Hydrophilic matrix ER tablets 亲水骨架缓释片	Forms a gel barrier on the tablet surface controlling the release rate 在片剂表面形成凝胶屏障，控制释放速率
Push-pull osmotic pump (PPOP) 推拉式渗透泵	High-MW grade as the bulking agent in the push layer; zero-order release 高分子量规格用作推动层膨胀剂，实现零级释放
Drug-layer suspending agent 药层助悬剂	Maintains uniform drug dispersion 维持药物均匀分散
Tablet binder / mucoadhesive 片剂黏合 / 黏膜黏附	Low to medium MW grades 中低分子量规格适用

4 Handling, packaging and storage 操作、包装与贮存

Standard pack 标准包装	[to be confirmed] (建议：25 kg 纸板桶，内衬双层聚乙烯袋)
Storage 贮存	Keep in the original sealed container, protected from light, in a cool dry place; recommended below 30 °C. 原包装密封、避光、阴凉干燥处，建议 30 °C 以下。
Handling 操作	Avoid dust generation; use local exhaust ventilation and suitable protective equipment.

避免扬尘，使用局部排风与适当防护装备。

Retest period 复验期	[to be confirmed]
Shelf life 有效期	见 CoA 与正式质量标准

5 Regulatory support and documents 法规支持与文件

Quality system 质量体系	Excipact GMP certificate issued by SGS; manufacturer registered with NMPA; China DMF filed SGS 签发 Excipact GMP 证书；生产企业在 NMPA 注册；已递交中国 DMF
Documents 文件	CoA per batch · specification · analytical methods · safety statements · impurity control · compendial compliance · batch and stability data 每批 CoA · 质量标准 · 分析方法 · 安全性声明 · 杂质控制 · 药典符合性 · 批间与稳定性数据
Technical support 技术支持	Grade selection and dissolution profiling support included 含型号选择与溶出曲线研究支持
Audit 审计	Site audit welcomed; written supplier questionnaire accepted in most cases 欢迎现场审计；多数情况可先以书面问卷评估

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