

Benzalkonium Chloride — Technical Data Sheet

苯扎氯铵 —— 技术数据表

Supply forms, use levels by route, handling and regulatory support.

供应形态、各给药途径用量、操作与法规支持。

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Product 产品	Benzalkonium Chloride (BKC) 苯扎氯铵
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1 Product profile 产品概况

Chemical name 化学名称	Benzalkonium Chloride 苯扎氯铵 · Alkylbenzyldimethylammonium chloride (ADBAC)
CAS No.	8001-54-5
Function 功能	Quaternary ammonium cationic surfactant with broad-spectrum antimicrobial activity against bacteria, fungi and enveloped viruses. The most widely used preservative in multi-dose ophthalmic and nasal formulations. 季铵盐类阳离子表面活性剂，对细菌、真菌与包膜病毒具广谱抗菌活性，是多剂量滴眼剂与鼻用制剂中最常用的抑菌剂。
Appearance 性状	White to yellowish-white powder or gelatinous fragments; also supplied as a 50% solution 白色至类黄白色粉末或胶状碎块；亦可提供 50% 溶液
Solubility 溶解性	Freely soluble in water, ethanol and acetone 易溶于水、乙醇与丙酮
Standards 质量标准	Current EP · USP · JP · ChP
Grade 级别	Excipient grade 辅料级 · API grade 原料药级

2 Supply forms 供应形态

Form 形态	Characteristics 特性	Compliance 符合标准
Powder 粉末	White to yellowish-white powder or gelatinous fragments; hygroscopic — store in tight containers, protected from light 白色至类黄白色粉末或胶状碎块；具吸湿性，需密闭避光保存	EP / USP / JP / ChP
50% solution 溶液	Clear, colourless to slightly yellow aqueous solution; ready-to-use concentrate for easy handling and accurate dosing 澄清、无色至微黄色水溶液；即用型浓缩液，便于操作与准确计量	EP / USP / JP / ChP
Custom solution 定制溶液	Prepared to the customer's solution specification 按客户指定的溶液规格配制	符合客户要求

3 Typical use levels by route 各给药途经常用量

Route 给药途径	Typical level 常用量	Note 说明
Ophthalmic 眼科	0.001 – 0.025% w/w	Preservative in multi-dose eye drops 多剂量滴眼剂抑菌剂
Nasal 鼻用	0.005 – 0.1% w/w	Preservative in nasal sprays 鼻喷剂抑菌剂
Otic 耳用	0.005 – 0.1% w/w	Preservative in ear drops 滴耳剂抑菌剂
Small-volume injectables 小容量注射剂	~0.01%	注射剂抑菌剂
Antiseptics / disinfectants 消毒防腐	按成品处方	API grade 原料药级

Use levels are indicative and quoted from the product literature. Confirm against the applicable regulation and the approved formulation for each market. 用量为产品资料中的指示性数据，请结合适用法规与已批准处方确认。

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

Standard pack 标准包装	Powder: [to be confirmed] (建议：25 kg 纸板桶，内衬双层聚乙烯袋) 50% solution: [to be confirmed] (建议：200 L 塑料桶或 IBC)
Storage 贮存	Keep in the original sealed container, protected from light, protected from moisture and freezing. 原包装密闭、避光、防潮、防冻。
Handling 操作	Avoid contact with skin and eyes; concentrated solutions are irritant. Use protective equipment. 避免皮肤与眼睛接触；浓缩液具刺激性，请使用防护装备。
Retest period 复验期	[to be confirmed]

5 Regulatory support and documents 法规支持与文件

Quality system 质量体系	GMP compliant; the manufacturer is registered with NMPA GMP 合规；生产企业已在 NMPA 完成注册
DMF 备案	DMF support available according to the target market and route 可根据目标市场与给药途径提供 DMF 支持
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
Audit 审计	Site audit welcomed; written supplier questionnaire available first 欢迎现场审计；可先提供书面供应商问卷

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