Pharmaceutical Quats

Highest regulatory compliance on the market for quaternary ammonium compounds (Quats)

Our pharmaceutical grade Quats are manufactured in accordance with cGMP Guide ICH Q7 for Active Pharmaceutical Ingredients, the highest available quality standard.
We offer full compliance with multicompendial pharmacopoeias, including substance monographs, and relevant general chapters and notices in:

- Ph.Eur.
- USP/NF
- JP
- BP

Our pharmaceutical Quats are used in many different drug products approved by regulatory bodies worldwide. Novo Nordisk Pharmatech is regularly audited by major and minor pharmaceutical companies, as well as health authorities. We adhere to the highest levels of manufacturing quality:

- Manufacture in accordance with cGMP (ICH Q7)
- FDA inspected
- ISO 9001 certified
- Qualified & validated manufacturing and analytical processes
- Adhering to all relevant ICH Quality guidelines:
  - Q1A Stability
  - Q2 Analytical validation
  - Q3A / Impurities in new drug substances/ Q3C Residual Solvents / Q3D Elemental Impurities
  - Q6A Specifications
  - Q4B Sulphated Ash/Microbiological examination of non-sterile products
  - Q8 Pharmaceutical Development
  - Q9 Quality Risk Management
  - Q10 Pharmaceutical Quality System
  - Q11 Development and Manufacture of Drug Substances
  - Q12 Lifecycle management
- Registered as "Known Consignor"
- Compliant with the EU Guidelines 2015/C95/01 on Good Distribution Practices for APIs
- REACH compliant: All relevant products pre-registered with ECHA in 2008. Lead Registrant for FeF® Cetrimide and FeF® CTAB (registered in 2013). FeF® Benzalkonium Chloride to be registered in 2018
- Environment and safety: DS/EN ISO 14001 and OHSAS 18001 certified. We also follow Novo Nordisk CO2 Reduction program and People Policy
- "Triple Bottom Line:" We follow the Novo Nordisk business principle for conducting our activities in a Financially, Environmentally and Socially responsible way

Comprehensive documentation and services:

- cGMP certificate
- ISO 9001, ISO 14001 and OHSAS 18001 Certificates
- Certificate of Analysis (current version of pharmacopoeias)
- Customer audits
- Declarations, statements (stability, residual solvents, TSE/BSE, GMO, allergens, environment, etc.)
- Change Notification
- Answering of questionnaires
- Process flowchart
- Packaging details
- Certificates of Suitability (CEP) and European Active Substance Master File (ASMF)

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