



Pharmacopoeia sodium chloride pyrogen free

Active pharmaceutical ingredients:

- dosage forms for enteral and parenteral nutrition (infusions)
- peritoneal dialysis solutions
- pharmaceutical applications (eye drops ...)

esco API-NaCl is manufactured according to Q7A guidelines for Industry, Good Manufacturing Practice (GMP) Guidance for Active Pharmaceutical Ingredients (API).

Scope of the GMP inspection:

- Quality system, manufacturing and quality control operations

Inspections:

- AFSSAPS (French Health Products Safety Agency)
- Bezirksregierung Düsseldorf (German Health Authorities)

esco - european salt company is the leading pharmaceutical sodium chloride supplier of major international pharmaceutical companies in Europe and exports significant volumes to Africa, Middle East, Asia, South America.

We offer premium grade pharmacopoeia sodium chloride for pharmaceutical applications where the highest quality standards must be maintained.

esco pharmacopoeia sodium chloride is manufactured using the vacuum process method from a special and high purity brine and consists of purest vacuum salt. It contains no additives.

- Directive 2004/27/EC (amending Directive 2001/83/EC) – October 30th 2005 – demands from pharmaceutical companies manufacturing APIs to rigorously select starting materials suppliers who guarantee GMP compliance.
- esco API-NaCl has been developed in regard to the requirements of API manufacturers in accordance with Directive 2004/27/EC. All steps of production, analysis and control comply with the strict principles of GMP, which guarantee highest reliability and security for your products and customers.
- esco API-NaCl, pyrogen free is ideal for applications such as enteral and parenteral dosage forms as well as peritoneal dialysis solutions.

API-NaCl product range

esco API-NaCl is packed in special dedicated, clean lines separated from all other salt production lines.

25 kg PE coated paper bags
(1000 kg/EURO pallet)

50 kg PE coated paper bags
(1050 kg/EURO pallet)

1000 kg one way FIBC (EURO pallet)



*API (Active Pharmaceutical Ingredient)

Production

- Manufactured according to ICH Q7A Guidance for APIs
- Manufactured and tested according to the latest versions of the European, American and Japanese pharmacopoeia (other pharmacopoeias on request)
- Produced in strict batch lots

Analysis

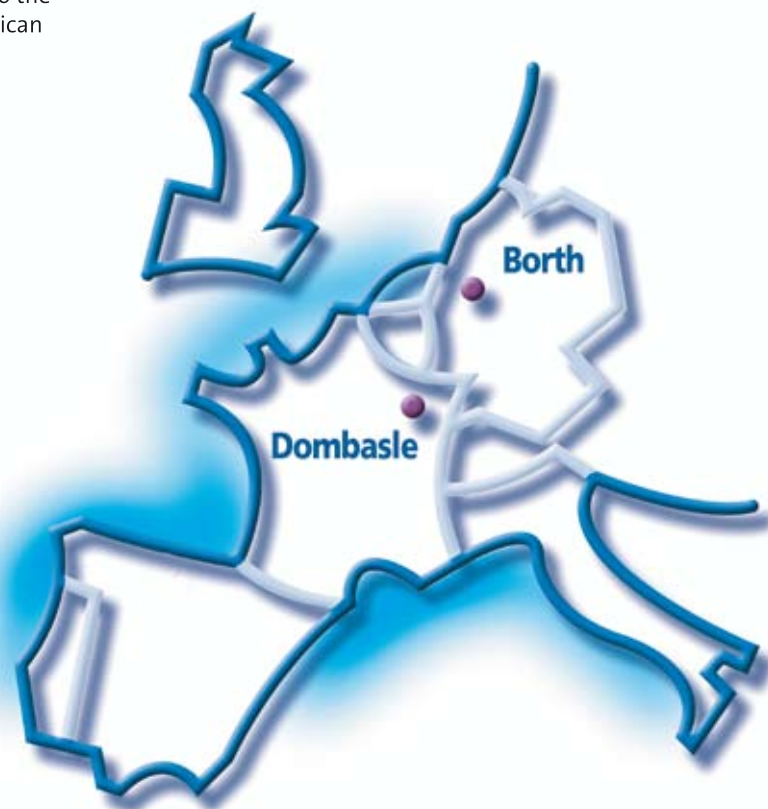
- Batch tested
- Certificate of analysis provided with each lot

Quality control

- Full traceability system
- Quality system conforms to ICH Q7A Guidance for APIs and ISO 9001, application of the HACCP System according to Codex Alimentarius
- Facilities regularly audited by major pharmaceutical companies and external experts
- Facilities audited by Public Authorities (GMP certificates available on request):
 - AFSSAPS (French Health Products Safety Agency)
 - Bezirksregierung Düsseldorf (German Health Authorities)

API-NaCl production sites

2 sites in the heart of Europe
guarantee high reliability.
Exports from Antwerp / Hamburg harbors.



Additional information available on our technical data sheet.

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