CTAB USP/NF for vaccine downstream processing

Manage risks in downstream vaccine purification

CTAB stands for "Cetyl Trimethyl Ammonium Bromide" and can also be called Hexadecyl trimethyl ammonium bromide or Cetrimonium Bromide. It is a powerful cationic surfactant for use in vaccine downstream purification steps. It is recommended by the WHO[1) 2)] for the precipitation of polysaccharide-based bacterial vaccines.

CTAB is also used as a purification agent of viral antigens, whether the vaccine is egg-based, cell-based or recombinant (DNA).

Whether you are manufacturing bacterial or viral vaccines, you want to minimize risks in your process by only using the purest and safest ingredients and materials.

Utilizing cGMP manufactured, pharma grade ingredients and processing aids can help you secure your vaccine production and minimize your risks.

Novo Nordisk Pharmatech's CTAB is used by many of the world's leading vaccine producers, as we are the only manufacturer offering CTAB in cGMP pharmaceutical grade for APIs, in full compliance with ICH Q7.

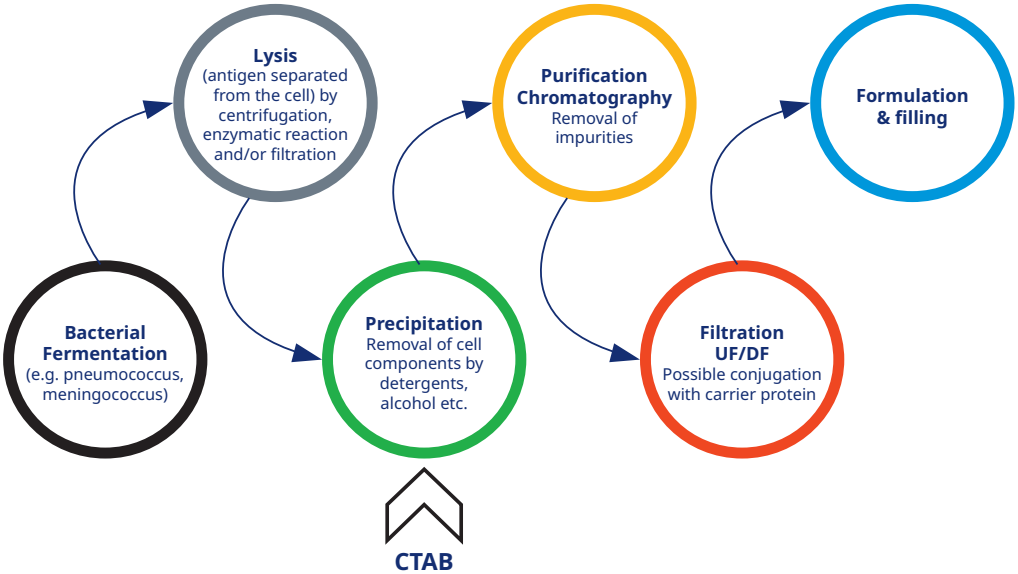
This means:

- Original manufacturer with full traceability
- High product purity
- Full USP/NF compliance
- Audit access
- Full regulatory documentation package
- Manufactured under fully validated processes

Process steps

CTAB can be used in the process steps illustrated below:

ProccPolysaccharide-based vaccine manufacturing (simplified)



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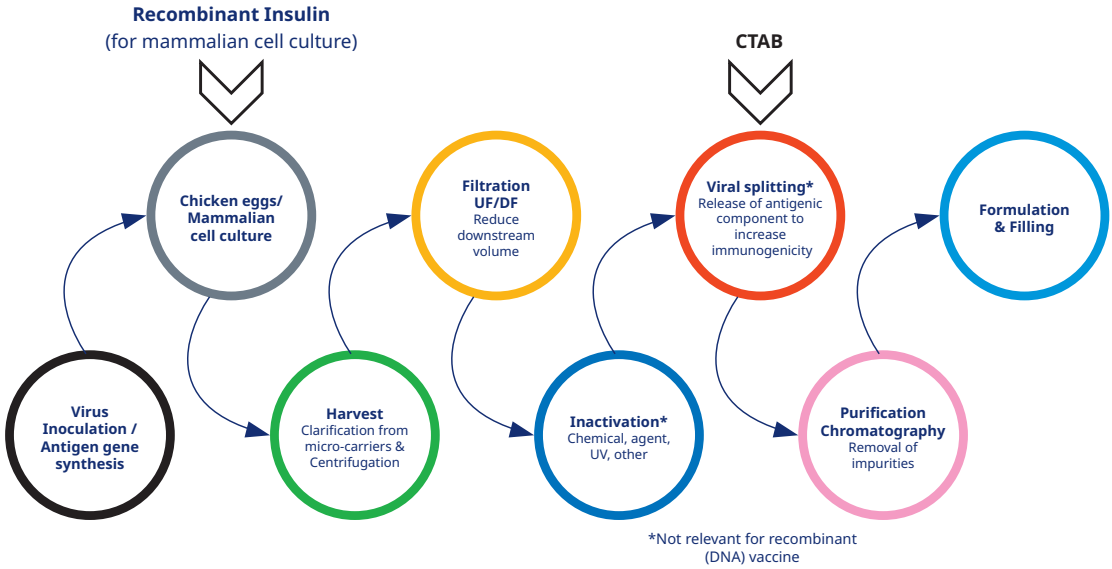
Viral vaccine manufacturing at a glance



Sub unit isolation can be done using a mixture of Tween 80 with CTAB, to separate RNP (Ribonucleoprotein) particles from the surface antigen proteins by centrifugation.

Highest market standards

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

- Manufacture in accordance with cGMP (ICH Q7)
- ISO 9001 certified
- Qualified & validated manufacturing and analytical processes
- Adhering to all relevant ICH Quality guidelines (Q1A, Q2, Q3A, Q3C, Q3D, Q6A, Q8, Q9, Q10, Q11)
- Registered as "Known Consignor"
- Compliant with the EU Guidelines 2015/C95/01 on Good Distribution Practices for APIs
- REACH registered with ECHA
- Environment and safety: DS/EN ISO 14001 and 45001 certified.

Novo Nordisk Pharmatech A/S has more than 70 years' experience in manufacturing Quats. We are part of Novo Nordisk, a Danish healthcare company and world leader in diabetes care.

We are the leading worldwide supplier of recombinant insulin for cell growth media and pharmaceutical grade quaternary ammonium compounds (Quats) for the pharmaceutical and biopharmaceutical industries.

Contact us for more information.

1) World Health Organization (WHO) Technical Report, Series No. 924, 2004 Annex 2 "Recommendations for the production and control of meningococcal group C conjugate vaccines"

2) Guidelines on the Quality, Safety and Efficacy of Typhoid Conjugate Vaccines" (WHO, 2013)

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