

# Quantitative and qualitative evaluation of mRNA vaccines after sterile filtration

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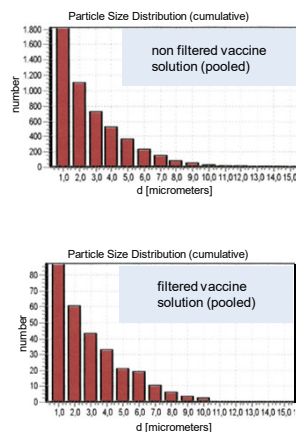
**Background and Importance** The importance of mRNA-based vaccines increased rapidly due to the COVID-19 pandemic. However, little is known on the challenges linked to handling shortages and extended stability of these new type of substance. Since vaccine remnants have to be discarded according to the Summary-of-Product-Characteristics, we hypothesise that sterile filtration after pooling is suitable to save vaccine material for clinical application.

**Aim and Objectives** Aim of the present pilot study was to compare quality parameters of remnants derived from ready-to-use mRNA vaccine solutions before and after sterile filtration. Therefore, we pooled mRNA vaccine solution remnants from Corminaty® vials (BioNTech/Pfizer) and compared particle size, distribution and quantity of the lipoplexes. In addition, quantity and/or quality of the mRNA was determined.

**Results:** After pooling the remnants of the vials we found a substantial increase of particulates >1µm when compared to fresh vaccine samples. This effect was likely due to contamination of the examined probes with particles from ambient air. As expected, all these particulates were eliminated by sterile filtration. Size distribution and concentration of the lipoplexes were comparable between unfiltered and filtered samples. With respect to the mRNA, we identified the fragment of interest in all examined samples. Sterile filtration did not change the concentration, purity and integrity of the mRNA.

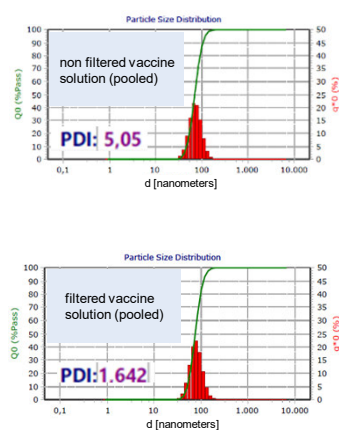
## Micro particulates

Light obscuration



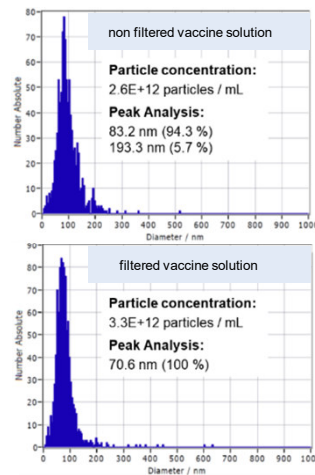
## Nano particulates

Dynamic Light Scattering (DLS)



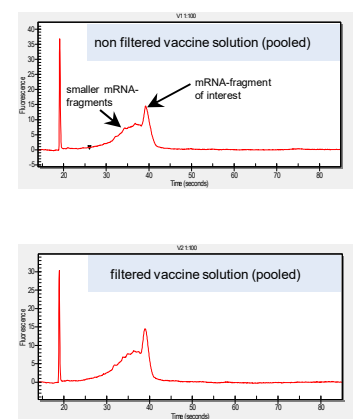
## Nano particulates

Nanoparticle Tracking Analysis (NTA)



## RNA – Analysis

(Capillary Electrophoresis)



**Material and methods:** Measurements of invisible particulates in the range of 1-50µm were performed by light obscuration according to PhEur.10. The size of lipoplexes was measured with nanoparticle tracking (NTA) analysis to determine hydrodynamic diameter and particle concentration. Dynamic light scattering was employed complementarily to the NTA-technique to focus on particle size from 0.3nm-10µm. The concentration, purity and integrity of the mRNA was analysed by UV-spectrophotometry and capillary electrophoresis after mRNA purification.

**Conclusions** Our results indicate that sterile filtration of pooled remnants from Corminaty® vials (BioNTech/Pfizer) eliminates particle contamination from the vaccine solution while the concentration of lipoplex nanoparticles was not altered. Moreover, neither quantity nor quality of the mRNA was affected by the filtration process. The results of our pilot study provide the first data on the stability of mRNA vaccines and help to fill the gap of knowledge when dealing with these substances in hospital pharmacy.