3PC-016 DOES A HOSPITAL COMPRESSOR SYSTEM CONTINUOUSLY DELIVER MEDICINAL AIR ACCORDING TO THE EUROPEAN PHARMACOPOEIA?

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Background and Importance Hospitals in Norway produce medicinal air for patient treatment. The medicinal air is produced by a compressor central and supplied by a pipeline system for patient treatment at the hospital. The quality of the medicinal air is controlled annually according to the European pharmacopoeia. The monograph for medicinal air in the European pharmacopoeia includes tests for O_2, C0, CO_2, SO_2, NO_x, oil and H_2O. Both ambient air composition and components in the compressor central have influence on the medicinal air quality. The time for periodic control may therefore affect the result. There are no publications presenting results from continuous monitoring of hospital produced medicinal air quality.

Aim and Objectives The aim of the study was to confirm that hospital produced medicinal air continuously is safe and in compliance with the European pharmacopoeia. Based on a risk assessment it was chosen to monitor O_2, C0 and H_2O as indicators for air quality. Other test in the European pharmacopoeia was included in the periodic control.

Material and Methods The compressor central is situated in Oslo, about 500 metres from a main road. The components of the compressor central are compressor (*Atlas Copco ZR 75VSD*), pressure tank (*Maskinspecialisten, type B+F*), adsorption dryer (*Atlas Copco, BD185+)*, carbon filter/hopcalite catalyst (*Atlas Copco, QDT HOC 185*) and filters (*Atlas Copco, PDp*). The air quality was monitored downstream the compressor central by detectors for O_2, C0 and H_2O (Kimessa Monoline 504/404 and CS-instruments FA500). The period for monitoring was two weeks to include daily variations.

Results The results from the monitoring complies with the European pharmacopoeia at all times during the test period. Monitoring data: $O_2$20,4 – 21,4%, CO <5 ppm, and H_2O <67 ppm.

Conclusion and Relevance The monitoring data shows that a hospital compressor central is able to continuously deliver medicinal air according to the European pharmacopoeia, even with daily variations in the ambient air quality and compressor system. This is relevant information for pharmacist and technical staff when planning quality control strategies for a compressor central.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-017 IMPACT OF AGITATION ON PEMBROLIZUMAB (KEYTRUDA®) SAFETY AND EFFICACY: AGGREGATION AND FUNCTIONALITY

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Background and Importance Pembrolizumab (Keytruda®) is a human IgG4 monoclonal antibody (mAb) from the group of immunomodulators, which binds to programmed death receptor 1 (PD-1). Given its structural complexity, physical aggregation and chemical degradation can occur throughout its life, and even modest environmental stresses can cause extensive damage which may affect the safety and efficacy of the medicine.[1]

Aim and Objectives To assess the impact of agitation on pembrolizumab (Keytruda®, 25 mg/mL) safety and efficacy through the study of aggregation and functionality when mishandling in real hospital conditions.

Material and Methods Pembrolizumab (Keytruda®, 25 mg/mL) fresh opened vials were used. Agitation stress was carried out in a mechanical laboratory shaker (300 rounds/min, 24h, 25°C) and gentle agitation was performed manually (1 min, 25°C). Aggregation was assessed by Dynamic Light Scattering (DLS) and Size–Exclusion Ultra–High–Performance Liquid Chromatography (SE/UHPLC–UV). Pembrolizumab functionality was evaluated by Enzyme-Linked Immunosorbent Assay (ELISA).

Results Pembrolizumab control sample (25 mg/mL) showed a single particulate population with hydrodynamic diameter (HD) of 9.5 ± 2.8 nm corresponding to pembrolizumab monomers. SE/UHPLC–UV chromatograms of the control sample revealed a main chromatographic peak assigned to pembrolizumab monomers and a small one assigned to native dimers. DLS and SE/UHPLC–UV showed that agitation stress did not promote increase in aggregation. However, pembrolizumab functionality was affected after applying agitation stress since ELISA revealed a significant loss of functionality. As a consequence, a gentle agitation of pembrolizumab was performed in order to investigate if this loss of functionality could also happen in less stressful conditions. As a result, ELISA also revealed a significant loss of functionality in gently agitated pembrolizumab.

Conclusion and Relevance The exposure to agitation stress did not induce aggregate formation in pembrolizumab. Nevertheless, both agitation stress and gentle agitation led to a loss of its functionality not related to agitation. Thus, we recommend preventing pembrolizumab from agitation when handling in hospitals.

REFERENCE

1. M.R. Nejadnik et al. J.Pharm.Sc.107(2018)2013-2019.

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3PC-018 TIME TO AVAILABILITY OF INJECTABLE ANTICANCER DRUGS FOR OUTPATIENTS: REASSESSMENT IN A FRENCH COMPREHENSIVE CANCER CENTRE

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