



To Whom It May Concern

Dato: 25.06.2018

Certificate of Compliance and Release

EudraCT no: 2017-003829-15
Trial Reference Code AID-ICU
Product: Haloperidol 5 mg/mL / Placebo
Lot Number 8203431
Date of Expiry 05-2020

Rawmaterial	Lotnumber	Expiry
Sodium Chloride 0,9 % 1 mL ampule	202821	05-2020
Serenase (Haloperidol) 5 mg/mL 1 mL ampule	V25B	01-08-2022

The Trial medicine consists of two groups: 1) Serenase (Janssen CILAG) - an already marketed, non-manipulated or otherwise changed product purchased and paid for by CRIC, and ordered by the Capital Hospital Pharmacy's department for purchases, delivered by a Danish distributor of the product, and 2) corresponding ampoules with isotonic sodium chloride manufactured by the Capital Hospital Pharmacy. Both products are relabeled and labeled, respectively, to ensure a blinding of the trial medicine.

The medicine is delivered to the clinical sites at hospitals/hospital pharmacies by an international courier provider, and transported under temperature controlled conditions.

It is hereby certified, that all procedures in the production, packaging, labelling and quality control of this product is performed in accordance with the requirements of current Danish legislation and EU GMP-guidelines.

It is also certified, that this batch complies with the requirements of Article 13.3 a of Directive 2001/20/EC "

The quality management is under responsibility of the qualified person:
Else Skamriis, Head of Quality, QP, MSc (Pharm)

The product is released by delegated QP

Date: 25-06-2018

Sign: *Edyta Bonni Opri*

Example batch numbers may vary