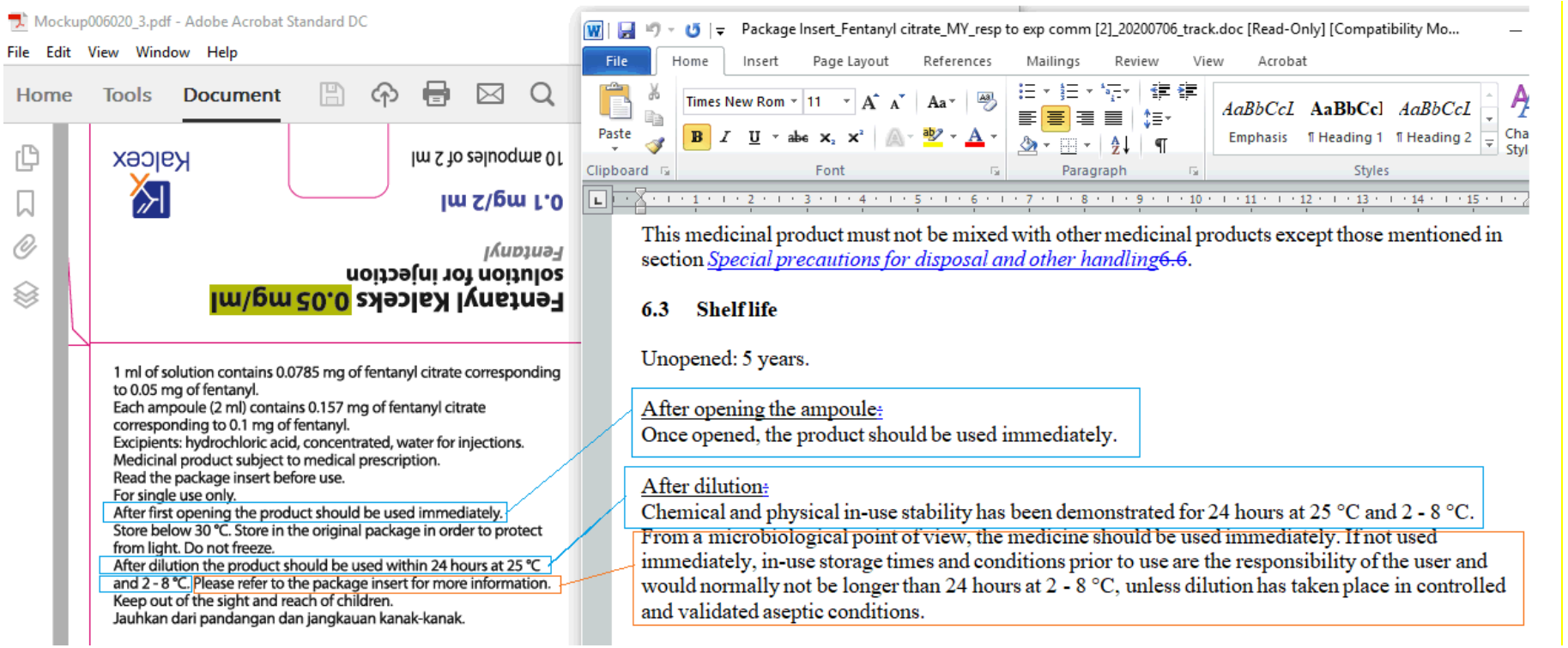
D2 Outer Label

The in-use storage condition is different from A20. Please clarify on the storage condition (25celcius or 2-8 celcius). According to SMPC from emc reference and other registered product, the storage condition is at 2-8 celcius.

Response: The storage conditions in section A20 and section D2 Outer Label are the same.
Please refer to submitted section A20 and section D2 Outer Label.
The Outer Label has been updated adding “Ubat Terkawal”. Please refer to updated Outer Label.



We reviewed the Package Insert for FENTANYL-HAMELN 50 MCG/ML INJECTION, FENTANYL-PIRAMAL and Fentanyl 50 micrograms/ml Solution for infusion that are registered in MY and based on the storage conditions for in-use determined in the Package Insert of these drug products. Please see below the summary of storage conditions for in-use of above mentioned drug products:

Drug product name	MAH	Storage conditions for in-use
Fentanyl 50 micrograms/ml Solution for infusion	MAH Mercury Pharmaceuticals Limited	**6.6 Special precautions for disposal and other handling** The injection is for single patient use and should be used immediately after opening. The injection should not be used if particles are present. Any unused portion should be discarded. Fentanyl for infusion may be prepared by dilution with infusion fluids containing 5% glucose or 0.9% sodium chloride. Fentanyl 5 microgram/ml in 5% glucose or 0.9% sodium chloride exhibited no loss due to sorption to PVC infusion solution containers. Chemical and physical in-use stability of the diluted product has been demonstrated for 48 hours at 25°C and at 2 - 8°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours at 2 - 8°C, unless dilution has taken place in controlled and validated aseptic conditions.
FENTANYL-PRIMAL	DKSH MALAYSIA SDN BHD	**Incompatibilities** The injectable solution must not be mixed with other products. If desired, FENTANYL-PIRAMAL may be mixed with sodium chloride or glucose intravenous infusions. Such dilutions are compatible with plastic infusion sets. These should be used within 24 hours of preparation.
FENTANYL-HAMELN50MCG/ML INJECTION	IDAMAN PHARMA SDN. BHD.	**6.4. Special precautions for storage** Keep the vial/ ampoules in the outer carton Chemical and physical in-use stability has been demonstrated for 24 hours at 20-25°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C, unless dilution has taken place in controlled validated aseptic conditions.

The storage conditions for in-use of Fentanyl Kalceks 0.05 mg/ml solution for injection have been determined based on the in-use stability study at release and at the end of shelf-life. The both studies have been submitted to NPRA (doc: P8 In use stability data (infusions) 0520, P8 In use stability data (end of shelf life) 0520). The results of both studies confirm to the in-use specification requirements at 25'C and 2-8'C during 48 h.