

V12. COLLABORATIVE STUDY AMONG BIO-MANGUINHOS/ FIOCRUZ, PATH AND WHO USING YELLOW FEVER VACCINES IN A CONTROLLED TEMPERATURE CHAIN.

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INTRODUCTION The live attenuated Yellow Fever (YF) vaccine is used for active immunization in adults and children. This vaccine is freeze-dried and should be stored at 2-8°C. It is reconstituted with diluent (water for injection) stored at 15-30°C and 24 hours before use should be kept at 2-8°C.

OBJECTIVE The present study aims to assess the feasibility to use YF vaccines in a controlled temperature chain (CTC), defined as the temperature out of 2-8°C range, which can occur in the field, but shouldn't exceed 40°C. The study was conducted at 40°C using 5 and 10 doses vaccines and respective diluents.

METHODOLOGY Batches of YF 5 and 10 doses have been used in the following CTC studies:

1. Vaccines and diluents, separately, submitted at 40°C for 28 days. Potency and moisture content were performed in 7, 14, 21 and 28 days.
2. CTC study after reconstitution:
 - a) Vaccines at 40°C was reconstituted with diluent at 40°C and maintained at 40°C for 6 hours;
 - b) Vaccines at 2-8°C was reconstituted with diluent at 2-8°C and maintained at 40°C for 6 hours;
 - c) Vaccines at 2-8°C was reconstituted with diluent at 40°C and maintained at 2-8°C for 6 hours.
3. Vaccines with VVM14 stored at 2-8°C for 18 months, was submitted at 40°C for 3 days and returned to 2-8°C until the end of shelf life.

RESULTS

1. The potency test and moisture content results of the vaccines at 40°C showed stable and within specification for 21 days.

2. a) Both vaccine and diluent submitted at 40°C/28days and maintained for 6 hours at 40°C showed very rapid loss of the titre in 30 minutes and out of specification;

2. b) Both vaccine and diluent maintained at 2-8°C and after reconstitution submitted at 40°C showed that in this condition the reconstituted vaccine are not stable;

2. c) When vaccines maintained at 2-8°C and the diluent at 40°C/28 days and after reconstitution kept at 2-8°C, the titres are maintained during 6 hours within specification, demonstrating its stability.

3. The vaccines with VVM stored at 2-8°C and exposed at 40°C for a maximum of 3 days (the VVM do not reach the end-point), the potency titres is maintained under specification and can be stored again at 2-8°C for future use until it reaches the end of shelf life.

CONCLUSION The study of freeze-dried vaccines and diluents in CTC conditions showed satisfactory results for potency test for 21 days and 28 days for residual moisture content. The potency results are not satisfactory when the reconstituted vaccines are maintained at 40°C.

KEYWORDS Yellow Fever vaccine, potency, CTC.