

STABILITY STUDY : THERMAL SHOCK VALIDATION

Product : Optochin test

Reference : 55912: 2 bottles of 30 discs

Introduction:

The stability of Optochin test, reference 55912, has been verified by performing real time stability study including thermal shocks sequence to simulate delivery process.

Protocol:

This study is carried out according to the EN 13640 "Stability testing of in vitro diagnostic reagent" recommendations. The storage temperature of Optochin test is 2-8°C. The thermal shocks out of temperature specification to which the product has been submitted includes a passage of 96 hours at 18-25°C, 48 hours at <-5°C and 48 hours at 35-39°C. This study supports product performance during shelf life.

Summary of the stability study protocol:


The trials that have been performed consist of verifying conformity of appearance and bacteriological activity. Several points have been tested during the stability study:

T₀ = initial point

T_i = middle point

T_x and T_{x+1} (T_x corresponding to the shelf-life)

The performances are maintained until expiration date.

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