



THIOMERSAL RELATED AUDIT SITUATIONS & FINDINGS – CASE STUDY

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Introduction

Thiomersal is widely used preservative for vaccines. As Thiomersal is absorbed by stoppers and plungers, they are soaked in Thiomersal solution (with WFI) to saturate them before sterilization and filling.

Case 1

During the walkthrough as part of your audit, auditors observed white spots on the stoppers, and several interventions during the aseptic fill to dislodge stoppers which were sticking to the chute of stoppering station (e.g. hitting and shaking the hopper). Customer complaints had also been received related to white spots on stoppers.



Case 2

Review the stability study provided.

Case 3

Complaints were received related to contamination which appeared after several days in opened containers of a multidose vaccine with Thiomersal as preservative. Review stability studies provided

Case 4

Complaints were received related to contamination of unopened vials of a multidose vaccine with Thiomersal as preservative. Review stability studies provided.



Instructions to the group

1. As auditors, briefly discuss and prepare an audit checklist and the associated documentation. Draw conclusions and identify the probable cause!
2. Briefly, write in bullet-point format in your flipchart.
3. Make a brief presentation to the class justifying the points to be audited.
(Reference: WHO Policy Statement: Multi-dose Vial Policy – MDVP; ICH Q 5 C Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products).

THIOMERSAL RELATED AUDIT SITUATIONS & FINDINGS – CASE STUDY 2

