Validation of Ethylene Oxide and Steam Half Cycle Sterilant Penetration and Shelf Life Testing for Steriking ® Sterilization Pouches

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Objectives:

To validate the Steriking® Self seal and Heat seal sterilization pouches produced by Wipak Oy for sterilant penetration into the pouches when processed in Ethylene Oxide (EO), Pre-vacuum steam, and Gravity steam half cycle sterilization processes, and to conduct a shelf life study for stability of the Steriking® Sterilization pouches post sterilization.

Materials:

EO Sterilizer	Steriking® Self Seal Pouches	Chemical Indicators (CI)
Pre-Vac and Gravity Sterilizer	Heat Sealer	Data Loggers
Steriking® Heat Seal Pouches	Biological Indicators (BI)	Silicone Tubing

Procedure:

- Test pouches were inspected upon receipt for evidence of shipping damage.
- Following visual inspection, pouches to be exposed to half cycle steam sterilization and those to be exposed to half cycle EO sterilization were prepared. They were seeded with standard silicone tubing with BI and CI (only for steam sterilization). The pouches were used as single pouches as well as double pouches.
- In order to provide information on sterilization conditions within the pouch, for each sterilization load, temperature data loggers were placed inside representative pouches and geometrically distributed within the load (front, center, back).
- Seeded pouches were then sealed using the 160-180ºC setting for paper/poly pouches located on the heat sealer provided by Healthmark. The actual sealing temperature recorded for sealing was 170ºC
- The pouches were then tested for sterilant penetration.
- Heat seal pouches were then tested for ambient and accelerated aging, and for manufacturer's seal strength and seal integrity, using ASTM methods.
- Time points for ambient storage were decided to be 0 months, 12 months, 36 months and 60 months. This testing is still on going. The corresponding stability testing for accelerated ageing is complete.

Results:

- All cycle parameters were met for each sterilization cycle for the single and double pouches.
- The results of this study verified the ability of the sterilant to penetrate through the Steriking® self-seal and heat-seal sterilization pouches for both single and double pouches, and deliver a sterility assurance level (SAL) of 10^{-6} using a BI overkill method when exposed to EO, Gravity displacement, or Pre-Vac steam sterilization processes.
- All BIs processed in the half cycles were negative indicating that pouches allowed sufficient sterilant penetration in all conditions to produce a 6 log reduction, therefore EO, pre-vac and gravity full cycles would deliver a sterility assurance level (SAL) of 10^{-6}. All positive control BIs exhibited growth indicative of the indicator organism.
- Although not all CIs processed in the gravity cycle showed the appropriate color change for a 121ºC exposure, this did not impact the lethality of the half cycle as all BIs were negative. Per the manufacturer, the CIs were validated for use at 121ºC for 30 minutes there exposure at 121ºC for 15 minutes was not sufficient for color change.
- Seals of the aged heat sealed pouches met the seal strength specification. The results of the seal peel testing on the aged samples demonstrated that the seals were not significantly weaker than the seals of the baseline samples.
- Dye penetration under all sterilization conditions for aged heat seal pouches demonstrated no channels or leaks.

Conclusion:

This study demonstrated that the Steriking® self-seal and heat-seal sterilization pouches produced by Wipak Oy were effective in allowing sterilant penetration into the pouches when processed in Ethylene oxide (EO), Pre-vacuum steam, and Gravity steam half cycle sterilization processes.

The results of the accelerated aged samples of heat sealed pouches produced by Wipak Oy, processed in EO, Pre-Vacuum Steam and Gravity steam sterilization cycles and stored in accordance with the requirements of ASTM F1980-07 support a sixty month or 5 year expiration date for the pouches. Testing of real time aged samples is being conducted to confirm this claim.

Study Date: The validation study was completed in June 2014.