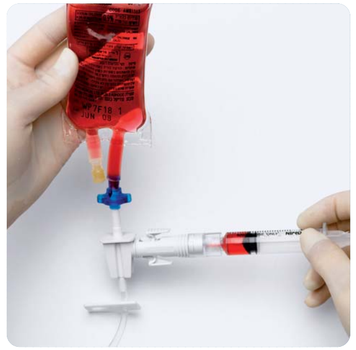
Maintaining Sterility, Ensuring Safety with Tevadaptor

Performed by AminoLab Laboratories, ISRAEL, March 2006



TEVADAPTOR®
When Safety and Simplicity Click

Summary

Maintaining the sterility of pharmaceutical preparations remains a challenge, especially as preparation shelf life is extended. Tevadaptor, a closed drug reconstitution system developed by Teva Medical Devices to prevent the spread of hazardous drug species, was tested to evaluate its integrity in maintaining sterility during repeated use. 1 ml of sterile water was aseptically transferred each day from Tevadaptor vial assemblies connected to test tubes containing Tryptic Soy Broth (TSB) or Fluid Thioglycollate Medium (FTM). The test tubes were incubated for 14 days. A separate vial, not connected to Tevadaptor, served as control. No bacterial growth was observed after incubation.

Objective

To assess the abitlity of the Tevadaptor closed system in maintaining sterility of pharmaceutical preparations.

Materials & Methods

Part I

Five Tevadaptor assemblies each consisting of a Tevadaptor Vial Adaptor mounted onto a 20 ml vial of sterile PO water were set according to Tevadaptor protocol. Each day, 1 ml of sterile water was aseptically transferred using a Tevadaptor Syringe Adaptor from each of the assemblies into a test tube containing 30 ml TSB medium, and 1 ml was transferred into a test tube containing 30 ml FTM. After each sampling, the assemblies were capped and maintained in a non sterile area. The FTM tubes were incubated at 31 1°C for 14 days and the TSB tubes were incubated at 24 1°C for 14 days. During this period, the test tubes were examined for turbidity (growth of micro organisms). The same procedure was applied to a vial, marked TC. A sterile needle was used instead of Tevadaptor. The negative control of each of the sterile media was a test tube without any manipulation, incubated along with the other treated samples (NC).

Part II

The broth media used for the sterility test was then checked for the ability of certain micro organisms to use it as growth medium. The liquid medium FTM was divided into 3 test tubes, while the liquid medium TSB was divided into 4 test tubes. The test tubes were inoculated with 10 100 CFU of S. aureus, P. aeruginosa, C. sporegenes, E. coli, B. subtilis, and C, albicans. All test tubes were incubated at the appropriate conditions and time and examined daily for the appearance of growth. The test ceased when growth was observed.

Results

At the end of the experiment, no micro organism growth was observed in any of the test tubes. Growth in the control inoculation confirms that the growth media were, in fact, supportive of bacterial growth.

Conclusion

Tevadaptor, a closed drug reconstitution system prevents the escape of hazardous drug species, is able to maintain the sterility of the drug preparation over repeated use.

Fluid Thioglycollate Medium (FTM) Growth (+) / No Growth (-)

Sample	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
2	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
3	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
4	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
5	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
NC	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
NC	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)

Tryptic Soy Broth (TSB) Growth (+) / No Growth (-)

Sample	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
2	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
3	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
4	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
5	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
NC	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
NC	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)

Control /noculation

Test Microorganism	Inoculum Size (CFU/0.1 ml)	FTM	Inoculum Size (CFU/0.1 ml)	FTM
Staphylococcus aureus	50	Growth	41	Growth
Pseudomonas aeruginosa	78	Growth	61	Growth
Clostridium sporogenes	10-100	Growth	10-100	Growth
Test Microorganism	**Inoculum Size (CFU/0.1 ml)**	**TSB**	**Inoculum Size (CFU/0.1 ml)**	**TSB**
Bacillus subtilis	62	Growth	62	Growth
Staphylococcus aureus	-	-	41	Growth
Escherichia coli	-	-	50	Growth
Candida albicans	21	Growth	15	Growth
Aspergillus niger	38	Growth	-	-

ver.09.03