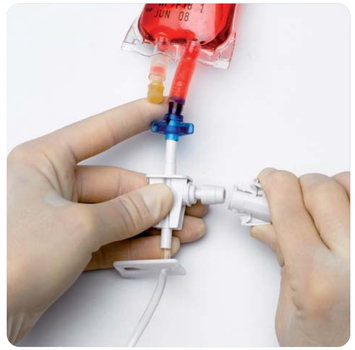
Tevadaptor Preserves Long-Term Sterility After Bacterial Challenge

Performed by Hy-Labs* Research Laboratories, ISRAEL, June 2007



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Summary

Ensuring drug sterility is of paramount importance when preparing and storing pharmaceuticals. Tevadaptor, a closed drug reconstitution system developed by Teva medical devices to prevent the escape of hazardous drug species, was tested to assess its ability to maintain drug sterility.
Bags containing appropriate media were attached to the Tevadaptor connecting set, stored for 14 days, challenged with S. marcescens and incubated for an additional 7 days. No bacterial growth was observed in any of the test systems.

Objective

To ascertain the ability of the Tevadaptor closed system to maintain sterility through a bacterial challenge test.

Materials & Methods

Phase I

For the first phase, 10 TevadaptorTm assemblies consisting of a bag filled with 50 ml Tryptic Soy Broth attached to the spike port connection (connecting set), along with 2 identical bags not attached to the Tevadaptor connecting set were prepared. All bags were initially stored at a temperature of 25°C-30°C in non-sterile conditions. After 14 days, all units were inspected for signs of bacterial growth.

Phase II

The two control bags were punctured to simulate defective closure of the system, and all units were immersed in Serratia marcescens-containing broth for 30 minutes. The samples were then rinsed, dried and transferred to a sterile container for further incubation at 30°C-35°C for an additional 7 days.
After 7 days, all units were inspected for signs of bacterial growth.

Results

Phase I

No bacterial growth was observed in any of the 10 Tevadaptor assemblies, nor in the two extra bags.

Phase II

After immersion in Serratia marcescens broth and incubation for 7 days, no growth was observed in any of the 10 Tevadaptor preparations.
Bacterial growth was observed, however, in the two control preparations.

Conclusion

The Tevadaptor closed drug reconstitution system ensures the sterility of drug preparations even upon substantial bacterial challenge.

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Microbial Challenge Test: S. marcescens	
Test Sample	**Sterility Test Conclusions**
1	No Growth
2	No Growth
3	No Growth
4	No Growth
5	No Growth
6	No Growth
7	No Growth
8	No Growth
9	No Growth
10	No Growth
Control Sample	
1	Growth
2	Growth

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