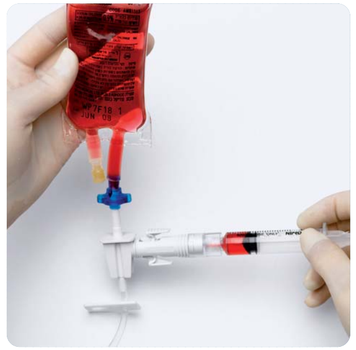
Ensuring Long Term Sterility of Pharmaceutical Preparations with Tevadaptor

Performed by AminoLab Laboratories, ISRAEL, April 2006



TEVADAPTOR®
When Safety and Simplicity Click

Summary

Tevadaptor a closed drug reconstitution system developed by Teva Medical Devices to prevent the escape of hazardous drug species, was tested for sterility. Tevadaptor assemblies containing 5% Dextrose for injection were sampled weekly, and samples incubated in test tubes containing media conducive to growth of aerobic and anaerobic bacteria. Samples were then examined for turbidity.

At the end of 4 weeks, no bacterial growth was observed in any of the samples. Using Tevadaptor ensures that long-term sterility of pharmaceutical preparations is not compromised.

Objective

To test Tevadaptor's ability to maintain long-term sterility of pharmaceutical preparations.

Materials & Methods

Five Tevadaptor assemblies consisting of a Tevadaptor Spike Port Adaptor mounted onto a sterile bag with 100 ml 5% Dextrose for injection were set according to protocol.

Once a week, 1 ml of sterile Dextrose was aseptically transferred using a Tevadaptor Syringe Adaptor from each of the assemblies into a test-tube containing 30 ml TSB (Tryptic Soy Broth) medium, and 1 ml was transferred into a test-tube containing 30 ml FTM (Fluid Thioglycollate Medium).
After each sampling, the assemblies were maintained in a non-sterile area.

The Fluid Thioglycollate Medium tubes were incubated at 31 1°C for 14 days and the Tryptic Soy Broth tubes were incubated at 24 1°C for 14 days. Sterile, un-manipulated test tubes were also incubated and served as control (NC).

During the incubation period, the test tubes were examined for turbidiy (growth of microorganisms).

In control experiments, in order to ascertain that the contents of the assmbly bag were not bacteriostatic/bacteriocidic, assembly bags were inoculated with different test organisms, and observed for turbidity. All organisms grew satisfactorily.

Results

No bacterial growth was observed in any of the samples.

Conclusion

Tevadaptor was shown to maintain the long-term sterility of pharmaceutical preparations.

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

Sample	Week 1	Week	Week 3	Week 4
1	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
2	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
3	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
4	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
5	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
NC	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)

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

Sample	Week 1	Week	Week 3	Week 4
1	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
2	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
3	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
4	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
5	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)
NC	No Growth (-)	No Growth (-)	No Growth (-)	No Growth (-)

Control /noculation

Test Microorganism	Inoculum Size (CFU/0.1 ml)	FTM
Staphylococcus aureus	89	Growth
Pseudomonas aeruginosa	96	Growth
Clostridium sporogenes	10-100	Growth
Test Microorganism	**Inoculum Size (CFU/0.1 ml)**	**TBS**
Bacillus subtilis	59	Growth
Candida albicans	58	Growth
Aspergillus niger	89	Growth

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