

PharmaPack[®]

Sterile Multi-Pack Syringes and Cap Integrity Testing Summary

Purpose

To evaluate whether Helapet PharmaPack[®] BD luer lock syringes, in combination with three luer lock syringe caps, are suitable to be used as a container for storage. 1ml, 10ml and 60ml (50ml) sizes of the BD luer lock syringe were microbiologically immersion tested and dye intrusion tested based on the guidance document NHS Method: Protocols for the Integrity Testing of Devices*

Materials



1ml BD Luer Lock Syringe
XX3101BD



10ml BD Luer Lock Syringe
XX3110BD



60ml (50ml) BD Luer Lock Syringe
XX3250BD



TESTED WITH



Helapet Integrated Non-Vented Syringe Cap



Helapet Combi-Cap[®]
IV2102



Helapet Tamper-Evident IV Syringe Cap
IV5750R

Methods

i) Microbiological Integrity Testing involves each syringe/endcap combination being challenged by immersion in a culture of *Brevundimonas diminuta* and incubated at 30-35°C for 14 consecutive days[†].

ii) Structural Integrity Testing involves each syringe/endcap combination being subjected to a dye intrusion test to determine whether any dye appears to have entered the syringe barrel whilst under conditions matching those used for patient products[†].



Results

i) Microbiological Integrity Testing – Results of Immersion Challenge

	Microbial growth prior to immersion	Microbial growth following immersion	Results
1ml BD Luer Lock Syringe			
Integrated Non-Vented Syringe Cap	0 syringe in 20	0 syringe in 20	Complies
Combi-Cap	0 syringe in 20	0 syringe in 20	Complies
Tamper-Evident IV Syringe Cap	0 syringe in 20	0 syringe in 20	Complies
10ml BD Luer Lock Syringe			
Integrated Non-Vented Syringe Cap	0 syringe in 20	0 syringe in 20	Complies
Combi-Cap	0 syringe in 20	0 syringe in 20	Complies
Tamper-Evident IV Syringe Cap	0 syringe in 20	0 syringe in 20	Complies
60ml (50ml) BD Luer Lock Syringe			
Integrated Non-Vented Syringe Cap	0 syringe in 20	0 syringe in 20	Complies
Combi-Cap	0 syringe in 20	0 syringe in 20	Complies
Tamper-Evident IV Syringe Cap	0 syringe in 20	0 syringe in 20	Complies

ii) Structural Integrity Testing – Results of Dye Intrusion Test

	Number of syringes tested	Number of syringes showing dye ingress	Positive Control	Results
1ml BD Luer Lock Syringe				
Integrated Non-Vented Syringe Cap	20	0	Pass	Complies
Combi-Cap	20	0	Pass	Complies
Tamper-Evident IV Syringe Cap	20	0	Pass	Complies
10ml BD Luer Lock Syringe				
Integrated Non-Vented Syringe Cap	20	0	Pass	Complies
Combi-Cap	20	0	Pass	Complies
Tamper-Evident IV Syringe Cap	20	0	Pass	Complies
60ml (50ml) BD Luer Lock Syringe				
Integrated Non-Vented Syringe Cap	20	0	Pass	Complies
Combi-Cap	20	0	Pass	Complies
Tamper-Evident IV Syringe Cap	20	0	Pass	Complies

*NHS Method: Protocols for the Integrity Testing of Devices; 2nd Edition, revised April 2013

†Full test data available on request

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