Study Approval:

Department Manager	Name	Signature	Date
Plastmed Production	Nataly Shushan		16.03.10
Plastmed QA/RA	Elissa Burg		18.3.10

1. General

1.1. Closed-System Transfer Devices (CSTD) were first developed as a response to growing concerns regarding exposure of healthcare workers to hazardous substances while handling and administrating them to patients.

1.1.1. Although hazardous substance preparation is performed while wearing protective clothing in a controlled environment such as biological safety cabinets or clean rooms, studies have demonstrated that these measures are insufficient in protecting workers from exposure.

1.1.2. Studies have shown that exposure to hazardous substances may result in chronic health problems, adverse reproductive afflictions, and cancer.

1.2. The CSTDs offer a solution whereby the hazardous substance is fully contained within a sealed device during preparation, transfer, and administration.

1.3. For the CSTD to be effective, it must be airtight and leak proof, thus totally isolating the hazardous substance and completely preventing the occurrence of any spills, drips, aerosols and vapor escapes.

1.4. The *EQUASHIELD*™ system by Plastmed has been developed as a CSTD, for the intended use of isolating hazardous substances and effectively protecting healthcare workers from exposure to them.

2. Objective

Evaluation of *EQUASHIELD*™ closed system drug transfer device, during the preparation phase, for the purpose of verifying residual free dry connections between vial/syringe adaptors.

3. Responsibility

3.1. The Quality Manager is responsible for defining and recording the test described herein.

3.2. The Production Manager is responsible for the performance of the test described herein.

4. Materials

4.1. *EQUASHIELD*™ system components consisting of the following:

Quantity	Description	Article	Lot No.
10	Vial Adaptor	VA-20	VA-25-01-09
10	20ml Syringe Unit	SU-20	SU-25-01-09

4.2. Additional materials used for the test:

No.	Description	Raw Material	Supplier
1	Serum Vials, 100ml, 27ml	Clear Brosilicate glass	Voigt Global distribution Inc.
2	Serum Vial Stoppers – 20mm	Rubber	Voigt Global distribution Inc.
3	Flip Off- Serum Vial Seals – 20mm	Plastic Cap connected to Aluminum Seal	Voigt Global distribution Inc.
4	Hand Operated Crimper	Zinc plated	Voigt Global distribution Inc.
5	20ml Syringes	Polypropylene	Anhui
6	Preserved Lemon Juice	7296073074540	Shufersal Ltd.
7	Blue Litmus Paper	066202	Chen & Shmuel Chemicals

5. Method

5.1. The test was conducted on February 3rd, 2009, at the Plastmed testing facility, in Tefen, Israel, by Christina Polikashvili who received training for the test method by Marino Kriheli.

5.2. The evaluation simulated the preparation of hazardous drugs, as specified in Protocol No. 119 - Protocol for the Evaluation of Dry Connections in the *EQUASHIELD*™ Closed System Transfer Device:

5.2.1. Sealed vials filled with lemon juice were capped by *EQUASHIELD*™ Vial Adaptors and connected to Syringe Units.

5.2.2. 7ml of lemon juice was drawn into each syringe and 5ml were re-injected back into each vial, simulating the preparation of measured drug doses.

5.2.3. Each Syringe unit was then disconnected from its vial and checked for leaks by pressing the system's membrane against litmus paper.

5.2.3.1. Any leaks would be indicated by discoloration of the litmus paper.

5.2.4. Results were recorded as specified (see Appendix A).

5.2.5. This process was repeated for nine (9) additional times with each of the ten (10) systems, by withdrawing and re-injecting 5ml.

5.2.6. All manipulations were documented and close-up photographs were taken at the end of the process, after 10 manipulations (see Appendix B).

6. Results

6.1. Results indicated that 99 out of 100 manipulations showed no visible signs of leakage.

6.2. The 7th device leaked only during the 2nd manipulation.

7. Conclusions

Residual free dry connections between vial/syringe adaptors were verified according to the acceptance criteria (99%), indicating adherence to the intended use of a closed system drug transfer device that is leak-proof.

Appendix A

Test Date: February 3rd, 2009

Location: Plastmed Laboratory, Tefen, Israel

Performed by: Christina Polikashvili

Training for the performance of the test according to Protocol No. 119 was provided by: Marino Kriheli

Date: February 2nd, 2009

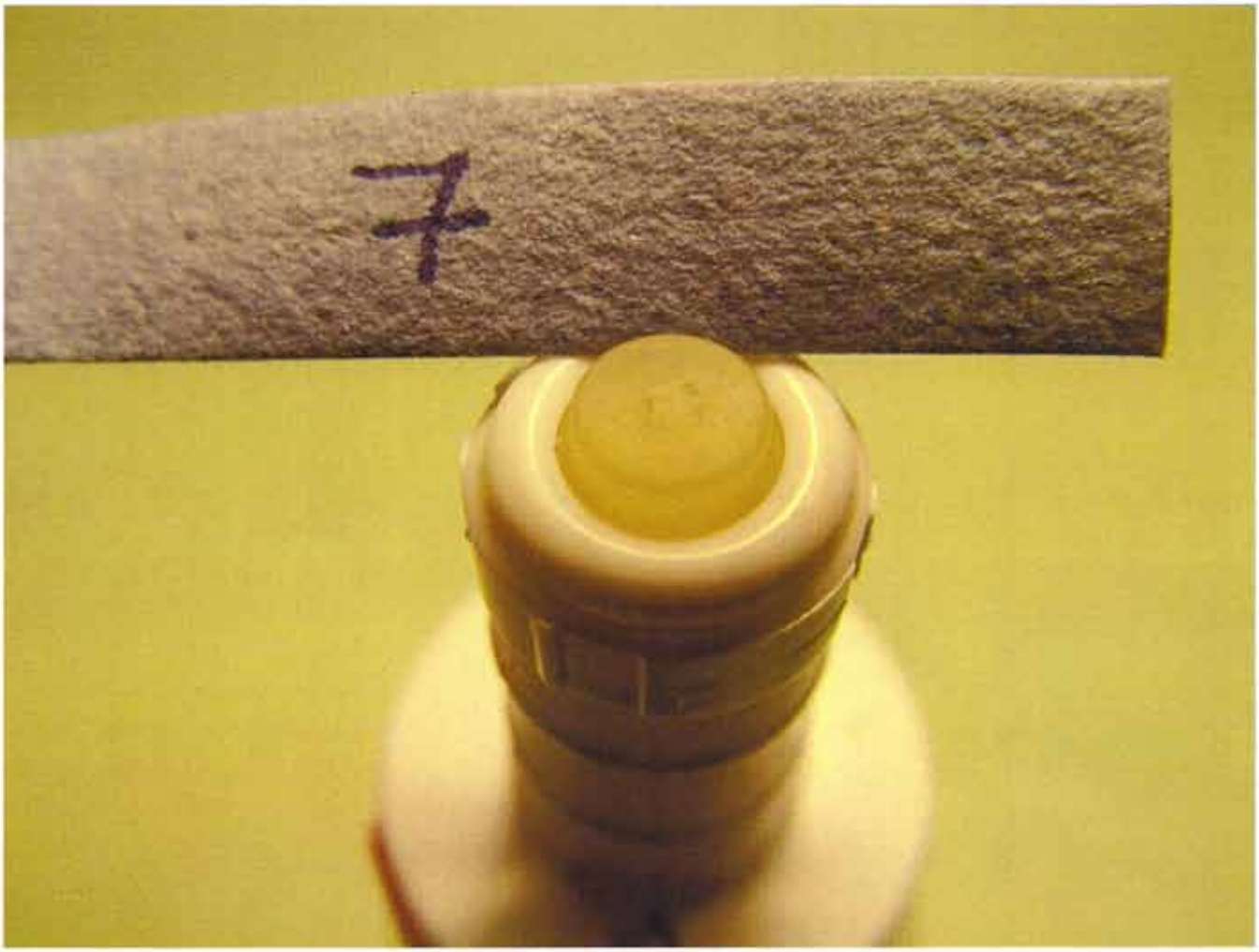
TEST RESULTS

Number of Manipulations	Vial Adaptor and Syringe Unit Connections 10 EQUASHIELD™ Systems									
	A1	A2	A3	A4	A5	A6	A7	A8	A9	A10
1	√	√	√	√	√	√	√	√	√	√
2	√	√	√	√	√	√	X	√	√	√
3	√	√	√	√	√	√	√	√	√	√
4	√	√	√	√	√	√	√	√	√	√
5	√	√	√	√	√	√	√	√	√	√
6	√	√	√	√	√	√	√	√	√	√
7	√	√	√	√	√	√	√	√	√	√
8	√	√	√	√	√	√	√	√	√	√
9	√	√	√	√	√	√	√	√	√	√
10	√	√	√	√	√	√	√	√	√	√

No leaks detected: √

Leaks detected: X

Appendix B



Micro leak