Prepared by: Dr. Igal Bar-Ilan (Igal@migal.org.il) & Edna Hadar
Date: Sunday, April 13, 2014 **Project No.1613** **Certificate of analysis: SO14013426**

Test Report

Project #: 1613

Evaluation of Equashield Close System Compatibility in Prevention of Environmental Contamination Alcohol vapors detection

Performing Laboratory:

Milouda&Migal Laboratories

P.O.B 831 Kiryat-Shmona ISRAEL 11016, Israel

Sponsor: Equashield

Performing Laboratory:

Milouda & Migal Laboratories

P.O.B 831 Kiryat-Shmona ISRAEL 11016, Israel

Study Director:

Dr. Igal Bar-Ilan

Head of Analytical Chemistry
&
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APPROVED
By Dr. Igal Bar-Ilan at 10:06 am, Apr 13, 2014

April 9, 2014

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Test Review and Approvals

Edna Hadar – Chemical Technician

Signature: _____ ; Date: 13 /04 /2014

Dr. Igal Bar Ilan – Study Director

Signature: _____ ; Date: 13 /04 /2014

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1. Study Objective

To assess the ability of Equashield CSTD to mechanically prevent the escape of hazardous drugs from the drug vial into the environment under chemically extreme-use-conditions during repeated accesses of the device.

2. Method

2.1. Limit of Detection (LOD) test was performed to allow quantification of results, by direct injection of Ethanol standard solution into split/splitless GC injector and detection using FID (Flam Ionization Detector).

2.2. Direct contamination of the small closed chamber was performed using 0.1 and 0.5 µl of 10% alcohol solution directly dropped inside the chamber and air sampling according to test procedure.

2.3. Impingers liquid volume: 15 ml of DDW (Doubled Distilled Water).

2.4. 10 Equashield systems, consisting of a Syringe Unit and a Vial Adaptor were used. The vial adaptors were assembled with 20ml vial, which is filled with 15 ml 70% alcohol in DDW. Each system was activated 5 repeated times, creating a total of 50 repeated accesses representing extreme case conditions.

2.5. Air sampling pump flow rate was set and calibrated at 1 L/min

2.6. Sampling duration was set to 40 min.

2.7. Environmental temperature was recorded at the beginning and ending of sampling time.

2.8. Positive and negative controls were analyzed accordingly.

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3. Study Results

3.1. Limit Of Detection (LOD)

LOD was determined by direct injection into GC-FID.

Spike concentration [µg/ml]	Chamber Concentration [ng/ml air]	remarks
0 (DDW)	No peak	-
0.670	No peak	-
1.054	53	**UDL**
1.412	71	-
3.431	172	-
3.793	190	-
5.060	253	-
9.636	482	-
13.890	694	-
26.641	1332	-

3.2. Direct contamination of chamber

The chamber was contaminated with ethanol spikes.

Spike concentration [µg/ml]	Chamber Concentration [ng/ml air]	Remarks
Blank	UDL	-
0.1	131	-
0.5	229	-

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3.3. Gas Chromatograph Analysis Results

Impinger sampling details and results are described on the following table.

Test Description	No of Equashield Systems	Air pump flow rate [ml/min]	Sampling duration [min]	Volume of water in impinger at end of test [ml]	Temp [C°]	Chamber Concentration [µg/L-air]
Test article Equashield System, 5 repeated accesses	10 systems	1000	40	15	25	UDL

* UDL – Under detection level

3.4. Positive and Negative Control Results

Impinger sampling details and results are described on the following table.

Test Description	Air pump flow rate [ml/min]	Duration [ml/min]	Volume of water in impinger at end of test [ml]	Temp [^{O}C]	Chamber Concentration [ng/ml air]
Negative Control (Blank)	1000	40	15	25	UDL
Positive Control #1 (standard needle)	990	40	15	25	26500

* UDL – Under detection level

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4. ACCEPTANCE CRITERIA

4.1. Tested articles must represent no alcohol residuals, presented as UDL (under detection level)

4.2. Positive control must demonstrate drug residuals

4.3. Negative control will be negative in all tested device

5. Conclusions

5.1. Based on the above analytical results, all tested samples are in accordance to the acceptance criteria.

5.2. No contamination was detected in all repeated 6 accesses of the Equashield system.

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