Filtration of Viscous Materials for Microbial QC

Summary

Membrane filtration is the preferred method for sterility testing. Viscous products, such as oils, creams and ointments can prove difficult to filter. As per USP <71> viscous oils may be diluted as necessary with a suitable sterile diluent such as isopropyl myristate shown not to have antimicrobial activity in the conditions of the test. Sterile isopropyl myristate (IPM), has been shown to have no anti-microbial activity in test conditions. This study investigates the effectiveness of IPM as a diluent by comparing filtration times with unfiltered oils.

Materials

- Sterile Isopropyl myristate
- Pall MicroFunnel™ filter funnel 0.45 µm GN-6 (PN 4807, representative of any MicroFunnel with GN-6 membrane)
- Rinsing Fluid A
- Rinsing Fluid K
- Appropriate growth media
- Water bath
- Pall Laboratory Manifold (PN 4889)
- Vacuum source
- Olive oil
- Sesame oil
- Canola oil

Methodology

1. Place the sterile IPM and rinsing fluids in a 37 °C water bath.
2. Once the IPM is at temperature, clean the bottle thoroughly with 70/30 isopropyl alcohol/water.
3. See Tables 1-3 for details regarding materials tested and dilution rates. Using aseptic technique dilute the product to be tested using the IPM. If being used in sterility testing follow local pharmacopeia guidelines on volumes required.
4. Place the Pall MicroFunnel filter funnel on the Pall Laboratory manifold.
5. Aseptically wet the membrane with approximately 5 mL of warm IPM.
6. Aseptically dispense the diluted product into the MicroFunnel and using the manifold gradually filter the solution through the membrane.
7. Once the product has been completely filtered add 100 mL of the warm Fluid K into the MicroFunnel and filter. Repeat this step a total of 3 times as per pharmacopeia guidelines.
8. Rinse with 100 mL of Fluid A to remove residuals of Fluid K.
9. Aseptically remove the membrane from the MicroFunnel filter funnel and place on appropriate growth media and incubate for appropriate time period.

Results

Examples of filtration times for viscous solutions were carried out under laboratory conditions by Pall Laboratory. Three oils (sesame, canola and olive) were filtered without IPM dilution. For comparison, a corresponding set of oil samples were filtered after 1:1 dilution using IPM (50 mL IPM + 50 mL oil). Ten samples were tested for diluted samples, while only 5 samples were run for the non-diluted sample due to the long sample filtration time.Tables 1-3 show the filtration data comparing non-diluted and diluted samples.

Table 1

Filtration data for Canola oil

Sample	Time with Dilution (Hr:min:sec)	Time without Dilution (Hr:min:sec)
1	00:01:05	00:12:21
2	00:02:28	00:13:02
3	00:01:35	00:12:26
4	00:01:42	00:12:58
5	00:01:35	00:12:55
6	00:01:45	No sample
7	00:01:29	No sample
8	00:01:32	No sample
9	00:01:45	No sample
10	00:01:40	No sample

Table 2

Filtration data for Sesame oil

Sample	Time with Dilution (Hr:min:sec)	Time without Dilution (Hr:min:sec)
1	00:03:06	>02:00:00
2	00:02:16	>02:00:00
3	00:01:41	>02:00:00
4	00:02:40	>02:00:00
5	00:03:35	>02:00:00
6	00:03:09	No sample
7	00:02:55	No sample
8	00:03:25	No Sample
9	00:03:03	No sample
10	00:03:11	No sample

Table 3

Filtration data for Olive oil

Sample	Time with Dilution (Hr:min:sec)	Time without Dilution (Hr:min:sec)
1	00:01:32	00:19:01
2	00:01:45	00:21:05
3	00:01:40	00:15:55
4	00:01:34	00:18:21
5	00:01:41	00:19:45
6	00:01:54	No sample
7	00:01:49	No sample
8	00:01:34	No sample
9	00:01:35	No sample
10	00:01:30	No sample

Conclusion

The data shown in tables 1-3 conclusively indicates a faster process using IPM as a diluent for viscous products versus undiluted product. It is important to carry out the membrane flush at the end of the filtration using both Fluid A and K (<USP 71>) to remove any residual IPM that may inhibit bacterial growth. It is important to note that this report provides guidance only and does not replace the need for internal method validation.

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