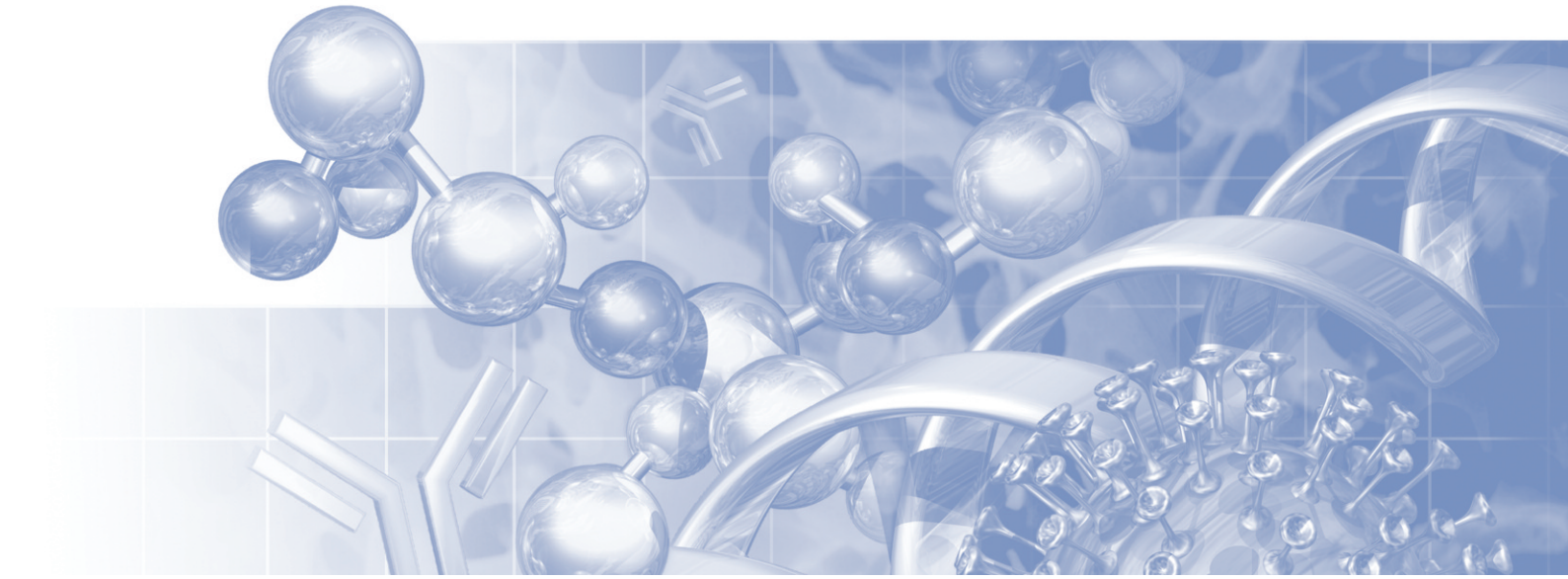
PALL Life Sciences

Application Note

USTR 2821

Scientific and Technical Report – *In-Situ* Drying of Pall® Hydrophobic Air Filters Prior to Moist Heat Sterilization



*Filtration. Separation. Solution.*SM

Contents

Test Summary

Pall hydrophobic AB-Style and capsule filters, containing Emflon® II and Emflon PFR membrane, were pre-weighed, then subjected to wetting, which simulated preparation for Forward Flow (FF) or Bubble Point (BP) Integrity Testing. The filters were then subjected to *in situ* drying using compressed air as a drying gas at two different pressures, then were re-weighed at periodic intervals.

Based on the post-drying weights obtained, the following is a guideline for the drying times and pressures required to prepare Pall hydrophobic filters for moist heat sterilization, following an FF or BP Integrity Test:

Drying Times for Pall Hydrophobic Filters

Filter Description	Minimum Drying Time @ 30 psig (2070 mbar)	Minimum Drying Time @ 50 psig (3450 mbar)
Capsule filters (e.g. Kleenpak, DFA)	60 minutes	30 minutes
AB05 (5 in.), AB1 (10 in.)	120 minutes	60 minutes
AB2 (20 in.), AB3 (30 in.)	180 minutes	120 minutes
Multi-around assemblies	Not recommended	Study required – contact Pall

It is recommended that end-users verify these results using their own apparatus to ensure the drying criterion is met (described herein).

1. Introduction

Pall hydrophobic membrane filters, such as Emflon® PFR and CPFR PTFE filters and Emflon II V002 PVDF filters used in sterile vent and gas sterilizing applications, are frequently integrity tested by the Forward Flow (FF) or Bubble Point (BP) test method. This requires that the filters be fully wetted with a low surface tension liquid, most commonly a mixture of isopropanol and water.

A fully wetted membrane is impenetrable to the bulk flow of gases at low gas pressures, whereas bulk flow of gas (e.g. air and steam) is a requirement for sterilization by either Steam-In-Place (SIP) or to a lesser extent, by autoclaving.

A membrane filter that remains wet after integrity testing will not allow the bulk flow of air or steam though the filter. During SIP procedures, this can result in high differential pressure across the filter at an elevated temperature. The potential for damage to the filter (membrane stretching or rupture and/or core collapse) and loss of filter integrity is increased under these conditions.

It is well known that simply subjecting a filter to a BP test where the Bubble Point is exceeded is insufficient to dry the filter in preparation for Moist Heat Sterilization (SIP or autoclave). A simple “blow-down” of the filter at a pressure above the minimum BP can also be insufficient. The reason for this is that a simple “blow down” with a drying gas may only dry out a small portion of the flow pathways through the filter (e.g. the largest pathways or pores), and the bulk of the flow of the drying gas will flow through these pathways, leaving the remainder of the filter matrix still in a wetted or partially wetted state. In some cases, a filter that has been subjected to a simple blow-down can spontaneously re-wet, as the dried area of the membrane will tend to draw in liquid by capillary action from the filter areas that remain wetted.

There are many factors involved in ensuring a filter is sufficiently dried after FF or BP integrity testing, in preparation for sterilization. It is not always enough to rely on measurement of gas pressure differential during drying to deem a filter sufficiently ‘dry’. The flow rate of the drying gas (typically compressed air or nitrogen) is a critical factor, and is influenced by the relative humidity of the gas and configuration of the drying apparatus: pipe or tubing ID, regulator orifice diameter, size of the filter, etc. However, the use of pressure measurement to establish filter drying conditions is preferred due its simplicity.

This report gives a guideline on the approximate pressures and drying times required to dry Pall hydrophobic membrane filters. ***It is intended as a process development guide only. As every set-up is different, it is recommended that the test described herein be repeated by the end-user to establish sufficient filter drying for the user’s application.***

2. Summary of Test Methods

Different configurations of Pall Emflon PFR and CPFR and Emflon II V002 filters (capsules, 10 in. cartridges) were pre-weighed dry, out-of-box. They were then subjected to wetting using a solution of 60:40 IPA:water (vol:vol) as recommended in preparation for a Forward Flow (FF) or Bubble Point (BP) integrity test. The filters were then re-weighed to establish a baseline for drying.

The filters were not integrity tested in order to produce a worst-case scenario for drying (compression of the filter under gas pressure during integrity testing will reduce the total residual wetting liquid volume).

The filters were subjected to drying at starting regulated air pressures of 30 psig (2070 mbar) and 50 psig (3450 mbar). The pressure was not altered during the drying. It is expected that the inlet pressure would begin to drop as the filter became drier and resistance to air flow decreased.

It is important to note that the published BP values for Emflon PFR and CPFR and Emflon II V002 filters, when wetted with 60:40 IPA:Water are as follows:

Filter Grade	Minimum Expected Bubble Point (60:40 IPA:Water wet)
Emflon PFR	19 psi (1320 mbar)
Emflon CPFR	19 psi (1320 mbar)
Emflon II V002	16 psi (1110 mbar)

The filters were subjected to 30 minutes of drying at both 30 psig and 50 psig (2070 mbar and 3450 mbar), were removed, and re-weighed. If they were not sufficiently dried (using the criteria outlined in Table 1), the filters were re-installed into the drying system and subjected to 15 minutes of further drying (without re-adjusting the air pressure), and re-weighed. This was repeated until the criteria in Table 1 was met. A maximum of 90 minutes of drying time was applied. The test was performed in triplicate using 3 different filters.

The values in Table 1 are based on the known membrane hold-up volume of the various filters, and incorporate a safety margin to guard against spontaneous re-wetting.

Table 1
Drying Criteria

Filter	Part Number	Criteria
Kleenpak assembly with Emflon PFR membrane	KA3PFRP1G	Dry to within 1 g of the original dry weight
Emflon PFR 10 in. filter cartridge	AB1PFR7PVH4	Dry to within 10 g of the original dry weight
Kleenpak assembly with Emflon II membrane	KA3V002PV1G	Dry to within 1 g of the original dry weight
Emflon II 10 in. filter cartridge	AB1V0027PVH4	Dry to within 10 g of the original dry weight

3. Test Results

Table 2

Results of Drying Kleenpak Filter Capsule With Emflon II Membrane P/N KA3V002PV1G

Time	Filter Weight Difference As Compared to Out-of-Box Weight – Dried at 30 psig (2070 mbar)				Filter Weight Difference As Compared to Out-of-Box Weight – Dried at 50 psig (3450 mbar)			
	Filter 1	Filter 2	Filter 3	Average	Filter 1	Filter 2	Filter 3	Average
Initial	72.5 g	72.6 g	71.7 g	72.3 g	71.6 g	72.6 g	72.6 g	72.3 g
30 min	3.2 g	6.7 g	2.7 g	27.3 g	0.7 g	0.6 g	0.1 g	0.5 g
45 min	0.3 g	0.7 g	0.1 g	0.4 g	-	-	-	

Table 3

Results of Drying AB-Style Emflon II Filter Cartridge P/N AB1V0027PVH4

Time	Filter Weight Difference As Compared to Out-of-Box Weight – Dried at 30 psig (2070 mbar)				Filter Weight Difference As Compared to Out-of-Box Weight – Dried at 50 psig (3450 mbar)			
	Filter 1	Filter 2	Filter 3	Average	Filter 1	Filter 2	Filter 3	Average
Initial	219.9 g	170.7 g	219.0 g	203.2 g	189.5 g	180.8 g	209.6 g	193.3 g
30 min	43.6 g	31.3 g	43.5 g	39.5 g	18.4 g	25.1 g	25.0 g	22.8 g
45 min	36.6 g	23.6 g	37.0 g	32.4 g	9.2 g	16.5 g	16.1 g	13.9 g
60 min	29.4 g	16.0 g	29.7 g	25.0 g	1.8 g	10.2 g	9.5 g	7.2 g
75 min	23.2 g	9.9 g	20.2 g	17.8 g	-	4.7 g	4.8 g	4.75 g
90 min	17.7 g	5.1 g	9.0 g	10.6 g	-	-	-	-

Table 4

Results of Drying Kleenpak Filter Capsule With Emflon PFR Membrane P/N KA3PFRP1G

Time	Filter Weight Difference As Compared to Out-of-Box Weight – Dried at 30 psig (2070 mbar)				Filter Weight Difference As Compared to Out-of-Box Weight – Dried at 50 psig (3450 mbar)			
	Filter 1	Filter 2	Filter 3	Average	Filter 1	Filter 2	Filter 3	Average
Initial	74.5 g	74.8 g	72.6 g	74.0 g	72.9 g	75.8 g	72.3 g	73.7 g
30 min	5.7 g	2.8 g	2.0 g	3.5 g	1.0 g	0.8 g	0.9 g	0.9 g
45 min	2.8 g	0.8 g	1.0 g	1.5 g	-	-	-	-
60 min	0.9 g	-	-	0.9 g	-	-	-	-

Table 5

Results of Drying AB Style Emflon PFR Filter Cartridge P/N AB1PFR7PVH4

Time	Filter Weight Difference As Compared to Out-of-Box Weight – Dried at 30 psig (2070 mbar)				Filter Weight Difference As Compared to Out-of-Box Weight – Dried at 50 psig (3450 mbar)			
	Filter 1	Filter 2	Filter 3	Average	Filter 1	Filter 2	Filter 3	Average
Initial	155.9 g	156.9 g	155.5 g	156.1 g	153.9 g	155.5 g	148.1 g	152.5 g
30 min	30.5 g	31.9 g	29.7 g	30.7 g	16.1 g	27.7 g	19.4 g	21.1 g
45 min	23.9 g	22.7 g	22.1 g	22.9 g	8.4 g	19.8 g	12.4 g	13.5 g
60 min	16.4 g	17.8 g	14.9 g	16.4 g	0.9 g	10.5 g	4.5 g	5.3 g
75 min	12.4 g	13.0 g	8.6 g	11.3 g	-	0.9 g	-	0.9 g
90 min	8.4 g	6.1 g	2.6 g	5.7 g	-	-	-	-

4. Conclusions

1. The drying of all filters was more effective at a starting pressure of 50 psi as compared to 30 psi. One of the 10 in. filters was not sufficiently dried using 30 psi, even with a 90 minute drying time. All 10 in. filters met the drying criteria within 60 minutes using 50 psi. If a drying pressure of 30 psig is used, a minimum drying time of 120 minutes is indicated.
2. The rate of drying varies with the surface area of the filter. While all capsules (0.15 m^2) were sufficiently dried within 30 minutes at 50 psi, the 10 in. filters (filter areas 0.62 m^2 for Emflon II V002; 0.8 m^2 for Emflon PFR) took up to 60 minutes.
3. There is no significant difference between the required drying times of Emflon II versus Emflon PFR filters.

5. Recommendations

A study using the method described in this report is recommended to verify adequate drying of Pall hydrophobic membrane filters prior to steam sterilization. The following can be used as a guideline to establish the best drying procedure.

Table 6

Drying Times for Pall Hydrophobic Filters

Filter Description	Minimum Drying Time @ 30 psig (2070 mbar)	Minimum Drying Time @ 50 psig (3450 mbar)
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Multi-around assemblies	Not recommended	Study required – contact Pall

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