Technical Brief

Evaluating the Impact of Various Parameters on NovaSeptum® Sterile Sampling Flow Rate

Introduction

In today's biopharmaceutical market, sampling your product is critical for every manufacturing process. An imprecise or false positive result can lead to quarantine as well as the need to repeat the analysis or worse, the inability to release the batch. The NovaSeptum® Sampling System is an ideal solution for all your sampling needs, without the worry of contamination.

This technical brief summarizes results of studies performed to understand the impact of various parameters on flow rate during sampling using NovaSeptum® devices.

Test Methods

To test different viscosities, aqueous glycerine solutions of various concentrations were used. Given that viscosity is highly dependent on temperature, the viscosity was calculated at the temperature of each test. To simulate the hydrostatic pressure in a vessel, a vertical tube was filled at different heights to simulate such pressure. A separate experimental set-up was also used in which the samples were pressurized to enable the measurement of the impact of higher pressures on the sampling flow rate.

Results

The following tables summarize results from several tests performed under various conditions. Unless otherwise stated, all results were obtained using a 2-mm diameter needle device and aqueous glycerine solution if the viscosity was different to 1 cP, the 2 mm needle device is usually preferred to the 1 mm when there is a need to maximize the flow. It is important to note that the following results are to be used as guidelines only, as they may be impacted in particular by the design of the sample paths (tubing length, complexity, etc.).

EMD Millipore is a division of Merck KGaA, Darmstadt, Germany

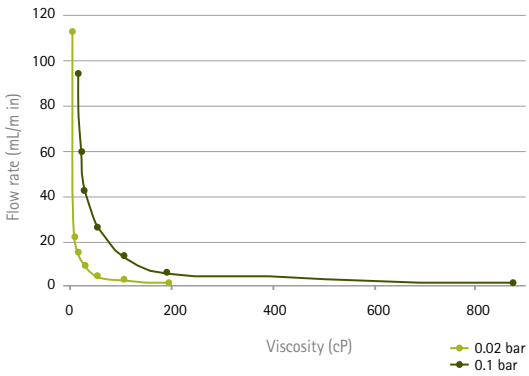
Table 1.

Hydrostatic Pressure Test Results

Viscosity (cP)	Pressure (Bar)	Flow rate (mL/min)
192	0.02	2
111	0.02	4
58	0.02	6
31	0.02	9
24	0.02	14
16	0.02	22
1	0.02	114
876	0.1	1
192	0.1	6
111	0.1	14
58	0.1	27
31	0.1	42
24	0.1	61
16	0.1	95

Figure 1.

Viscosity vs Flow rate at 0.02 and 0.1 bar of hydrostatic pressure



1. Flow rate measurement under hydrostatic pressure

For a vessel operated under atmospheric pressure, the sampling flow rate is impacted by the hydrostatic pressure (proportional to the liquid height). Results in Table 1 were obtained by filling a vertical tube with a defined liquid height to reach the desired hydrostatic pressure.

Table 1 and Figure 1 show the major impact of the viscosity on the sampling flow rate as well as the impact of the hydrostatic pressure. Only low viscosities permit acceptable flow rates at low pressure.

Table 2.

Test Results Using a Syringe under Hydrostatic Pressure

Viscosity (cP)	Pressure (Bar)	Flow rate (mL/min)
1583	0.1	9
1024	0.1	8
493	0.1	24
199	0.1	48
16	0.1	65

2. Flow rate measurement under hydrostatic pressure using a 20 mm syringe

Table 2 shows only a moderate impact on flow rate when a syringe is used for sampling. This limitation is mainly due to the low force generated by the syringe (delta pressure x surface) in comparison to the required force to move the fluid and overcome the drop of pressure induced by viscosity and length of fluid path. In addition, the results in Table 2 are only given as an indication as they are not reproducible due to the human interaction with the syringe (force applied on the syringe).

3. Flow rate measurement under pressure

Tests were performed under pressure in order to increase the flow rate as well as to represent sampling from a pressurised vessel. A test pressure of 0.5 bar was not exceeded so as to respect product specifications.

The tests performed with water (results corresponding to a viscosity of 1 cP) shows the important effect of the pressure on the flow rate. It was also observed that the configuration of the sampling device had an impact on flow rate, which may vary by +/- 20%. For the solution at 16 cP, the flow rate is almost 4 times higher at 0.5 bar than at 0.1 bar of hydrostatic pressure (Table 1).

Viscosity (cP)	Pressure (Bar)	Flow rate (mL/min)
1494	0.5	5
992	0.5	5
248	0.5	40
16	0.5	370
1	0.1	350
1	0.2	410
1	0.3	470
1	0.4	525
1	0.5	580

Table 3.
Pressure Test Results

4. Bag filling test

Table 4 summarizes the results of the time needed to fill sampling bags with water to their nominal volume depending on pressure and needle size.

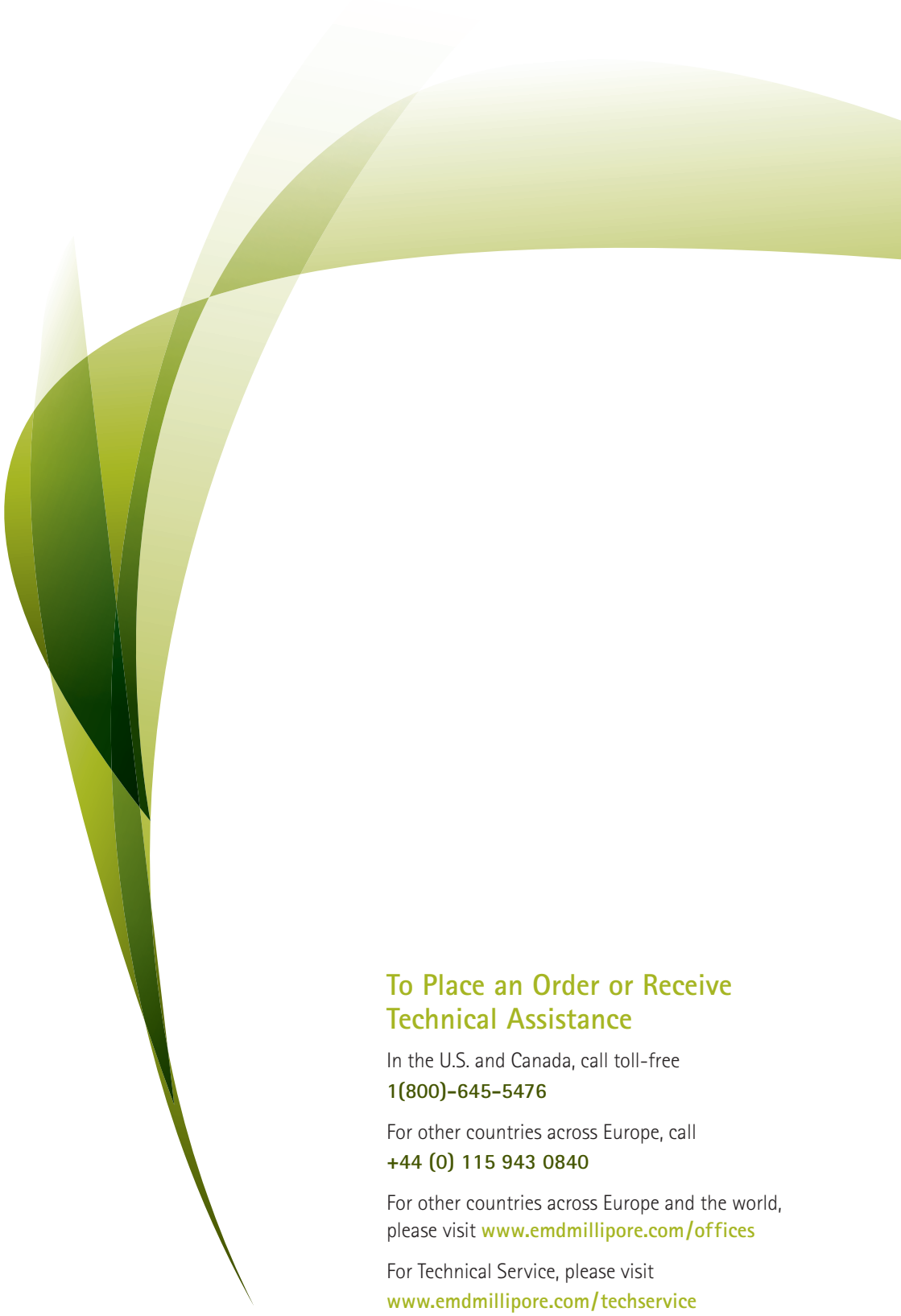
	1 mm – Green Cannula				2 mm – Blue Cannula			
Volume (mL)	50	100	250	1000	50	100	250	1000
Pressure (Bar)	Bag Filling Time							
0.1	25 s	50 s	2 min 05 s	8 min 20 s	8 s	20 s	40 s	2 min 50 s
0.2	20 s	20 s	1 min 25 s	5 min 30 s	6 s	15 s	30 s	2 min 05 s
0.3	15 s	15 s	1 min 10 s	4 min 45 s	6 s	10 s	30 s	1 min 50 s

Table 4.
Bag filling test results

Conclusion

The set of tests performed to evaluate the flow rate contingent on parameters such as needle diameter, pressure and viscosity shows the major impact they can have on the flow rate and bag fill time. While flow rate varies following a power function depending on viscosity, it varies linearly with pressure. The tests also showed that the effect of a syringe has limited capacity to increase the range of sampling viscosities with acceptable flow rates.

The information presented in this technical brief is to be used as a guideline only. We recommend that all specific applications be evaluated prior to implementation. Contact your local Application Specialist for assistance with any NovaSeptum® solution.



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