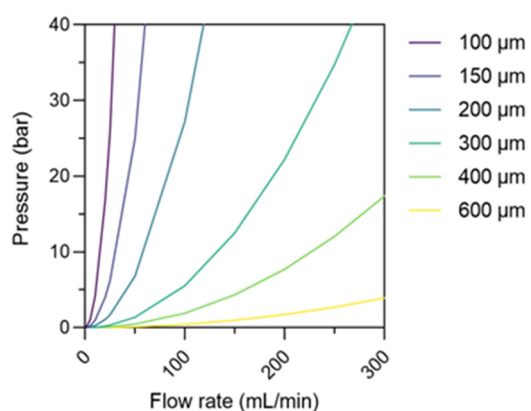


# TECHNICAL NOTE



## Operating LEON equipment with highly viscous solutions

LEON's FR-JET reactor and equipment—the NANOLab®, NANOME® and NANOUS®—including the precursor devices LSF and LKOS, are designed for process development and manufacturing of nanoformulations that are typically based on aqueous buffers or organic solvents with viscosities between 0.8 and 1.5 mPas. The systems were developed and tested using water as testing solution, and operation limits were deduced based on these solution and measurement parameters.



Pinhole	At 40 bar	At 30 bar
100 μm	31.0 mL/min	26.9 mL/min
150 μm	63.3 mL/min	54.8 mL/min
200 μm	121.2 mL/min	105.0 mL/min
300 μm	268.3 mL/min	232.3 mL/min
400 μm	455.5 mL/min	394.5 mL/min
600 μm	959.9 mL/min	831.3 mL/min

Figure 1: Dependence of pressure on fluid flow rate (water) for different FR-JET pinholes. The values shown in the table are the theoretical maximum flow rates of water through different FR-JET pinholes within a 40 or 30 bar pressure limit. Please refer to the flow rate ranges of the different devices.

The chart above illustrates the relation of flow rate and backpressure generated by different FR-JET pinholes when using water. Please refer to technical data sheets for recommended upper pressure ranges for each device, which determines the maximum flow rate for different FR-JET pinholes (see values in table).

It is possible to operate all LEON equipment with highly viscous fluids (in context of pharmaceutical manufacturing) taking into account that the maximum flow rates for the equipment within the set pressure limits will be lower (except in the LSF). This is driven by two factors: (a) an increase in pressures at the FR-JET pinholes from highly viscous fluids and (b) potential cavitation formation in the pump heads that may interfere with the ability of the pumps to generate a constant fluid flow. For example, natural oil with a viscosity of 50-60 mPas was used as highly viscous starting material with our micro-gear pump device (NANOLab®). Figure 2 illustrates the pressure generated by the flow of such high-viscous medium through different pinholes of the FR-JET. Overall, a maximum flow rate per pump of approx. 65 mL/min was found for this medium, the limiting factor being inconsistent medium flow into the pumps due to cavitation.

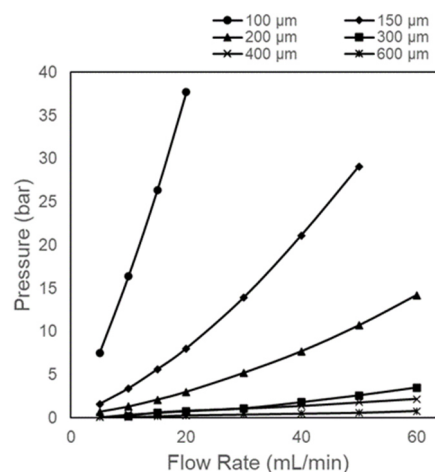


Figure 2: Dependence of pressure on the flow rate of a highly-viscous medium (natural oil with 50-60 mPas) for different FR-JET pinholes.

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