

Statement

Flow through neria™ and neria™ multi infusion sets at different pump pressures

The neria™ and neria™ multi products are intended for subcutaneous Immunoglobulin infusion for primary immune deficiency treatment^{1,2,3,4,5}. neria™ multi infusion set comes in bi- tri- and quad furcated versions.

Since immunoglobulin is a drug with high viscosity compared to water and air, a flow test was conducted with a liquid that resembles the viscosity of immunoglobulin's⁶.

The test was conducted with glycerin thinned with water to a viscosity of 16,02 cP +/-0,08 cP⁷ at 0,93 bar, 1,4 bar, 3,0 bar and 4,5 bar representing Freedom 60 pump, Niki T34 / Micrel MP101 pump, Crono S-PID 50 pump and Crono S-PID pump⁶.

The average flow rates from the test can be seen in the matrix:

	0,93bar [ml/h]	1,4bar [ml/h]	3,0bar [ml/h]	4,5bar [ml/h]
Single (neria™) 60 cm tubing	9	14	30	45
Bi-Furcator	25	37	78	117
Tri-Furcator	35	52	110	166
Quad-Furcator	40	60	127	192

The results demonstrate that neria™ multi products can be used with pumps working at different pressures and with the average flow rates as listed in the matrix⁶.

07-10-2014 / EVC / Eva Christensen

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¹ Unomedical 14, Drug Compatibility Study of Quadfurcated Infusion Device (neria™ multi) with Immunoglobulin Solution for Subcutaneous Infusion (Hizentra®). Approval date: 31.01.2012.

² Statement, Drug/Device Compatibility of neria™ multi with Subcuvia®, Vivaglobin®, and Gammanorm®. Approval Date: 15.12.2011.

³ Verification Test Report for UMA, Test ID V18 Device compatibility test. Approval Date: 12.12.2011.

⁴ Compatibility and stability testing of the catheter device Unomedical comfort with the Immunoglobulin Subcuvia. IKFE Report. July 23, 2009. Data on File Unomedical.

⁵ Transferability of biocompatibility test results from tests with Subcuvia to other corresponding drugs. IKFE No 09016. April 16, 2009. Data on File Unomedical.

⁶ Multi pressure flow test, project no. RD 2010-03, 14.02.2012. Data on File Unomedical.

⁷ According to information from CSL Behring dated November 23, 2010. Data on File Unomedical