OraChrom, Inc.

The Vanguard of Liquid Chromatography.

10-B Henshaw Street Woburn, MA 01801 USA

Phone (781) 932 0151 *E-mail:* info@orachrom.com Fax

(781) 932 0787 www.orachrom.com

APPLICATION NOTE

Simulated-MonolithTM, Beyond Monolith.

A Line of Stable Polymeric that Allows Universal Separations Convectively Fast to Accommodate the Speed and Scale of Vaccine Production at All Times Particularly During Pandemic Avoiding the Unnecessary Step of Polishing.

We have highlighted in this Application Note the speed and practicality of the use of Simulated-MonolithTM especially at times such as these and certainly in the future, where we can no longer afford the slow speed of soft gel to run the downstream production of vaccines crucial for the health care of the entire word.

Nor is it proper to deprive the population of the choice of tainted vaccines that need to be kept at sub-zero temperatures not to deteriorate.

<u>Leaching during downstream production cannot be</u> "polished". A tainted product remains tainted and needs sub-zero temperatures to keep it as such.

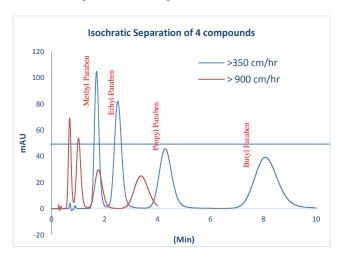


Table 1. Operating parameters.

HPLC System.	Agilent 1290 with thermostatted column compartment and
	binary pump.
Columns	STYROS® 1R 2.1 X 50 mm (0.173 ml volume)
Mobile phase.	A: H20, 0.075 % TFA
	B: 5% H20 in ACN, 0.075 % TFA
Flow rates	0.2 ml/min (347 cm/hr of linear velocity on an empty
	column)
	0.5 ml/min (867 cm/hr of linear velocity on an empty
	column)
Isocratic	57 % A, 43 % B
Temperature	30°C
Detection	254 nm
Injection volume	4 μ1
Pressure Drop	15 bars at 0.2 ml/min, 40 bar at 0.5 ml/min.
Sample:	Certified diagnostic test 48270-U Sigma-Aldrich.

Notice the low back pressure at low and high flow rates. These numbers are to be compared with 100 cm/hr that soft gel operates.

The leaching occurs even at low flow rates.

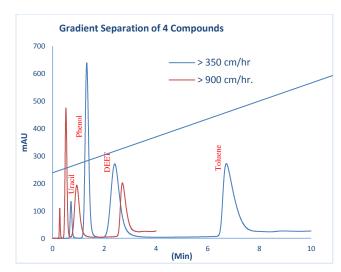


Table 2. Operating parameters.

HPLC System.	Agilent 1290 with thermostatted column compartment and
	binary pump.
Columns	STYROS® 1R 2.1 X 50 mm (0.173 ml volume)
Mobile phase.	A: H20, 0.075 % TFA
	B: 5% H20 in ACN, 0.075 % TFA
Flow rates	0.2 ml/min (347 cm/hr of linear velocity on an empty column)
	0.5 ml/min (867 cm/hr of linear velocity on an empty
	column)
Gradient	50 to 80 % B in 10 min or
	50 to 80 % B in 4 min
Temperature	30°C
Detection	254 nm
Injection volume	6 μl
Pressure Drop	15 bars at 0.2 ml/min, 40 bar at 0.5 ml/min.
Sample:	Certified diagnostic test 47641-U Sigma-Aldrich.

Unlike monolith, Simulated-MonolithTM is not prone to the "wall effects" and leaching that monolithic media suffers from.

