HALO®

PHARMACEUTICALS

Optimization of Rivaroxaban USP Monograph using Superficially Porous Particle Technology

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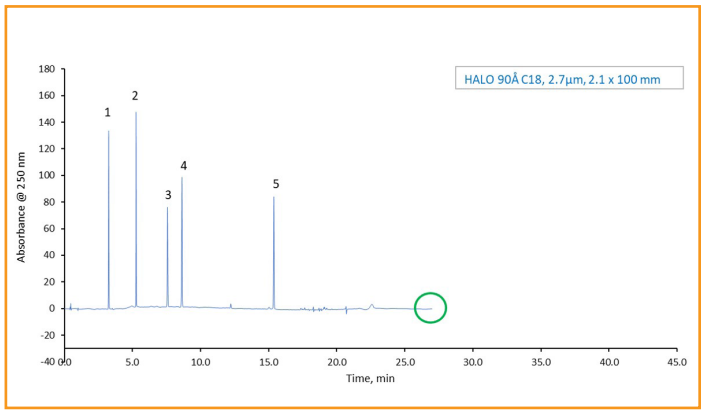

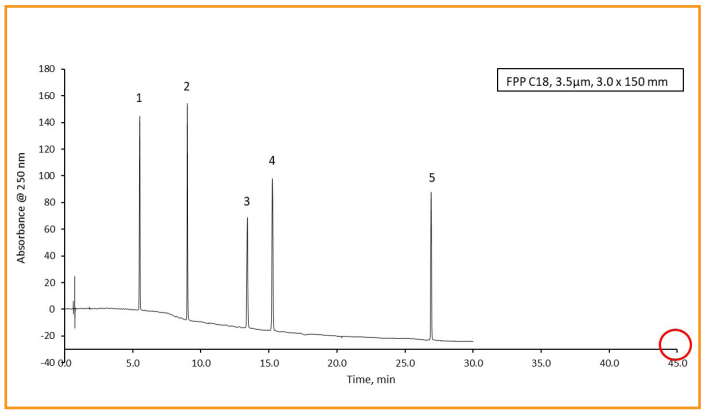

TEST CONDITIONS:

Column: FPP C18, 3.5 µm, 3.0 x 150 mm
Column: HALO 90 Å C18, 2.7µm, 2.1 x 100 mm
Part Number: 92812-602
Mobile Phase A: 5/95 Methanol/Solution A
Mobile Phase B: Acetonitrile
Solution A: Dissolve 1.36 g of potassium dihydrogenphosphate, 1 g sodium hexane sulfonate, and 200 µL of phosphoric acid in water. Dilute with water to 1 L.
Solution B: Dissolve 1.36 g of potassium dihydrogenphosphate and 200 µL of phosphoric acid in water. Dilute with water to 1 L.
Flow Rate: 1.0 mL/min (3.0 mm)
0.5 mL/min (2.1 mm)
Pressure: 210 bar (3.0 mm)
233 bar (2.1 mm)
Temperature: 60 ˚C
Detection: UV 250 nm, PDA
Injection Volume: 3 µL (3.0 mm)
0.9 µL (2.1 mm)
Sample Solvent: 40/60 Acetonitrile/ Solution B
Data Rate: 40 Hz
Response Time: 0.025 sec.
Flow Cell: 1 µL
Instrument: Shimadzu Nexera X2

Gradients:

FPP C18, 3.5µm, 3.0x150 mm

Time:	%B
2.00	2
8.00	16
25.00	36
37.00	80
38.00	2
45.00	2

HALO 90 Å C18, 2.7µm, 2.1x100 mm

Time:	%B
1.14	2
4.56	16
14.26	36
21.10	80
22.00	2
27.00	2

PEAK IDENTITIES

1. Rivaroxaban related compound B
2. Rivaroxaban related compound D
3. Rivaroxaban related compound G
4. Rivaroxaban
5. Rivaroxaban related compound J

Rivaroxaban is a drug used to treat blood clots in the legs and the lungs. The associated USP method calls for a fully porous particle using a 3.0 mm ID column. The method as written requires a 45 minute run time for the separation of 4 impurities associated with Rivaroxaban. Following the approved USP <621> modernization guidelines. The method can be improved with the use of HALO® column technology, which is a superficially porous particle and the use of a smaller column ID (2.1 mm) and length. The 45-minute run time can be cut down to only 27 minutes for a time savings of 40%. Along with the reduction of run time, there is a reduction in solvent and sample usage. With the HALO® Fused-Core® technology the USP method for Rivaroxaban can be optimized for time, solvent savings, and sample usage, while adhering to the strict guidelines of the USP.

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