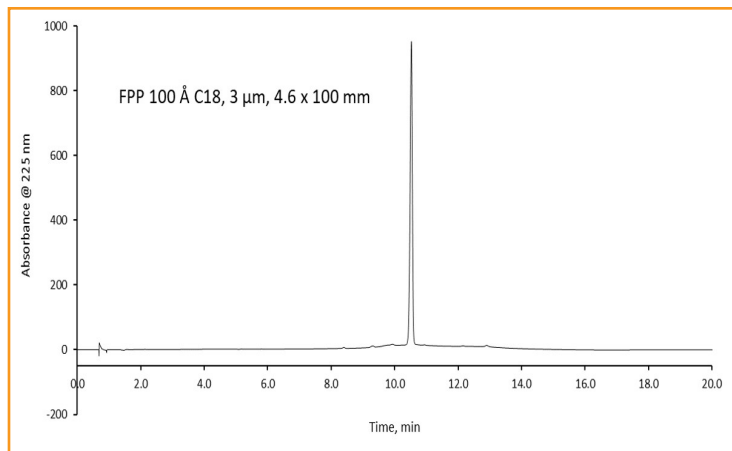




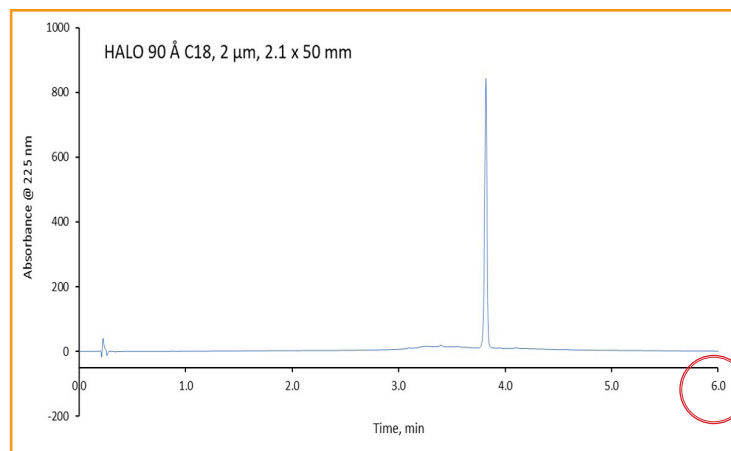
### Optimization of USP Monograph for Itraconazole

327



#### PEAK IDENTITIES

##### 1. Itraconazole



#### TEST CONDITIONS:

**Column:** FPP 100 Å C18, 3 µm, 4.6 x 100 mm

**Column:** HALO 90 Å C18, 2 µm, 2.1 x 50 mm

**Part Number:** 91812-402

**Mobile Phase A:** 13.6 g/L of tetrabutylammonium hydrogen sulfate in water

**Mobile Phase B:** ACN

Gradient:	Time	%B
4.6 x 100 mm:	0.00	20
	12.00	50
	16.00	20
	20.00	20

2.1 x 50 mm:	Time	%B
2.1 x 50 mm:	0.00	20
	3.75	50
	5.00	20
	6.25	20

**Flow Rate:** 1.5 mL/min (4.6 mm)  
0.5 mL/min (2.1 mm)

**Pressure:** 242 bar/4.6mm  
402 bar/2.1mm

**Temperature:** 30 °C

**Detection:** UV 225 nm, PDA

**Injection Volume:** 10 µL (4.6 mm)  
1 µL (2.1 mm)

**Sample Solvent:** 0.4% HCl in methanol

**Data Rate:** 100 Hz

**Response Time:** 0.025 sec.

Itraconazole is an antifungal medication used for the treatment of various fungal and yeast infections. With the newly approved <621> guidance for allowable changes to USP gradient methods, the method for itraconazole which was official as of 01-May-2020 from USP can be optimized to save time, reduce solvent consumption, and reduce sample if needed. The method specifies a 4.6 x 100 mm, 3 µm L1 column. By changing to a shorter length and smaller ID column with smaller particle size (HALO 90 Å, 2 µm, 2.1 x 50 mm), the total run time is reduced by more than 3 times and solvent consumption is reduced by 10 times. Additionally, the amount of sample injected is reduced from 10 µL to 1 µL. HALO® Fused-Core® technology enables USP gradient methods to be optimized for both time and solvent savings.

