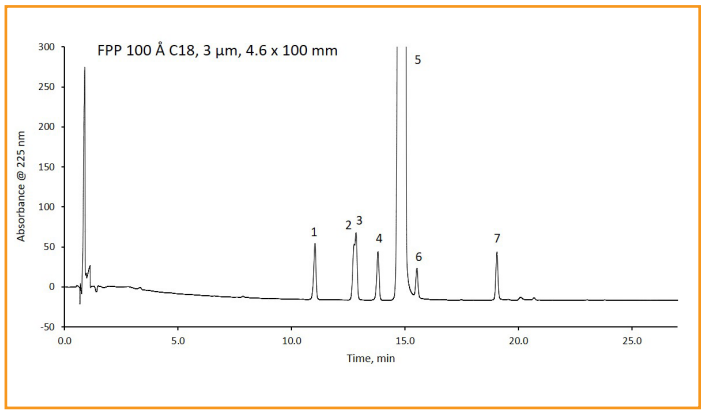
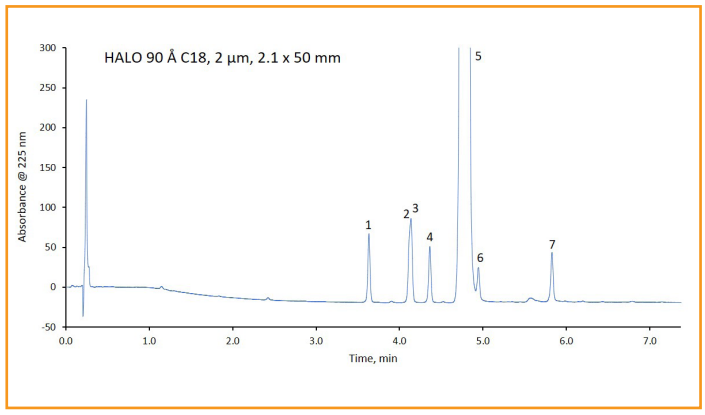
HALO®

PHARMACEUTICALS

# USP Itraconazole System Suitability Comparison

335




## 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:** 27.2 g/L of Tetrabutylammonium Hydrogen Sulfate in Water
**Mobile Phase B:** ACN
**Flow Rate:** 1.5 mL/min (4.6 mm)
0.5 mL/min (2.1 mm)
**Pressure:** 307 bar/4.6 mm
455 bar/2.1 mm
**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.
**Flow Cell:** 1 µL
**Instrument:** Shimadzu Nexera X2

**Gradients:**

FPP C18, 3 µm 4.6 x 100 mm:

| Time | %B |
|---|---|
| 0.00 | 20 |
| 2.00 | 20 |
| 22.00 | 50 |
| 27.00 | 50 |

HALO 90 Å C18 2 µm 2.1 x 50 mm:

| Time | %B |
|---|---|
| 0.00 | 20 |
| 0.55 | 20 |
| 6.00 | 50 |
| 7.37 | 50 |

## PEAK IDENTITIES

1. 4-Triazolyl Isomer
2. Propyl analog
3. Isopropyl analog
4. Epimer
5. Itraconazole
6. n-Butyl isomer
7. Didioxolanyl analog

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 system suitability 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 11 times. Even with these changes, the HALO® column passes the system suitability requirement of peak-to-valley ratio by 2 times the minimum. 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.



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