PHARMACEUTICALS

HALO

Optimization of USP Monograph for 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 hy drogen sulfate in water Mobile Phase B: ACN Gradient: Time %B

Gradiente		700
4.6 x 100 mm:	0.00	20
	12.00	50
	16.00	20
	20.00	20
2.1 x 50 mm:		
	Time	%В
	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 μ L (4.6 mm) 1 μ L (2.1 mm) Sample Solvent: 0.4% HCl in methanol Data Rate: 100 Hz Response Time: 0.025 sec.

PEAK IDENTITIES



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.



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