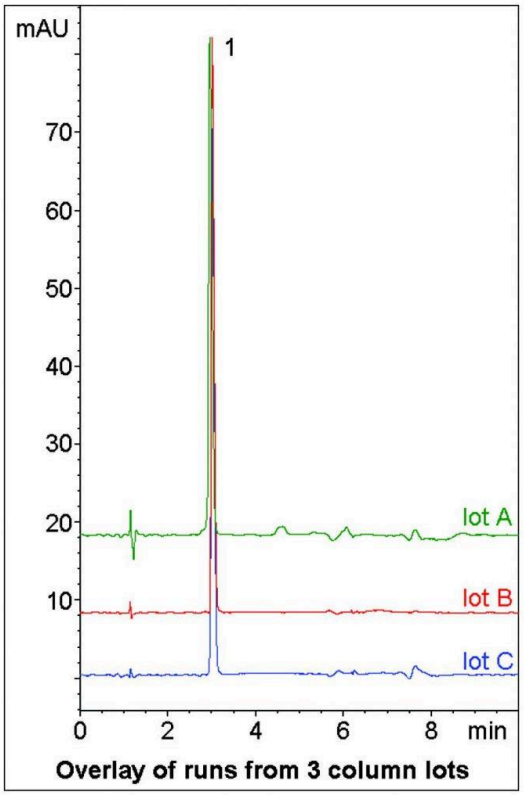
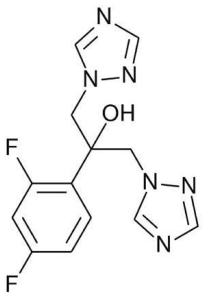
Fluconazole Tablet Analyzed with HPLC - AppNote

Assay Method for Amine Containing API

This Application Note shows a simple Gradient Method for Assay of Fluconazole Tablets. In Reversed Phase HPLC, notable tailing was observed due to the two heterocyclic amine groups. Use of Aqueous Normal Phase *(ANP)* HPLC produced a sharp Peak for this API. Data from three different Column lots is shown in order to demonstrate the Method Reproducibility and Robustness.





Peak:

Fluconazole

Method Conditions

Column: Cogent Diamond Hydride™, 4µm, 100Å

Catalog No.: 70000-7.5P
Dimensions: 4.6 x 75mm
Mobile Phase:
A: DI Water with 0.1% Formic Acid (v/v)
B: Acetonitrile with 0.1% Formic Acid (v/v)
Gradient:

Time *(minutes)*	%B
0	95
1	95
6	40
7	40

Post Time: 3 minutes
Injection vol.: 1µL
Flow rate: 1.0mL / minute
Detection: UV @ 260nm
Sample Preparation: 150mg strength Fluconazole Tablet was ground and added to 50mL volumetric flask containing 25mL 50:50 Solvent A / Solvent B diluent. The solution was sonicated 10 minutes, diluted to mark, and mixed. A portion was filtered through a 0.45µm Nylon Syringe Filter (MICROSOLV Tech Corp.).
t_0 : 0.9 minutes

Note: *Fluconazole is a triazole antifungal drug. Its mode of action is inhibition of fungal Cytochrome P450 enzyme 14a-demethylase. It is available under the trade name Diflucan®.*

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