

# HPLC Application

ID No.: 27271

## Ph. Eur. Azithromycin - Related Substances System Suitability Solution on Durashell 5 µm C18(L) 250 x 4.6 mm u

**Column:** N/A

**Dimensions:** N/A

**Order No:** N/A

**Elution Type:** N/A

**Eluent A:** 1.80 g/L solution of anhydrous disodium hydrogen phosphate adjusted to pH 8.9

**Eluent B:** Acetonitrile:Methanol = 75:25

<b>Gradient Profile:</b>	<b>Step No.</b>	<b>Time (min)</b>	<b>Pct A</b>	<b>Pct B</b>
	<b>1</b>	0	50	50
	<b>2</b>	25	45	55
	<b>3</b>	30	40	60
	<b>4</b>	80	25	75
	<b>5</b>	81	50	50
	<b>6</b>	93	50	50

**Flow Rate:** 1 mL/min

**Col. Temp.:** 60 °C

**Detection:** LC/UV (DAD, PDA) @ 210.000000000 nm (nanometers) (ambient)

**Analyst Note:** mobile phase A: 1.80 g/L solution of anhydrous disodium hydrogen phosphate R adjusted to pH 8.9 with dilute phosphoric acid R or with dilute sodium hydroxide solution R; Diluent buffer: 1.73 g/L solution of ammonium dihydrogen pH adjusted to 10.0 with ammonia  
Diluent: Diluent buffer: Acetonitrile: methanol = 35:30:35 (v/v/v)



### ANALYTES:

- 1** Azithromycin Impurity F  
Retention Time: 23.97 min
- 2** Azithromycin Impurity J  
Retention Time: 25.48 min
- 3** Azithromycin Impurity H  
Retention Time: 35.8 min

