

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

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

