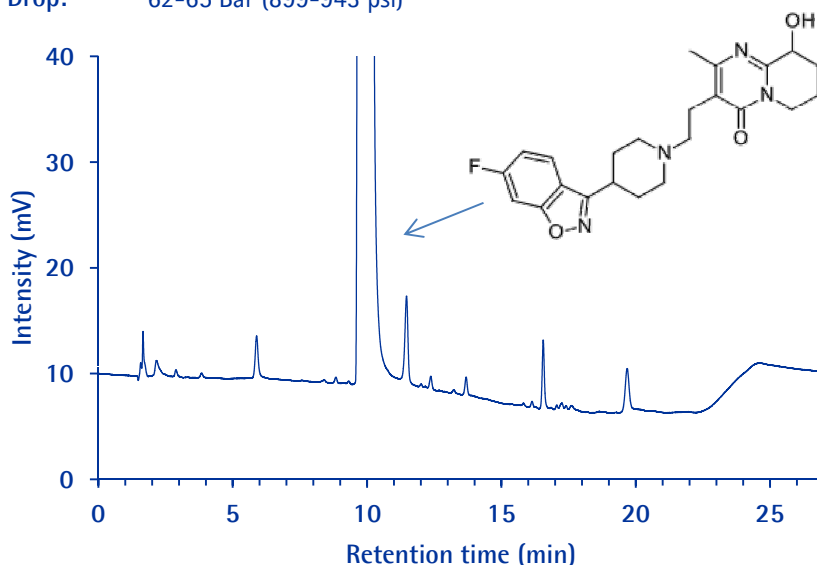


Paliperidone and Related Substances

Chromolith® HighResolution RP-18 endcapped

Chromatographic Conditions

Column:	Chromolith® HighResolution RP-18 endcapped 100x4.6mm	1.52022.0001
Injection:	10 µL	
Detection:	UV 238 nm	
Flow Rate:	1.0 mL/min	
Buffer:	Dissolve 1.36 g of potassium dihydrogen phosphate in 1000 mL with Milli-Q water. Adjust pH to 2.0 with orthophosphoric acid. Mobile phase A: buffer and mobile phase B: acetonitrile	
Gradient	See table	
Temperature:	25 °C	
Diluent	Buffer and acetonitrile 80:20 (v/v)	
Reference solution:	1ppm solution of hydroxyimpurity in 1000 ppm of Paliperidone standard in diluent.	
Sample:	Dissolve 10 mg of sample in 10 ml diluent.	
Pressure Drop:	62–65 Bar (899–943 psi)	



Time	A %	B %
0	90	10
2	90	10
15	70	30
20	70	30
22	90	10
27	90	10

Chromatographic Data

No.	Compound	Retention Time (min)	Resolution	Relative Retention Time
1	Hydroxy Impurity	5.9	0.0	0.60
2	Paliperidone	9.8	10.6	1.00
3	Impurity 1	11.5	4.6	1.17
4	Impurity 2	12.4	5.0	1.27
5	Impurity 3	13.7	8.4	1.40
6	Impurity 4	16.6	18.7	1.70