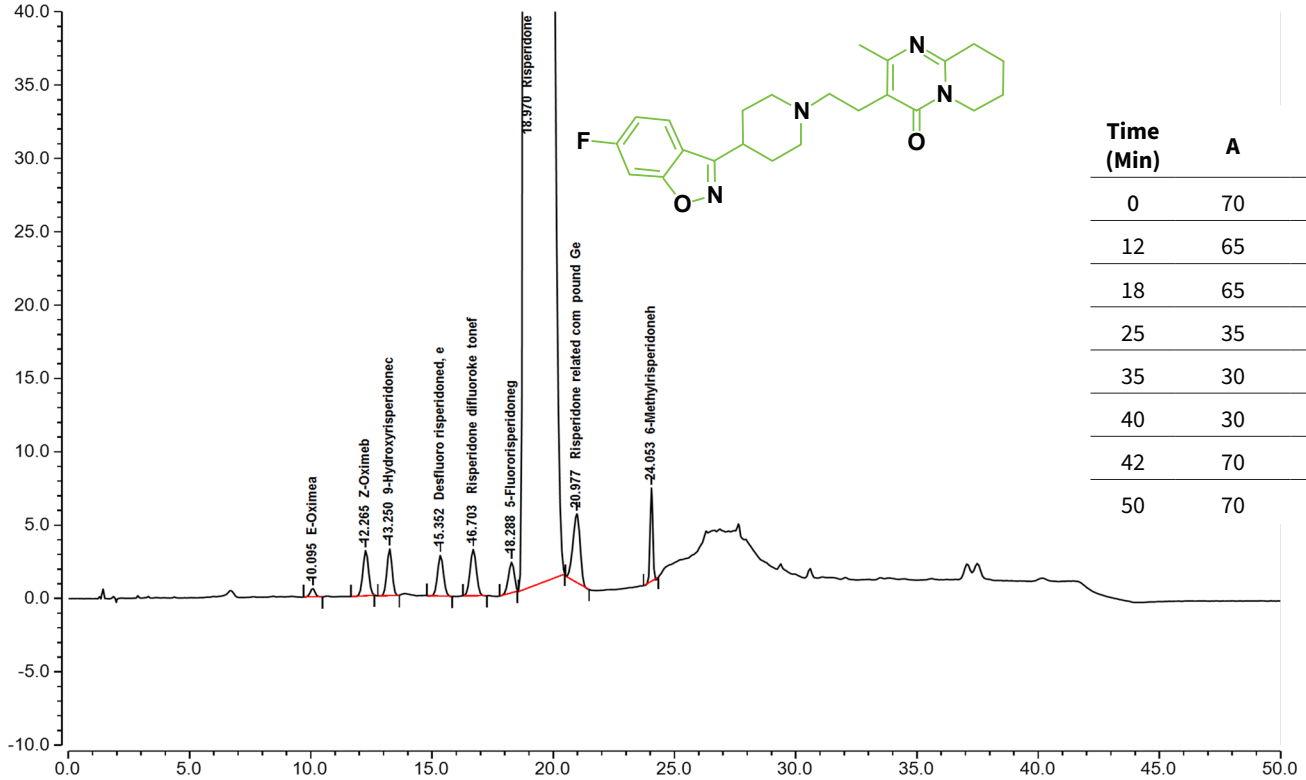




Risperidone USP

Rubitas® C8 XM 5µm 250X4.6



Time (Min)	A	B
0	70	30
12	65	35
18	65	35
25	35	65
35	30	65
40	30	70
42	70	30
50	70	30

Test Condition (As USP)

Column:

Rubitas® C8 XM 250x4.6 mm, 5µm

Injection: 10 µL

Detection: UV 260 nm

Flow Rate: 2.0 mL/min

Mobile Phase A: 5 g/L Ammonium Acetate and adjust pH to 6.0 with glacial acetic acid

Mobile Phase B: Acetonitrile : Methanol (40:60)

Buffer: 0.7 ml of 85 % orthophosphoric acid in 1000 ml Water

Gradient: See Table

Diluent: Methanol

Temperature: 50°C

Autosampler temperature: 5°C

Sample preparation:

20 µg/mL of USP Risperidone Related Compound G RS and 10 mg/mL of USP Risperidone RS in methanol. Sonication may be used to aid in dissolution.

Chromatographic data

Compound	Ret. Time (min)	Resolution	Tailing Factor	RRT
E-Oxime	10.095	n.a.	0.87	0.53
Z-Oxime	12.265	5.33	1.02	0.65
9-Hydroxyrisperidone	13.25	2.42	0.99	0.7
Desfluoro risperidone	15.352	4.97	1.02	0.81
Risperidone difluoroketone	16.703	2.83	0.99	0.88
5-Fluororisperidone	18.288	3.25	0.85	0.96
Risperidone	18.97	0.91	2.89	1.00
Risperidone related compound G	20.977	2.54	0.89	1.11
6-Methylrisperidone	24.053	8.23	0.99	1.27