Application No. L3043

Lurasidone Hydrochloride

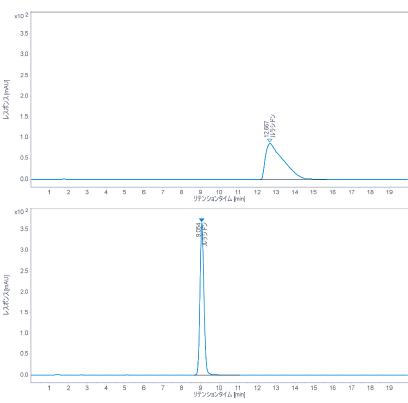
Lurasidone hydrochloride is an atypical antipsychotic known for its antagonistic effects on dopamine D2 receptors and serotonin

5-HT2 receptors. Generally, low retention and poor peak shape are observed in acidic eluents with a pH lower than the pKa of the basic substance. On the other hand, alkaline eluents exhibit better peak shape and greater retention. However, Lurasidone hydrochloride's retention in alkaline eluents is substantial, which increases the risk of salt precipitation. In this study, we compare the peak shape of Lurasidone hydrochloride in both acidic and neutral eluents.

Key words	:	Lurasidone Hydrochloride,	C18, ODS,	Antipsychotic,	Basic substance
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Column :	L-column3 C18 (USP	category: L1)
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[Analytical con	ditic	ons]
Column	:	<i>L-column3 C18</i> (5 µm, 12 nm); 4.6 mm I.D. × 150 mm L.; Cat. No. 822070
Eluent	:	CH ₃ CN/10 mmol/L Phosphoric acid (30/70 v/v)
		$CH_3CN/10 \text{ mmol/L}$ Phosphate buffer pH 7 (75/25 v/v)
Flow rate	:	1 mL/min
Temperature	:	40℃
Detection	:	UV 230 nm
Injection volume :		5 μL
System	:	Agilent 1260



Lurasidone Hydrochloride (500 mg/L) Sample solvent: $CH_3CN/H_2O(1/1)$

Sample:



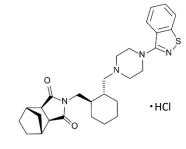


Fig. 1 Comparison of Lurasidone hydrochloride eluent (upper) phosphoric acid, (lower) phosphate buffer pH 7 $\,$

Noticeably poor peak shape and a large tail is observed for Lurasidone hydrochloride in an acidic eluent. Moreover, the organic solvent ratio is as low as 30% when compared to the neutral eluent. In contrast, the neutral eluent provides a significantly higher organic solvent ratio of 75%, resulting in a sharp peak and a tailing factor of Lurasidone around 1.1.

