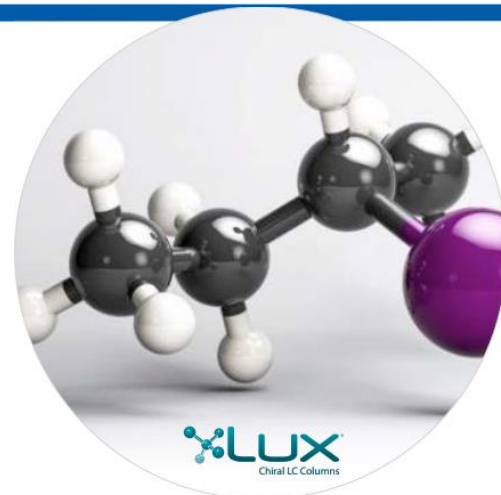


## Limit of Lacosamide S-enantiomer in USP Lacosamide Drug Substance using Lux® 5 µm Amylose-1 Column

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### Overview

Lacosamide is a chiral drug which is commercialized as pure enantiomer. It is an antiepileptic drug approved in the USA and Europe. The current trend is to commercialize drugs formulated in their enantiopure form, which means containing only the single enantiomer responsible for pharmaceutical activity. The S-enantiomer of Lacosamide, designated as Impurity A, is pharmaceutically inactive and therefore undesirable to have in the presence of the active R-Lacosamide.

In this application note, we report the enantiomeric separation between Lacosamide and its enantiomer (Impurity A) using the Lux Amylose-1 chiral column according to the USP monograph for Lacosamide.

System suitability per USP Monograph for enantiomeric purity of Lacosamide is for resolution of not less than (NLT) 3.0. The separation of the enantiomers was achieved and peaks corresponding to the Impurity A and Lacosamide had a resolution of 4.7, exceeding the system suitability requirement (**Figure 1**). The higher resolution indicates the powerful chiral recognition ability of Lux 5 µm Amylose-1 chiral stationary phase column.

The Lux Amylose-1 column provided a signal to noise ratio (S/N) of 41.8 for the S-enantiomer, greatly exceeding the required S/N of NLT 10. This suggests a level of quantitation (LOQ) for the S-enantiomer well below 0.5 % in Lacosamide.

All reference solutions were prepared as indicated in the USP Monograph for Lacosamide. Lacosamide CV (250 mg) (Catalog No. 1357103), and Lacosamide S-Enantiomer (30 mg) (Catalog no. 1357158) were purchased from USP.

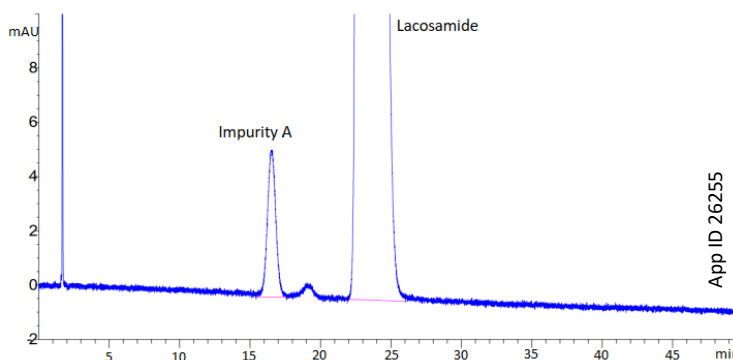
### LC-UV Conditions

**Column:** Lux 5 µm Amylose-1 (150 x 4.6 mm)  
**Part No.:** [00F-4732-E0](#)  
**Mobile Phase:** Water, 2-Propanol, Heptane (3:100:900, v/v/v)  
**Pressure (bar):** 81  
**Flow Rate:** 1 mL/min  
**Injection:** 20 µL  
**Temperature:** 25 °C  
**Detector:** UV @ 215 nm  
**System:** Agilent® 1260 Binary UHPLC

**Table 1.** Preparation of Solutions

Solution	Composition
System Suitability Solution	1 mg/mL of USP Lacosamide and 5 µg/mL of USP Lacosamide S-Enantiomer in Mobile phase
Sample Solution	1 mg/mL of Lacosamide in Mobile phase

**Figure 1.** System Suitability Solution



Peak	Time	Area	Height	Width	S/N	Resolution
Impurity A	16.5	225	5.5	0.6	41.8	4.7
Lacosamide	23.1	37231	556.6	99.4		



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