

Ph. Eur. Monograph 2737: Zolmitriptan Enantiomeric Purity on a Lux® 5 µm Amylose-1 column

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Overview

Zolmitriptan belongs to the class of serotonin receptor agonists and is used for the acute treatment of migraine attacks in adults.

In this application note we show the efficient separation of Zolmitriptan [(S)-4-[[3-[2-(dimethylamino)ethyl]indol-5-yl]methyl]-2-oxazolidinone] from its enantiomeric Impurity A [(R)-4-[[3-[2-(dimethylamino)ethyl]indol-5-yl]methyl]-2-oxazolidinone] according to Ph. Eur. monograph 2737.

The Lux Amylose-1 column used in this study exceeds the system suitability requirement for the resolution between Zolmitriptan and Impurity A (≥ 2.0), refer **Table 2.0**.

The reference solution (b) and test solution were prepared as indicated in Ph.Eur. monograph 2737 for Zolmitriptan. The following certified reference standards (CRS) were purchased from the European Directorate for the Quality of Medicines & HealthCare (EDQM) – Council of Europe; Postal address: Allee Kastner CS 30026, F - 67081 Strasbourg (France):

- Y0001975 Zolmitriptan CRS
- Y0001986 Zolmitriptan Impurity A CRS

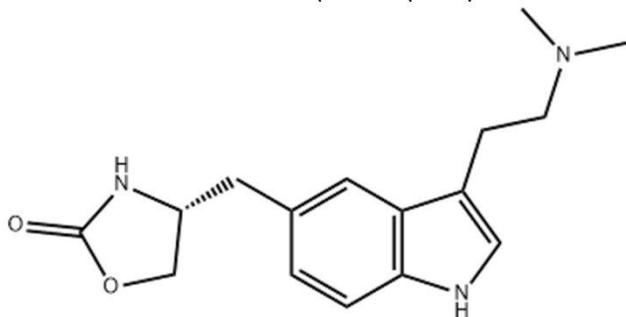


Figure 1. (S)-4-[[3-[2-(dimethylamino)ethyl]indol-5-yl]methyl]-2-oxazolidinone (Zolmitriptan)

Experimental

Table 1: Preparation of test and reference solutions

Solution	Composition
Test solution	Dissolve 25.0 mg Zolmitriptan CRS in mobile phase and dilute to 25.0 mL with mobile phase.
Reference solution (b)	Dissolve 5 mg Zolmitriptan Impurity A in 5.0 mL mobile phase. Mix 1.0 mL of this solution with 1.0 mL Test solution and dilute to 10 mL with mobile phase. 1.0 mL of this solution is diluted to 50 mL with mobile phase

LC/UV Conditions:

- Column:** Lux 5 µm Amylose-1
- Dimensions:** 250 x 4.6 mm
- Part Number:** [00G-4732-E0](#)
- Mobile Phase:** Diethylamine/ 2-propanol/ methanol/ heptane (0.1/10/15/75, v/v/v/v)
- Flow Rate:** 1.0 mL/min
- Injection:** 10 µL
- Detection:** UV @ 285 nm



Chromatographic Results

Figure 2: Reference solution (b) on Lux® 5 µm Amylose-1, 250 x 4.6 mm

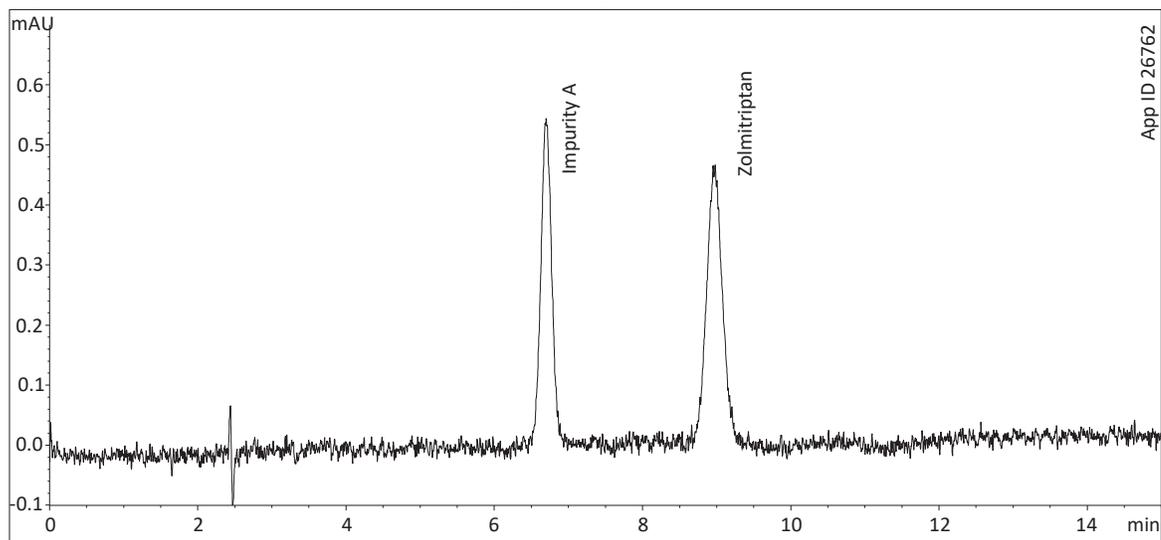


Table 2: Results of reference solution (b) on Lux 5 µm Amylose-1, 250 x 4.6 mm

Injection #	t _R Impurity A (min)	Peak Area Impurity A	t _R Zolmitriptan (min)	Peak Area Zolmitriptan	Resolution
1	6.70	5.8	8.95	6.9	6.9
2	6.68	5.8	8.94	7.4	6.9
3	6.71	6.0	9.00	6.9	7.0
4	6.70	5.8	8.97	6.9	6.7
5	6.68	5.5	8.93	7.0	6.9
6	6.70	5.9	8.98	7.2	7.0
Average	6.69	5.8	8.96	7.1	6.9
% RSD	0.14	2.89	0.31	2.94	1.46



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