

USP Tadalafil Assay on Luna® 5 µm C8(2) and Kinetex® 5 µm C8

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Overview

Tadalafil is a phosphodiesterase-5 enzyme (PDE-5) inhibitor used to treat erectile dysfunction and symptoms associated with enlarged prostate (BPH). Tadalafil is the generic drug of the brand name drug Cialis® (Eli Lilly). This application note for the LC-UV assay for Tadalafil drug substance is based on the official USP assay method which calls for an L7 (C8) 5 µm, 250 x 4.6 mm column under isocratic conditions. The mobile phase and standard solution for the assay was prepared in accordance with the USP monograph, using the USP reference standard for Tadalafil (catalog no. 1642879).

We show the results achieved using two different columns, both containing C8 bonded phase with TMS endcapping. Luna C8(2) is based on a fully porous silica, and Kinetex C8 is based on core-shell silica. Both columns met the system suitability requirements for the assay (**Table 1**): RSD NMT 0.73 % and Symmetry Factor (previously referred to as USP Tailing Factor) for the Tadalafil peak.

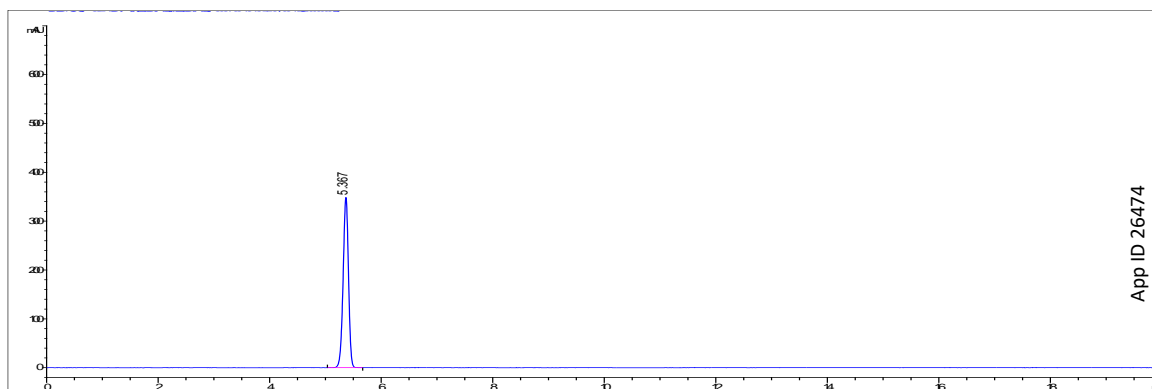
The morphology of the core-shell silica particle results in higher efficiency than the fully porous particle of the same size, resulting in narrower chromatographic peaks. The unique core-shell morphology of the Kinetex C8 also has lower carbon load than the high surface area, fully porous Luna C8(2), which results in shorter retention times and faster analysis times. Despite these differences in particle morphology the Kinetex C8 column easily meets all system suitability requirements for the assay of Tadalafil.

LC-UV Conditions

- Column:** Luna 5 µm C8(2) ([00G-4249-E0](#))
Kinetex 5 µm C8 ([00G-4608-E0](#))
- Dimension:** 250 x 4.6 mm
- Mobile Phase:** Acetonitrile and 0.1% TFA in Water, (45:55)
- Flow Rate:** 1.5 mL/min
- Temperature:** 40 °C
- Detector:** UV @ 285 nm
- Injection:** 20 µL
- System:** Agilent® 1100 (quaternary)
- Sample:** Tadalafil (0.1 mg/mL, USP Tadalafil RS)



Luna® 5 µm C8(2) 250 x 4.6 mm ([00G-4249-E0](#))



Kinetex® 5 µm C8 250 x 4.6 mm ([00G-4608-E0](#))

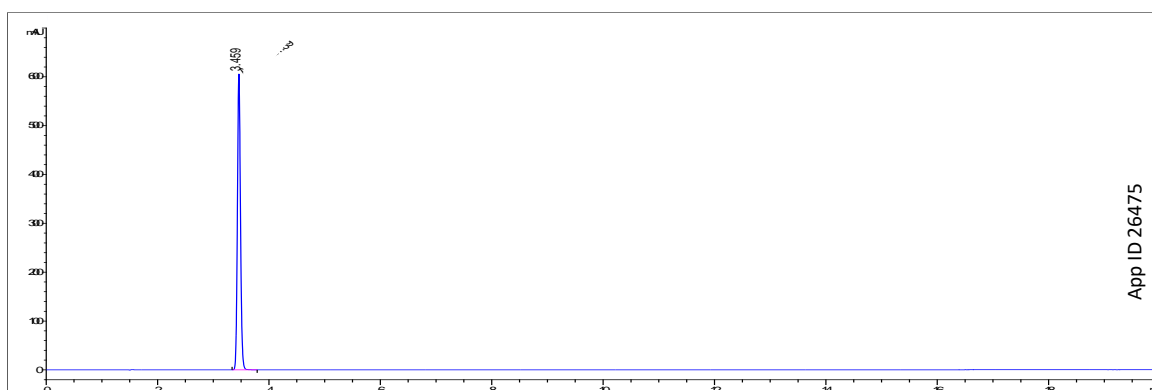


Table 1. Summary of Results for Tadalafil Assay

Column	Retention Time, min	% RSD (n = 6) (NMT 0.73 %)	Symmetry Factor (NMT 1.5)
Luna 5 µm C8(2)	5.367	0.16	1.0
Kinetex 5 µm C8	3.459	0.69	1.1



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