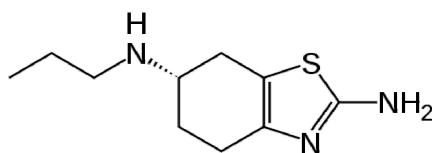


Pramipexole and Related Substances (USP)

Purospher® STAR RP-18 endcapped



Pramipexole

Pramipexole is a dopamine agonist used for treating Parkinson's disease (PD) and restless legs syndrome (RLS). Common brand names: Mirapex, Mirapexin, Sifrol.

The current USP monograph method for Olanzapine and related substances as well as for the assay method specifies the use of a 150x4.6 mm column with 5 µm L1 (RP-18) packing as stationary phase. System suitability requirements for related substances are; Resolution: NLT 6.0 between pramipexole related compound A and pramipexole; and a tailing factor NMT 2.0 for pramipexole. In addition, in the assay method the relative retention times for pramipexole related compound A and pramipexole are specified about 0.7 and 1.0, respectively.

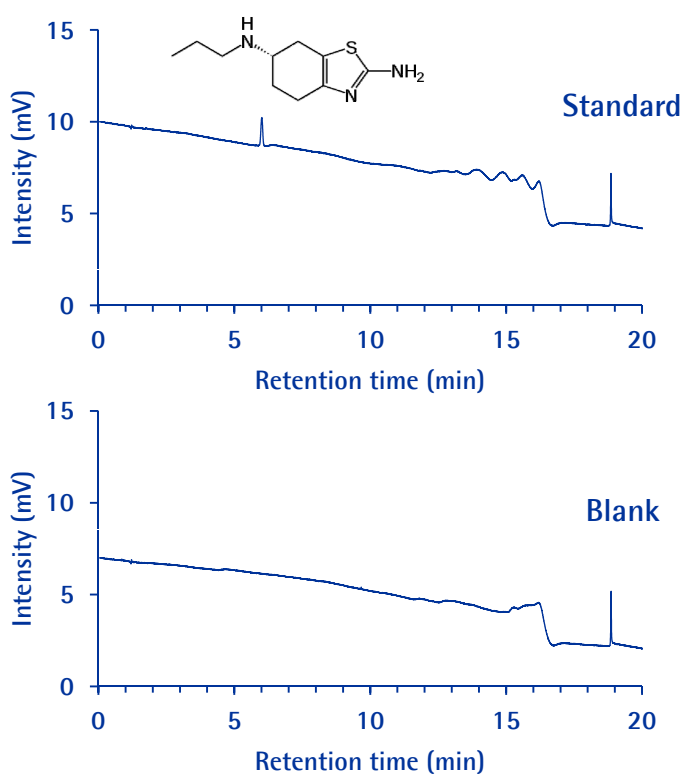
The following pages illustrate that the acceptance criteria are met for both the Pramipexole and related substances as well as the assay method by following the current USP monograph using a 150x4.6 mm Purospher® STAR RP-18 endcapped (5 µm) column.

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Chromatographic Conditions

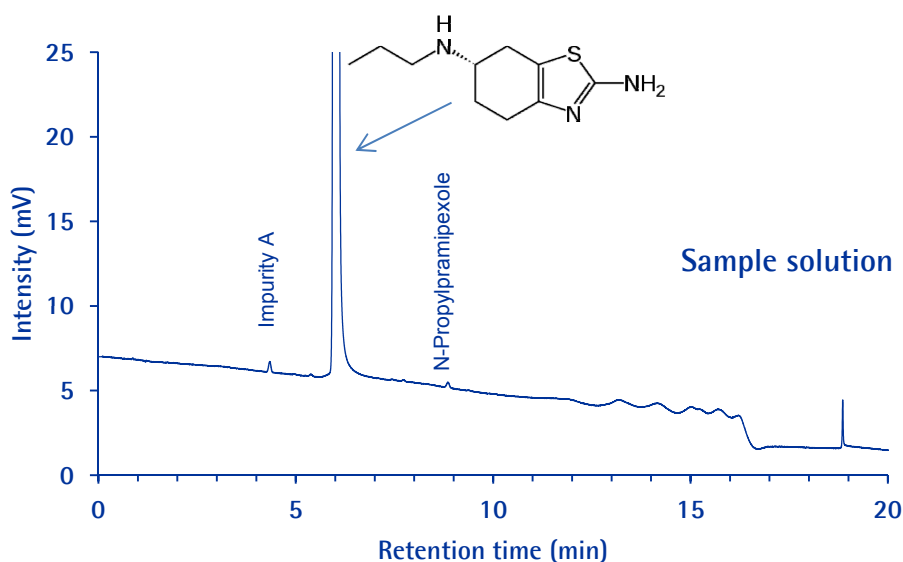
Column:	Purospher® STAR RP-18 endcapped (5 µm) Hibar® 150x4.6 mm	1.51455.0001
Injection:	5 µL	
Detection:	Shimadzu Prominence, UV 264 nm	
Cell:	10 µL	
Flow Rate:	1.5 mL/min	
Mobile Phase:	Solution A: Dissolve 9.1 g of potassium dihydrogen phosphate and 5.0 g of sodium 1-octanesulfonate monohydrate in 1 L of water. Adjust with phosphoric acid to a pH of 3.00 ± 0.05. Solution B: Acetonitrile and Solution A; 1:1 (v/v)	
Gradient:	See table	
Temperature:	45 °C	
Diluent:	Acetonitrile and Solution A; 1:4 (v/v)	
Resolution Solution:	1.5 µg/mL of USP Pramipexole Dihydrochloride in Diluent	
Sample solution:	1.5 mg/mL of Pramipexole Dihydrochloride in Diluent	
Pressure Drop:	209 - 215 Bar (3030 - 3117 psi)	



Time (min)	A (%)	B (%)
0.0	60	40
15.0	20	80
15.1	60	40
20.0	60	40

Pramipexole and Related Substances (USP)

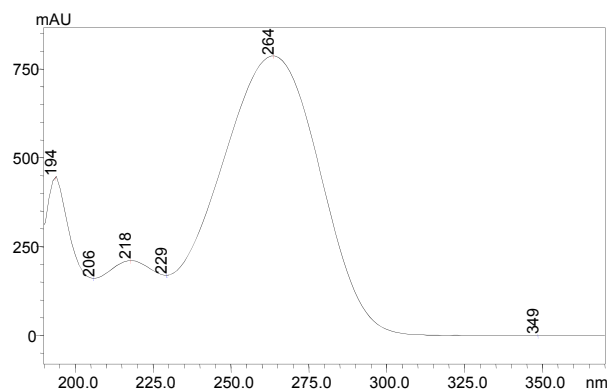
Purospher® STAR RP-18 endcapped



Chromatographic Data : Sample

No.	Compound	Retention Time (min)	Resolution	Tailing Factor	RRT
1	Impurity A	4.3			0.71
2	Pramipexole	6.0	13.9	1.00	1.00
3	N-Propylpramipexole	8.8			1.47

UV spectra - Pramipexole



Peak purity curve -Pramipexole

