

# Application Data

No. 1024A

ChromaNik  
ChromaNik Technologies Inc.

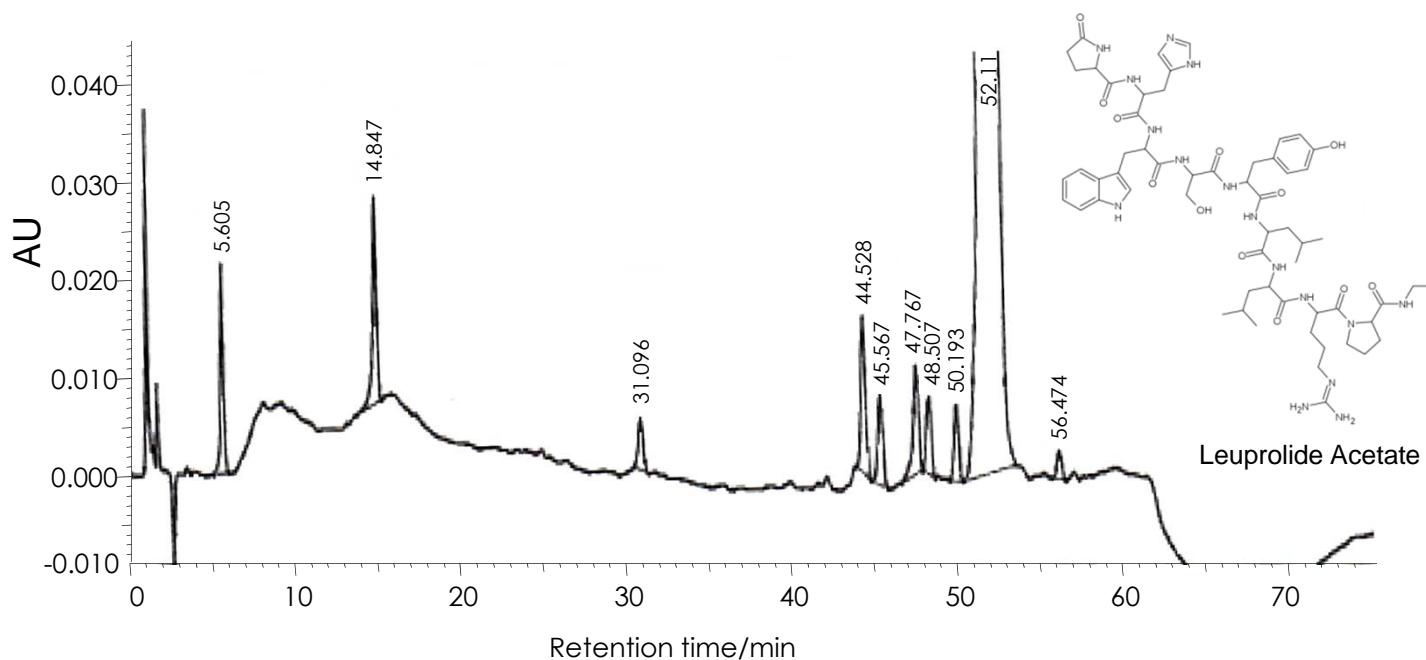
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Chromatographic Purity Test

Source Reference USP 2010

Leuprolide Acetate

SunShell C18 2.6  $\mu$ m, 100 x 4.6 mm i.d.



Column: SunShell C18 2.6  $\mu$ m, 100 x 4.6 mm i.d.

Mobile phase: A) Triethyleamine 15.2g/L adjust the pH 3.0 with o-Phosphoric Acid

B) Acetonitrile/ n-Propyl alcohol(3:2)

Gradient Program

Time (min)	0	4	60	68	76
%A (%)	95	95	80	95	95
%B (%)	5	5	20	5	5

Diluent Mobile Phase A(17 parts) + Mobile Phase B(3parts)

Flow rate : 1.0. mL/min

Detection : UV@229 nm

Column Temperature : 50 °C

Sample Temperature : 4 °C

Sample: Solution 100 mg Leuprolide Acetate in 100 mL Diluents

Injection Volume : 20  $\mu$ L

Degradation solution a) 5 mL Sample /standard solution 1 mg/mL) dilute to 50 mL Water

b) Solution (a) 5 mL +100 mL 1N NaOH.

c) Shake Vigorously and place in Oven at 100 °C for 1 hour

d)Cool and add 50 $\mu$ L 1M Phosphoric Acid