

Test Report of Cyproheptadine HCl

I. Sample Molecular Formula

Name	Molecular Formula
Cyproheptadine HCl	C ₂₁ H ₂₂ ClN

II. Sample Information

Chemical Name : Cyproheptadine HCl
Trade Name : (Confidential)
Test Type : Content of Cyproheptadine HCl tablets
Manufacturer : (Confidential)

III. Chromatographic System

Source of method : USP 36, 2013, "Cyproheptadine Hydrochloride Tablets", page 3132
Column : Welchrom C18, 5 μ m, 4.6 \times 150mm
Detector : UV 285 nm
Separation Mode : Isocratic
Mobile Phase : Acetonitrile : Isopropyl alcohol : 0.3% Methanesulfonic acid in water
: (20:15:65) adjust pH to 4.0 \pm 0.05
Temperature : Ambient (nominally 25 $^{\circ}$ C)
Flow Rate : 1.0 ml/min
Injection Volume : 20.00 μ l

Procedure:

- **Mobile Phase:**

Prepare the mobile phase with the composition as mentioned above, filter through 0.2 μ m membrane.

- **Standard solution:**

1. Accurately weight 40 mg of Cyproheptadine HCl standard, put it in 50 ml volumetric flask, dilute it with mobile phase to the volume.
2. Take 1.0 ml of the solution, put it in 10 ml volumetric flask, dilute it with mobile phase to the volume.
3. Filter it through 0.2 μ m syringe filter.

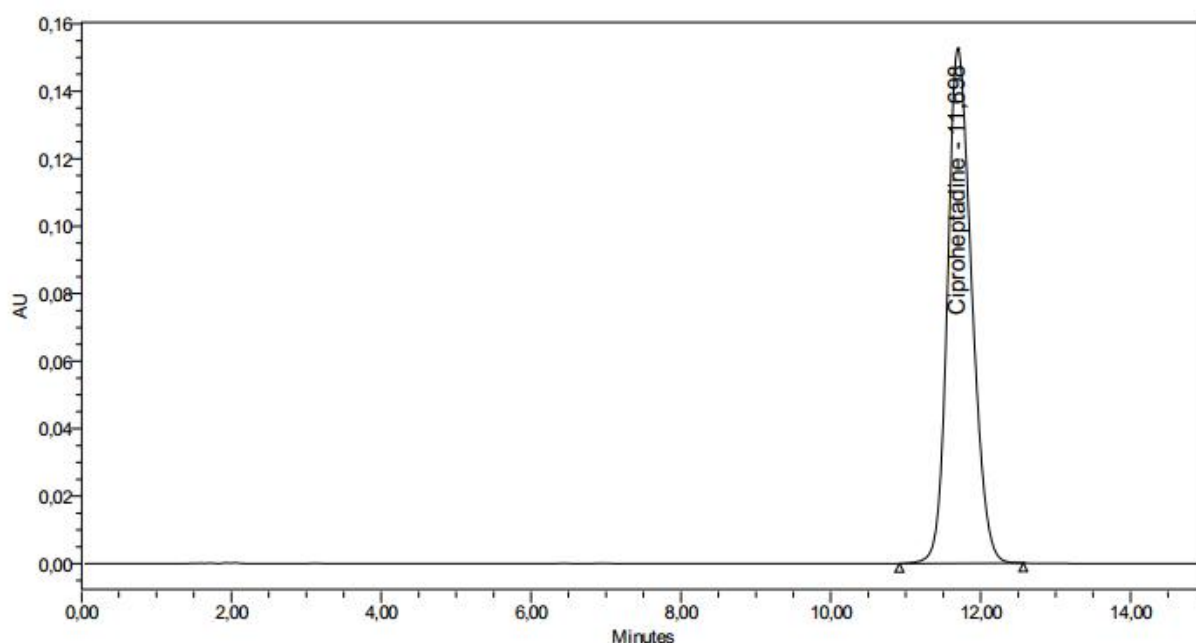
- **Sample solution:**

1. Take 10 tablets of Cyproheptadine HCl, crush it into powder.
2. Weight the powder that equal to 4 mg of Cyproheptadine HCl, put it in 50 ml volumetric flask.
3. Add 25 ml of mobile phase, sonicate for 15 minutes and shake for 30 minutes.
4. Dilute with mobile phase to the volume.
5. Filter it with 0.45 μ m syringe filter.

- **Suitability requirements:**

1. Plate count, MT 5000 plates.
2. Tailing factor, NMT 2.0.

IV. Chromatogram and Results



	Peak Name	RT	Area	% Area	Height	K Prime	USP Plate Count	USP Tailing
1	Ciproheptadine	11,698	3430531	100,00	152688	10,697928	6207,712522	1,198031