

Development, Analytical Validation and Stability Study of Low-Dose Atropine Eye Drops Prepared from Pharmaceutical-Grade Atropine Sulfate Powder

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INTRODUCTION / OBJECTIVE

The shortage of commercially available single-dose 1% atropine eye drops (Faure®) prompted the development of a compounding process for low-dose atropine ophthalmic solutions using pharmaceutical-grade atropine sulfate powder.

Objective : to develop a preparation process compatible with our aseptic compounding facilities and assess the physicochemical and microbiological stability of the resulting formulations.

MATERIALS AND METHODS

1-Preparation of Atropine 2 mg/mL stock solution

2-Preparation of atropine low-dose stock solution (1 L)

3-Dispensing and sterilizing filtration into multidose bottles

4-Stability Studies

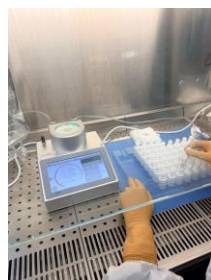


Dissolution of Atropine sulfate

Sterilizing filtration through a 0.22 µm membrane filter



	Atropine 0.01%	Atropine 0.05 %
Atropine 2mg/mL (mL)	50	250
0.9 % sodium chloride (mL)	950	750



- 1-Visual aspect, pH, Osmolarity
- 2-HPLC quantification
- 3-Subvisible particles
- 4-Sterility testing



➤ **HPLC-UV quantification**
Column: Kinetex XB-C18
Detection: 210 nm
Mobile phase: phosphate buffer / ACN (88:12, v/v)
Flow rate: 1.0 mL/min
Injection : 20 µL
RT: 5.4 min
 ➤ **Method validation**
 Range: **25–60 µg/mL**
 β-expectation tolerance interval = 85%

RESULTS

1-Validation studies

Fig.1 : Chromatogram of atropine

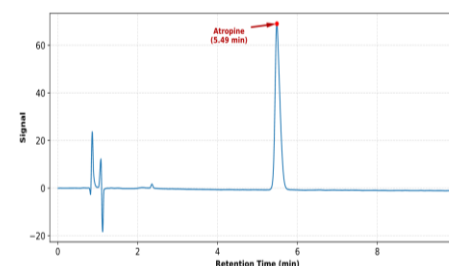


Fig. 2 : Atropine assay accuracy profile

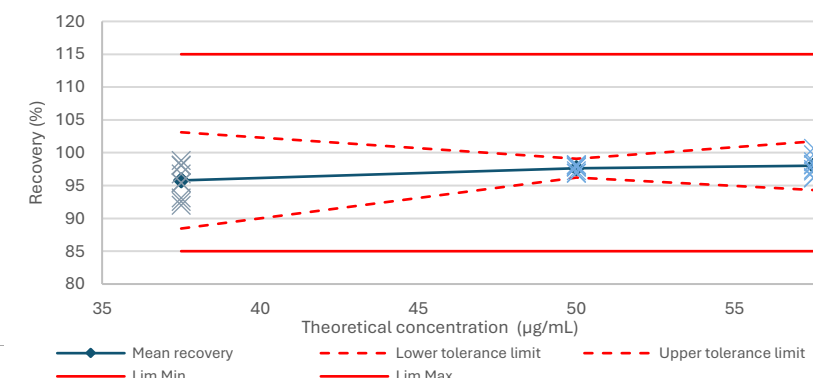


Table 1 : Analytical methods validation results

	CQ1	CQ2	CQ3	Final product (atropine 0.01%)	Final product (atropine 0.05%)
Repeatability (CV%)	0.61	0.18	0.81	0.35	0.7
Intermediate precision (CV%)	2.43	0.51	1.82	0.75	1.15
Accuracy (CV%)	3.03	0.57	1.56	0.65	1.20

2-Stability Studies

	Atropine 0.01 %			Atropine 0.05 %		
	T0	M1	M2	T0	M1	M2
pH	5.83	5.50	5.03	4.84	4.70	5.03
Osmolarity	287	287	288	286	288	289
HPLC quantification (µg/mL)	99.6	98.9	98.9	495.6	493.5	491.7
Subvisible particles	✓	✓	✓	✓	✓	✓
Sterility	✓	✓	✓	✓	✓	✓

CONCLUSION

The proposed compounding and quality control protocol enables the preparation of low-dose atropine eye drops from pharmaceutical-grade atropine sulfate powder, providing an effective alternative during supply shortages