

RENOVA LIFESCIENCES PRIVATE LIMITED

IN-HOUSE Specification

MYATRO L EYE DROPS

Specification number: FPSP4ATRO05-00

**IN-HOUSE SPECIFICATON**

RENOVA LIFESCIENCES PRIVATE LIMITED	MYATRO L EYE DROPS (Atropine Sulfate Ophthalmic Solution USP 0.025%w/v)	Specification number: FPSP4ATRO05-00
		Effective from the signing date

1. SCOPE

This specification specifies the requirements on quality, hygiene safety, label, storage condition, transportation for **MYATRO L EYE DROPS (Atropine Sulfate Ophthalmic Solution USP 0.025%w/v)** manufactured by **RENOVA LIFESCIENCES PRIVATE LIMITED**.

2. FORMULATION

Composition:

Each ml contains:

Atropine Sulfate USP	0.25 mg
Stabilized Oxychloro Complex (As Preservative)	0.05 mg
Sterile aqueous buffered vehicle	q.s

3. TECHNICAL REQUIREMENTS**3.1. Visual requirements**

Visual acceptance criteria is specified in the table 1.

Table 1: Visual requirements criteria of finished product

No.	Criteria	Requirement	Test method
1	Physical form	Solution	Sensory
2	Color	Featured	Sensory

3.2. Physical chemistry requirement

Physical chemistry acceptance criteria is regulated in the table 2

Table 2: Physical chemistry acceptance criteria of finished product

No.	Criteria	Unit	Acceptance criteria	Test method
1	Uniformity of Volume	ml	Not less than 91% and not more than 109 %	By laboratory test method.
2	Atropine sulfate	g	Identity	USP 44 or following the laboratory test method.

3.3. Microbiological requirement



Sterility test Report:

Sr. No.	Test Parameter	Limit	Observation
1.	Test for Bacterial Growth at 30°C-35°C (Medium used Fluid Thioglycolate medium 100 ml)	Growth/No Growth	No Growth
2.	Test for Fungal Growth at 20°C-25°C (Medium used Soyabean Casein digest medium 100 ml)	Growth/No Growth	No Growth

4. PACKAGING – LABELLING – STORAGE

- Packaging: This product is packaged in a box of one plastic bottle, labelled and the package insert.
- The label is followed requirement as regulated in Section 96 in The Drugs and Cosmetics Rules, 1945 of the Government on goods label.
- Store conditions: Store at temperature not exceeding 30°C. Protect from light & heat.
- Shelf life: 36 months from the manufacturing date

We, herewith declare that the above mentioned product meet the provisions of the Drugs and Cosmetics Rules, 1945 for medical devices.

Ms. Ruchita Nalun
Renova Lifesciences Private Limited
Head- Quality Assurance
Date: 28/04/2022