

Context:

ASED is a magistral preparation derived from human serum, indicated for the long term treatment of severe keratoconjunctivitis sicca unresponsive to first-line therapies.

Our ophthalmology department requested the implementation of an internal production process for ASED to treat a cohort of **5-10 patients**.

Objectives:

To assess the **feasibility** of ASED **production** at our hospital and describe the manufacturing and **quality control** steps.

Materials and methods:

Bibliographic searches

- **Reading** articles.
- **Simulations** of preparation.
- **Comparison** of protocol and control practices from 7 hospitals.

Goal: draft our own procedure.

Meeting with stakeholders

Goal: draft the hospital circuit.

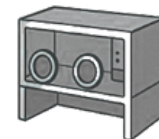
European Pharmacopoea Tests

Mediafill test
Fertility test
Goal: method validation.

MEDIAFILL TEST:

Dilution into an isolator:

Dilution 20% of **TSB**¹
(filled into collection tubs)
with **BSS**².



Sterilizing filtration and packaging:

Conditionning into 5mL
transparent tubs.



Incubation 30°C:

Visual inspection at Day
1,2,7,14.



FERTILITY TEST:

Dilution, sterilizing filtration and packaging:

Same procedure than our Mediafill
test.

Inoculation of six vials by bacteriologic strains:

Each vial by each strain required
by test 2.6.1 of European
Pharmacopoeia.



Incubation 30°C:

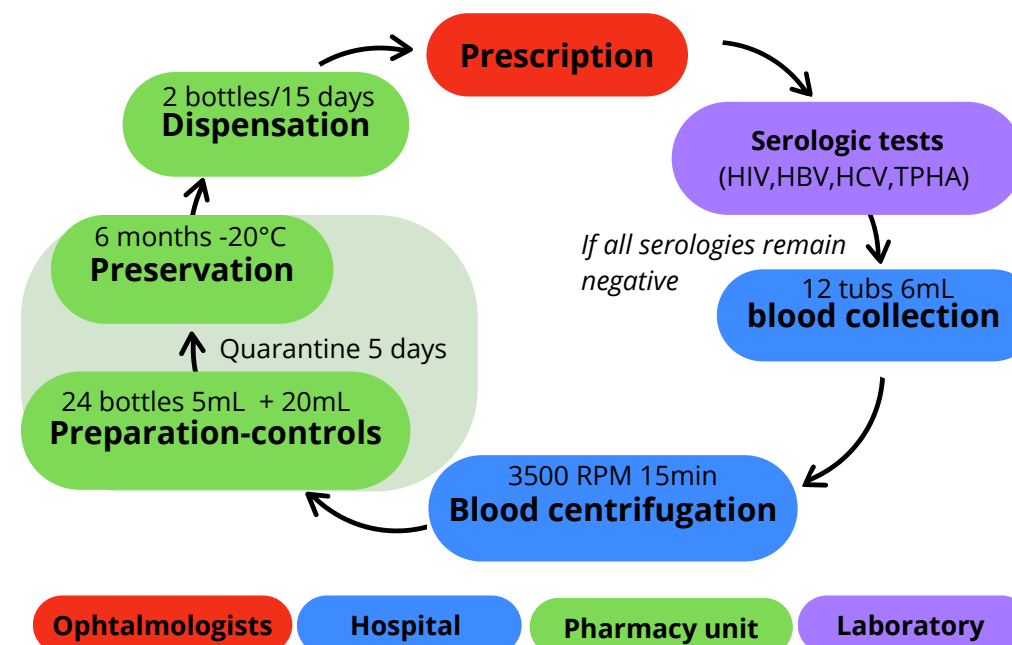
Visual inspection at Day
1,2,3,5.



¹ Tryptic Soy Broth, ² Balanced salt solution, ³Low density Poly ethylen,
⁴ Blood exposition accident.

Results:

Circuit and procedure:



Procedure:

→ Preparation each **6 months**, **24 bottles LDPE**³ **5mL**.

→ **Needle free** (use short catheter).
To prevent the risk of **BEA**⁴ during
compounding.



Discharge Controls:

→ **10mL** preparation inoculated into **2 aerobic / anaerobic BACTEC**[®] **blood culture bottle**.

→ Incubation **30°C 5 days** into
BACTEC[®] **blood cluture system**.



Conclusion:

- ✓ **Compliance** of sterility and fertility tests
Validated method.
- ✓ Procedure preventing **the risk of BEA**.
- ✓ **Validation** of an internal workflow.

Our **means** allow us to incorporate this activity into our hospital.

Mediafill and Fertility tests:

Mediafill Test

N° test	24h	48h	7 days	14 days
1	No growth	No growth	No growth	No growth
2	No growth	No growth	No growth	No growth
3	No growth	No growth	No growth	No growth

Medium duration of preparation : **01 h 15 min**.

Fertility Test

N° tub	strain	72h	5 days
1	A. brasiliensis	Growth	Growth
2	B. subtilis	Growth	Growth
3	C. albicans	Growth	Growth
4	C. sporogenes	No growth	Growth
5	P. aeruginosa	Growth	Growth
6	S. aureus	Growth	Growth
T	Neg control	No growth	No growth

Discussion : Next steps



Draft a **traceability system**.



Draft the **outpatient dispensing system**.



Targeting patients.