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Autologous Serum 20% in Sodium Chloride 0.9% Sterile Ophthalmic Solution

Version number: 1.0

Volume: 100mL

Autologous Serum, Sterile for Ophthalmic Solution	20mL
Sodium Chloride 0.9%, USP for Injection	80mL

This compound should be prepared in an ISO Class 5 environment by a licensed pharmacist or supervised pharmacy technician trained in proper aseptic technique. Review USP <797> and check with your state board(s) of pharmacy to ensure proper compliance with regulations on the preparation of CSPs. Personnel assessments, sterility, potency and endotoxin levels testing should be outlined in the pharmacy SOPs.

SUGGESTED COMPOUNDING PROCEDURES

1. After the hood and equipment have been sterilized (see precautions), withdraw 20mL of serum from collecting tubes into a 50ml sterile syringe.
2. Withdraw 20mL of Sodium Chloride 0.9% for injection from a 100mL bag, leaving 80mL.
3. Add 20mL of serum via syringe to the IV bag with Sodium Chloride (in step 2).
4. Gently knead the IV bag to thoroughly mix.
5. Aseptically spike the IV bag with a sterile administration set, or pump tube set.
6. Attach a sterile 0.2 micron low-protein binding filter to the IV tubing or pump set and attach a fluid-dispensing connector to the open end of the filter.
7. Allow the serum mixture to flow into 1mL sterile syringes with slip-tips or into sterile droppers for ophthalmic use.
8. Package and label. Freeze immediately upon completion.
9. Suggested Quality Assessments – follow pharmacy SOPs:
    a. Bubble point filter integrity
    b. Particulate
    c. Sterility
    d. Endotoxins – 1 to 1.43 EU/mL*
    d. Label - auxiliary labels, storage, BUD, compounded medication

Store Refrigerated or Frozen.

Note: According to USP Chapter <797>, in the absence of passing a sterility test the storage periods for compounded sterile preparations (high risk) cannot exceed the following time periods:

Controlled Room Temperature: not more than 24 hours
Cold Temperature: not more than 3 days
Or Refer to current USP chapter <797>.

No claims are made as to the safety or efficacy of this preparation. This formulation is provided solely at the unsolicited request of the pharmacist.

Beyond-Use Dates of preparations are conservative estimates by the formulator using reference books, peer-reviewed literature, and intended duration of therapy, formulation from commercially available products, organoleptic observations and current USP guidelines. Compounders may have stability studies performed by a reputable laboratory if they wish to extend the Beyond-Use Date.
It is recommended that you follow USP <795> recommendations for potency testing.

Beyond-Use Date is estimated to be 31 days if refrigerated and 181 days if frozen at -10°C.* ***Per CompoundingToday.com Formula # 2233***

Precautions:
Handling of biological fluids must be compliant with US FDA requirements for reinjection of processed biological preparations. This preparation requires working with active biological fluids or blood fractions in a sterile environment – appropriate precautions are required. Prior to compounding, all equipment and supplies should be wiped down with non-shedding towels wetted with 2% acidified bleach.

*Reed-Kane Dana, Carlson Rachel A, Kupiec Thomas C, Vu Nicole. Quality-Control Analytic Methods: Applications and Sterility of Autologous Eye Drops. International Journal of Pharmaceutical Compounding. 13(6);2004:647-652.

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