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Instructions and Guidelines for Use

Product #: 800001

Version: 1.0
Revision Date: 28 Oct 2013

Human Serum Albumin, Recombinant

(rHSA)

99%+, Lyophilized Powder, Expressed in Rice

Instructions

Aspira Scientific's recombinant human serum albumin (rHSA) is derived from rice grains (*Oryza sativa*), free of yeast, animal and human byproducts. It is supplied as an off-white lyophilized powder appearing clear, light to pale yellow at a pH range of 6.5 – 7.5 when reconstituted in sterile water at 200 mg/mL (w/v).

Prepare rHSA for use by reconstituting the lyophilized powder using proper aseptic techniques and perform handling in a controlled environment such as a laminar flow cabinet to maintain product sterility. If you are not familiar with these techniques or reconstituting lyophilized powder in injection vials, additional training must be undertaken and competencies assessed before using this product.

Reconstitution of the Lyophilized Powder

1. Remove the tamper-evident cap and top seal from the vial. Do not remove the rubber septum from the vial or aluminum overseal.
2. Wipe the rubber septum with alcohol.
3. Attach the appropriately sized sterile needle to a sterile syringe and draw the appropriate volume of sterile water into the syringe. The lyophilized powder should be suspended using the sterile water volume according to **Table 1**.

Table 1: Sterile Water Addition Recommended for Reconstitution

rHSA Quantity	Vial Size	Sterile Water	Final Concentration
1 g	20 mL	5 mL	200 mg/mL
5 g	100 mL	25 mL	200 mg/mL
10 g	150 mL	50 mL	200 mg/mL

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4. Hold the needled syringe so that the beveled edge of the needle is up. Pierce the rubber septum with the needle at a minimum of a 45° angle. Slowly push the syringe plunger to add the sterile water to the vial (**Figure 1**).

Figure 1: Reconstituting rHSA with Sterile Water



Important:

If sterile water becomes difficult to inject due to “back pressure” during reconstitution, do not continue to fill the vial. Use a push-pull technique, i.e., repeatedly remove small volumes of air before adding more volume of solution, until the required total volume is reached. This equilibrium method helps to minimize the build-up of pressure in the vial. Alternatively, the rubber septum can be pierced with a second needle to withdraw air from the vial to equalize the pressure in the vial by pulling back slightly on the plunger. *Do not fill the vial in excess of 35% of the vial size.*

5. Gently swirl the vial to mix.
6. Allow the powder to dissolve for 15 minutes.
7. Visually inspect the reconstituted suspension for particulate matter and discoloration. The reconstituted solution should be a uniform, homogeneous solution that is clear, light to pale yellow in color.
8. To prepare liquid stocks, withdraw the reconstituted solution from the vial using a sterile needle and syringe. Pierce the rubber septum with the needled syringe at a minimum of a 45° angle. With the vial still attached, invert the needled syringe to

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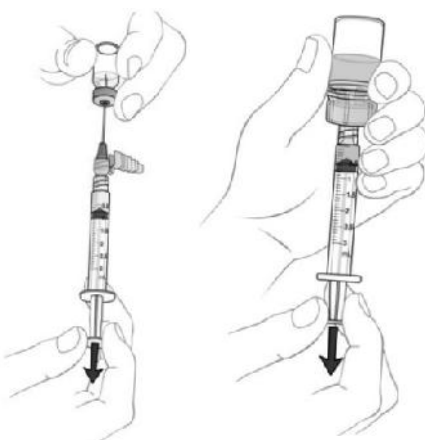
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a 180° angle and fill the syringe with the solution (**Figure 2**). Tap the syringe lightly to aggregate the air bubbles at the needle end.

Figure 2: Removing rHSA Solution from the Vial



9. Keep the needle in the vial and slowly depress the plunger to push the air into the vial. Release the plunger, keeping the solution in the syringe.
10. Withdraw the needled syringe containing the solution from the vial. Dispense the extracted volume by pressing down on the syringe plunger to release the appropriate working volume into appropriate containers.
11. Store the extracted solution frozen (-20 °C) in quantities according to the specific application to avoid freeze-thaw cycles. The headspace in the container should ideally be less than 25% of the container volume to reduce potential oxidation.
12. Engage in safe needle disposal- dispose the vials, adapter, needles, and syringe appropriately after use.

Handling

- Store lyophilized product at 2 – 8 °C. Do not freeze.
- Recommended reconstitution in sterile water at 200 mg/mL. Upon reconstitution, aliquot and store at -20 °C. Avoid freeze-thaw cycles.
- Bring to room temperature before use.
- See product label or lot-specific Certificate of Analysis for expiration date.

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- See MSDS for safe product handling information and precautions.

Use Recommendations

Aspira Scientific's rHSA is a higher purity product than pHSA and therefore, has a higher activity in many applications. This should be taken into account when adopting the use of rHSA to replace pHSA.

The end user should optimize the concentration of rHSA for the specific application to ensure optimum performance.

Cell Culture Media Supplementation

- rHSA is typically used in cell culture media formulations at concentrations of 0.5 – 2 g/L.
- Gradual adaptation over several passages using concentrations of 0.5 – 2 g/L is recommended when substituting rHSA in cell culture media. However, the optimum concentration of rHSA for cell culture applications varies with the type of cell and the composition of the medium. Following adaptation, optimized rHSA concentration should be determined and used for the specific cell line.
- In general, it is recommended that cell culture media is used within 7 days of rHSA supplementation.

For research use only.

This product has not been approved as a direct human therapeutic agent.

Manufactured by Healthgen Biotechnology Co., Ltd.

This product is produced in an ISO 9001:2008 certified manufacturing facility according to quality management system provisions and complies with local manufacturing GLP and GMP practices. This product is licensed under U.S. Patent No. 7,723,571 and corresponding Patent No. 1865064 in the European Union, Patent No. 4.680.237 in Japan and Patent Nos. ZL 2006 1 0019285.9 and ZL 20005 1 0019084.4 in China with patent pending in Canada.

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