

GEM-800-121 Human Serum Albumin Solution—20%

PRODUCT DESCRIPTION:

This diagnostic-grade product is an aqueous solution containing 20% human albumin (w/v). It is prepared by cold-alcohol fractionation from pooled human plasma obtained from venous blood. The USP Pharmacopeia requires that all fractionators add sodium caprylate and sodium tryptophanate as a preservative. All human plasma is collected from stringently screened donors at FDA-licensed collection centers in the United States.

Precautions: Non-Hazardous Ingredients: Blood Plasma (Human)

The product contains no substances that are considered hazardous to health at their given concentration. Although the human plasma used to manufacture this product has been tested and shown to be negative for infectious agents, no test is 100% accurate. All materials derived from human plasma should be handled as if capable of transmitting infection.

Not for clinical or therapeutic use.

INSTRUCTIONS FOR USE

Receipt and Storage:

Ships on dry ice. Store frozen at -20 to -10°C.

Thawing Instructions:

When preparing human serum albumin for use, it should be allowed to thaw gradually, either at room temperature or in a refrigerator at a temperature of 2-8°C overnight to minimize thermodynamic stress to the material.

Appearance:

Faint yellow color

Stability:

If stored frozen (-20 to -10°C), expiration is Lot Dependent. See Certificate of Analysis.

Preparation and Use:

We strongly recommend using the entire volume when first thawed. If it is not possible for your intended use, we recommend that you minimize the number of freeze/thaw cycles the product will undergo by aliquoting the human serum albumin into containers of a single-use volume.

QUALITY - TRACEABILITY - INTEGRITY

Life Science Production

The Science Centre, 1 Blydon Road, Sandy, Bedfordshire, SG19 1RZ

Tel: +44 (0) 1234 889180 Email: sales@lifesciencegroup.co.uk Web: www.lifesciencegroup.co.uk

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Microbiological Testing	
Bacteria	Not Detected
Fungi	Not Detected
Viral Testing	
HBsAg	Non-Reactive
Anti-HCV	Non-Reactive
Anti-HIV-1/HIV-2	Non-Reactive
Syphilis	Negative
HBV-NAT	Not Detected
HIV-NAT	Not Detected
HCV-NAT	Not Detected
Physical Testing	
Protein	Test and Report
Endotoxin	Test and Report

For Cell Culture, further Manufacturing and Research use only. Not for direct Therapeutic use.

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