## GRIFOLS HUMAN SERUM ALBUMIN

GRIFOLS

# **BioSupplies** Biological material solutions

#### **Proteins**

Human Serum Albumin



## The natural carrier

Human serum albumin is widely used in the cell therapy, pharmaceutical and biotechnology field. Some of its applications are:





## A high quality service: Our expertise

# Experts in worldwide product registration

- Regulatory requirements are increasingly more stringent and, consequently the process of registering biological products is particularly complex
- As a manufacturer of biological products that are registered worldwide, Grifols has valuable expertise in regulatory compliance in different parts of the world
- We can help you to remove any obstacles and smooth the pathway to product registration in all corners of the world

#### Working in partnership with you

Grifols experts are committed to assisting your regulatory staff to achieve the registration of your products:

- Providing documentation such as our annually updated plasma master file, albumin registration data and technical support
- Offering assistance in meeting with health authorities such as the US Food and Drug Administration (US FDA) and the European Medicines Agency (EMA), and addressing questions that might arise related to our Human Serum Albumin (HSA)
- Guaranteeing up-to-date registration and compliance with each country's future requirements

## Grifols Human Serum Albumin: When quality is the key

#### Only top quality products Grifols Human Serum support excellence and success

Pharmaceutical and biotech manufacturing processes need the best product excipients, drug carriers and culture media. A significant number of products require albumin for these purposes.

### **Albumin: Quality from** donor to finished product

- Manufactured from plasma originating from own US Plasmapheresis Centers, in compliance with current good manufacturing practice (cGMP), voluntary international Quality Plasma Program (IQPP) standards of the Plasma Protein Therapeutic Association (PPTA) and fulfilling additional requirements set by Grifols
- Production processes and facilities certified according to the US FDA and EU regulations
- Pasteurized, high purity albumin solution
- Grifols Human Serum Albumin is licensed according to the European and United States pharmacopoeia requirements



#### Grifols has a network of more than **300 US-based plasma donation centers**



As of April 30, 2023.

#### STATE-OF-THE-ART FACILITIES AND RELIABLE SUPPLY

Grifols has the capacity to fractionate more than 17 million liters of plasma per year.

Our manufacturing plants are located in:



Parets del Vallès (Barcelona), Spain



Clayton (NC), U.S.



Los Angeles (CA), U.S.



Grange Castle (Dublin), Ireland

For ordering information contact us here:



Grifols Worldwide Operations Ltd. Grange Castle Business Park Grange Castle, Clondalkin, Dublin 22, Ireland Tel: +353 (O) 1 464 7938 biosupplies@grifols.com www.grifols.com

#### \*Including Biotest

### **GRIFOLS**