

Kedrion Human
Serum Albumin

Khsa

Solutions for Biopharma
& Life Sciences

Kedrion
Biopharma

KEDRION BIOPHARMA

Plasma expertise, powered by connection

Kedrion Biopharma is a **global biopharmaceutical company** committed to improving the lives of people affected by rare, ultra-rare, and serious diseases. We operate **worldwide** through our integrated plasma collection, manufacturing, and **distribution network**, to develop and distribute plasma-derived therapies that help **prevent and manage debilitating conditions**, including coagulation and neurological disorders, immunodeficiencies, and Rh sensitization.





KEY FACTS



Headquartered in Italy

with subsidiaries across Europe, the United Kingdom, North America, Latin America and Asia



€1.65 billion

turnover in 2025a



75 plasma collection centres

67 in the United States and 8 in the Czech Republic



7 manufacturing plants in 5 countries



600+ marketing authorisations



5th player worldwide

in plasma-derived products*



5,400+ employees worldwide



3 million litres of plasma collected



39 products



Commercial presence in 100+ countries

*Source: Marketing Research Bureau, The Worldwide Plasma Protein Market 2024, and publicly available information.

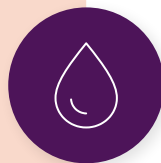
Quality starts at the source

Through a network of **70+ specialised plasma centres*** across the U.S. and Europe¹, Kedrion ensures donor qualification, donation testing and full traceability throughout the plasma collection process.²⁻⁶

PLASMA COLLECTION & TRACEABILITY

The following steps ensure complete traceability in plasma collection:

- 1 Each plasma donor is assigned a unique **Donor ID** for life.²
- 2 Each plasma bottle is assigned a **Unit ID**.³
- 3 A required amount of sample units are collected for testing and assigned a **Sample ID**, these tie back to the plasma bottle and donor.⁴
- 4 Each unit is assigned a **Case ID**. The shipment is cleared upon receipt of negative results from all external laboratory tests.^{3,5}
- 5 Each case is then assigned to a Shipment **Code ID**.⁶



Kedrion's plasma collection network is approved and regularly inspected by the FDA* and the EMA, adhering to GMPs and PPTA's voluntary IQPP standards.⁷

Manufacturing under rigorous control

Kedrion manufacturing facilities operate within stringent quality assurance systems aligned with applicable quality guidelines from **U.S. FDA, EMA, ICH, EU-GMP, and PPTA's voluntary QSEAL standards**.^{8,9}



* New centers may be awaiting FDA license.

Abbreviations: FDA: Food and Drug Administration; EMA: European Medicines Agency; GMPs: Good Manufacturing Practices; PPTA: Plasma Protein Therapeutics Association; IQPP: International Quality Plasma Program; ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; QSEAL: Quality Standards of Excellence, Assurance and Leadership.



Product information

Albumin is the most abundant protein in human plasma and plays a critical role in **maintaining physiological balance** within the body. While widely used in therapeutic applications, Human Serum Albumin also serves as a valuable component in **biopharmaceutical manufacturing processes**, where it acts as a stabilising, protective and carrier agent for sensitive biological substances.^{10,11}

Across cell therapy and other advanced bioprocessing applications, **HSA is used at different stages of manufacturing**, either as a processing aid during production or as an excipient in the final product formulation. Its proven safety profile, biological origin and functional performance make it a trusted component for a wide range of **non-therapeutic applications**.^{10,11}



Product application



Biopharmaceutical Formulation & Stabilization^{11,12}

Albumin helps support the stability and performance of vaccines, biologics and protein-based formulations.



Cell Culture & Bioprocessing¹³

Albumin can support cell growth, viability and performance in culture and bioprocessing applications.



Drug Delivery & Nanotechnology^{14,15}

Albumin offers a biocompatible platform for drug binding, conjugation and nanoparticle-based delivery.



Diagnostics & Bioimaging Technologies^{16,17}

Albumin can contribute to diagnostic reagents, reference materials and imaging technologies.



Tissue Engineering & Support Biomaterials^{18,19}

Albumin can be used in biomaterials, coatings and regenerative medicine applications.

Solutions for Biopharmaceutical and Life Sciences

With decades of experience in the development and manufacture of Human Serum Albumin (HSA), Kedrion combines deep scientific expertise, robust manufacturing capabilities and rigorous quality standards to deliver reliable therapeutic-grade human albumin.

Kedrion Human Serum Albumin provides a reliable and versatile offering for biopharmaceutical manufacturing and advanced therapy applications:

- ✓ At high purity and low contaminant concentrations.^{20,21}

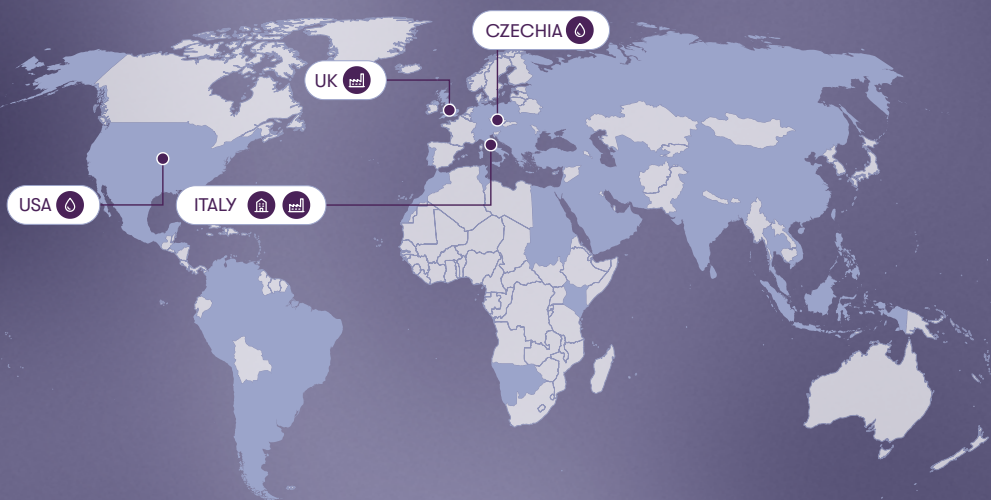
- ✓ Manufactured in accordance with applicable major international **pharmacopoeial standards**, such as European Pharmacopoeia (Ph. Eur.), United States Pharmacopeia (USP) and Chinese Pharmacopoeia (ChP).^{20,21,22}

- ✓ Our Albumin options include products that are FDA, EMA and NMPA approved, with additional approvals across key markets.

- ✓ Obtained from plasma collected in our centres in the U.S. and Europe that ensure **full traceability**²⁻⁷ and **adherence to international requirements** from U.S. FDA and EMA, GMPs standards and PPTA's IQPP standards.⁷

- ✓ Manufactured in Italy and in the UK under applicable FDA, EMA and GMPs requirements, as well as adhering to PPTA's voluntary QSEAL standards.^{8,9,23}

Abbreviations: FDA: Food and Drug Administration; EMA: European Medicines Agency; GMPs: Good Manufacturing Practices; PPTA: Plasma Protein Therapeutics Association; IQPP: International Quality Plasma Program; ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; QSEAL: Quality Standards of Excellence, Assurance and Leadership.



HEADQUARTER



PRODUCTION



PLASMA COLLECTION

Highlighted countries indicate where at least one Kedron Albumin product is registered.

Safety & Pharmacovigilance Service

Through its global Pharmacovigilance and Product Safety network, Kedrion provides continuous oversight of product safety, ensuring the timely collection, assessment, and management of safety information, as well as robust product traceability and support to customers worldwide.²⁴



Regulatory and Technical Support

With decades of experience navigating global regulatory frameworks, Kedrion provides comprehensive support for product registration, compliance and documentation.

Documents provided:

- ✓ Albumin technical dossier with stability and viral safety data
- ✓ CoA and Batch Release
- ✓ Annually updated plasma master file (PMF)
- ✓ GMPc and ML certificates
- ✓ Certificate of Pharmaceutical Products
- ✓ Quality and safety documents according to local regulations



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