

40. Title: Production of recombinant human serum albumin (rHSA) using *E. coli* as an expression system

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Keywords: Human serum albumin

Domain: Life Sciences (Biotech)

Summary:

Human serum albumin (HSA) has many applications in treatment of diseases (like hypovolemia, shock, burns, blood loss, liver disease, hypoalbuminemia, etc.), as drug delivery vehicle, as excipient for drug formulations/vaccines, as biomarker, as supplement in cell culture medium, as nutrient and stabilizer in cell therapies as well as biotechnological applications like coatings for medical devices, imaging reagents, surgical adhesives/sealants, fusion proteins, etc. HSA is mainly produced as fractionated product of collected blood. This is not economical, blood supply is sporadic and collected blood may be contaminated by blood-derived pathogens like HIV, hepatitis. Thus, there is need to develop low-cost methods for obtaining animal-free albumin. Recombinant HSA products from host systems such as yeasts, transgenic animals/plants, cell lines are available. However, such processes are capital intensive, time consuming, give lower yields and have problems like incorrect processing, poor export, hyper-glycosylation, improper folding and complex downstream processing.

The invention relates to expression and isolation of rHSA using *E. coli* host. Production has been enhanced by optimizing parameters like intracellular environment, temperature, induction type and duration, cell lysis conditions, exogenously employed chaperone systems, etc. A simple down-stream process overcoming protein aggregate formation has been developed. The process leads to high yield of functionally active soluble rHSA which has physicochemical and functional properties similar to plasma-derived HSA. It is biocompatible for various applications like supplement for mammalian cell growth, diagnostics, proteomics and lab research purpose.

Advantages:

- » *E. coli* is the most convenient and well-studied host system; Production is simple, less time consuming and cost-effective; Simple down-stream processing
- » Animal free product; no risk of contamination with various blood-derived pathogens
- » Not dependent on sporadic and unethical blood supply
- » High yield of functionally active protein
- » Product is biosimilar and compatible to the commercially available products

Applications: Pharma and drugs

Scale of Development: Lab-scale production with high protein yield achieved, biocompatibility studies done

Technology Readiness Level: 4

IP Status: Indian Patent Application 201611027096, US Granted Patent 10301373, Indian Granted Patent 355892