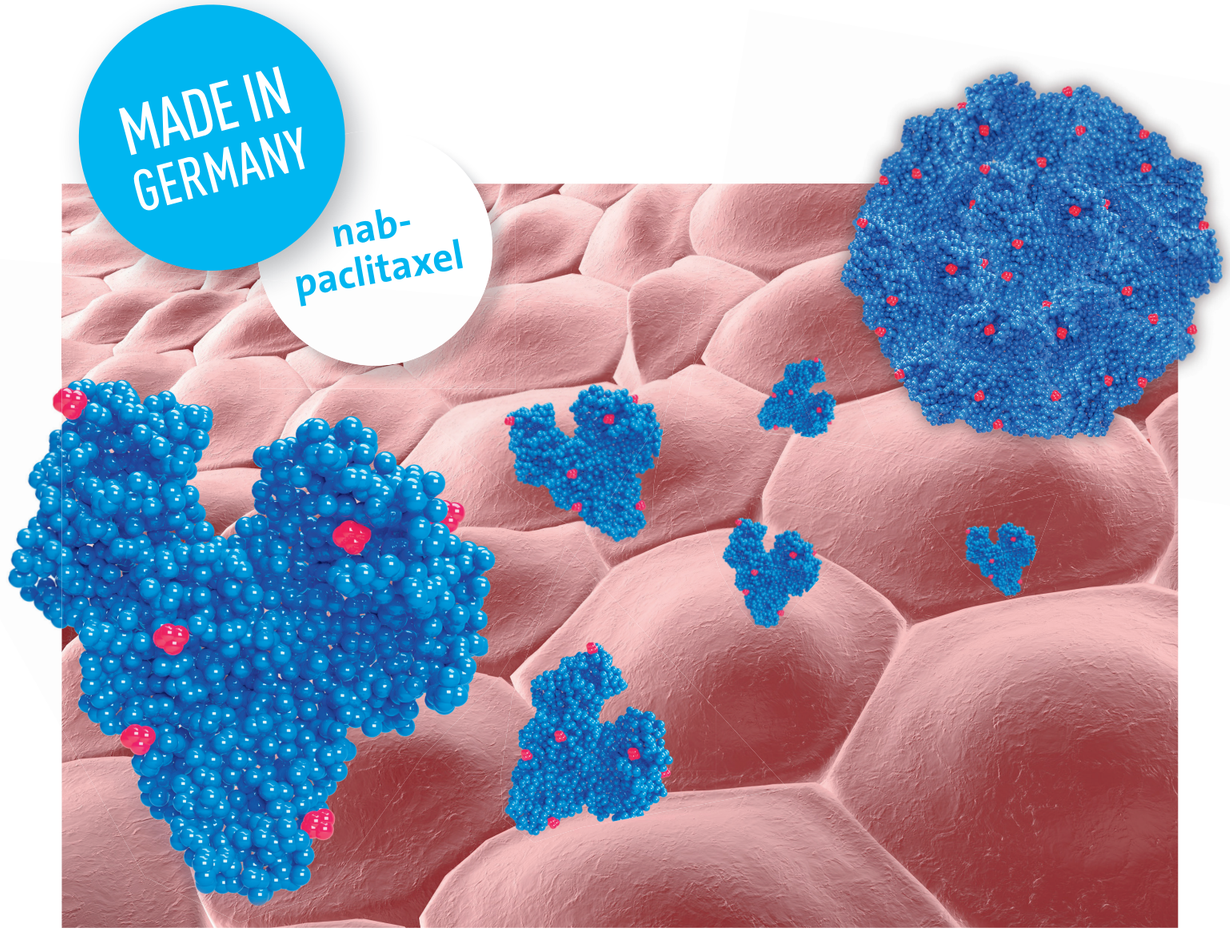
Biotest
Human Serum Albumin

A multifunctional excipient

For Manufacturing and Research Use | Pharmaceutical, Biotechnology and Diagnostic Industry



We love what we do.

High quality products for valued customers with a personal commitment.

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For information about equipment to make nab-formulations check

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Oktober 2022 | **698623106**

Biotest

From Nature for Life

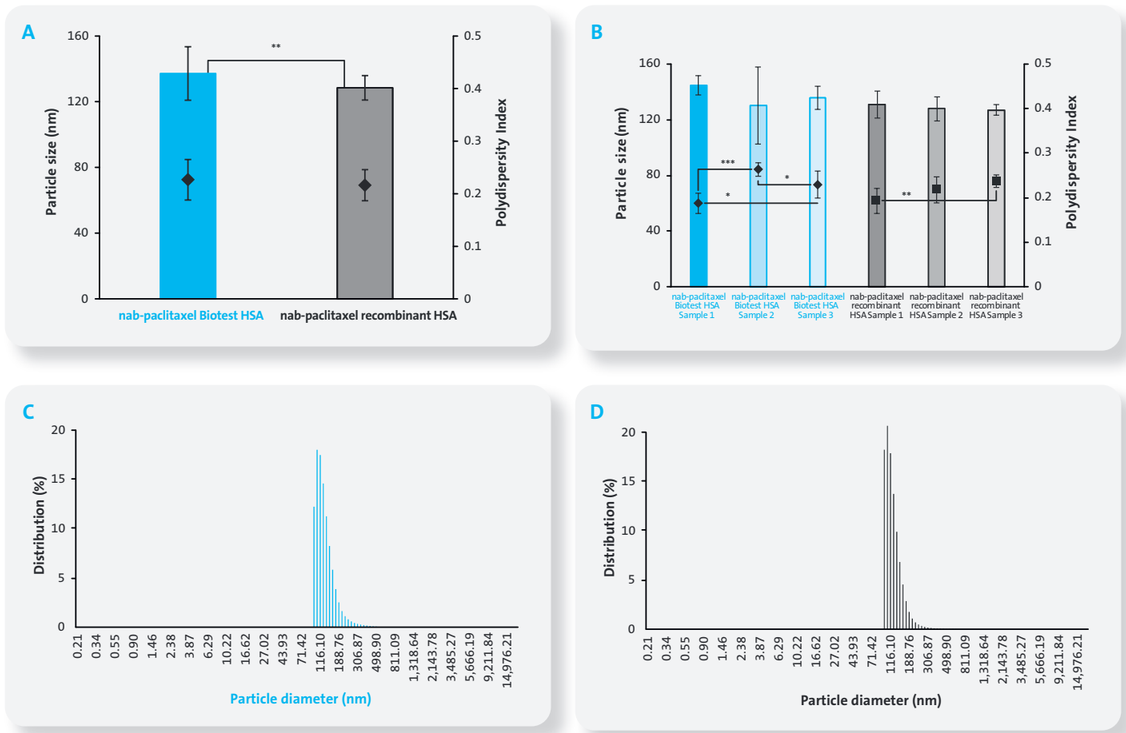
Human Serum Albumin in nab-technology

Human Serum Albumin (HSA) is used as a promising material for nanoparticle (NP) preparation (Michaelis et al., 2006; Steinhauser et al., 2006). Thereby HSA molecules aggregate in solution, form intermolecular disulfide bonds, and thus assemble into HSA-NPs (Elzoghby, Samy and Elgindy, 2012). The outstanding properties of HSA-NPs include their biocompatibility, biodegradability, non-toxicity and non-immunogenicity (Lomis et al., 2016).

An already approved formulation is Abraxane®, which contains paclitaxel as the active molecule. This medication uses the physiological property of HSA, including the ability to bind metabolic and/or hydrophobic and hydrophilic active substances and allows a more targeted delivery to the cancer cells (Maeda et al., 2000; Lomis et al., 2016). For the production of HSA-NPs, as for example Abraxane®, the so-called nanoparticle albumin-bound (nab)-technology is applied (Spada et al., 2021, Fraguas-Sánchez et al., 2022).

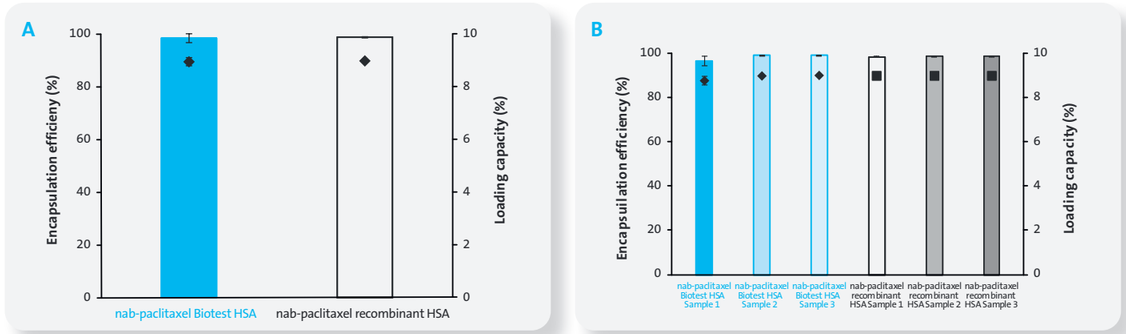
Here, we evaluated the processability and properties of nab-paclitaxel with Biotest HSA in comparison to a commercially available recombinant HSA. Nab-paclitaxel was prepared using a Microfluidizer® Processor LM20. It was demonstrated that Biotest HSA showed similar results and is an excellent material to be applied for the production of nab-paclitaxel.

Particle Size and Particle Size Distribution



A Particle size (nm; primary y-axis; bar chart) and polydispersity index (secondary y-axis; dot chart) of nab-paclitaxel Biotest HSA in comparison to nab-paclitaxel recombinant HSA. **B** Particle size (nm; primary y-axis; bar chart) and polydispersity index (secondary y-axis; dot chart) of nab-paclitaxel Biotest HSA samples 1-3 and nab-paclitaxel recombinant HSA samples 1-3. **C** Representative particle size distribution histogram of nab-paclitaxel Biotest HSA. **D** Representative particle size distribution histogram of nab-paclitaxel recombinant HSA. Significant differences are marked as *, ** and *** which correspond to a p-value ≤ 0.05, 0.01 or 0.001.

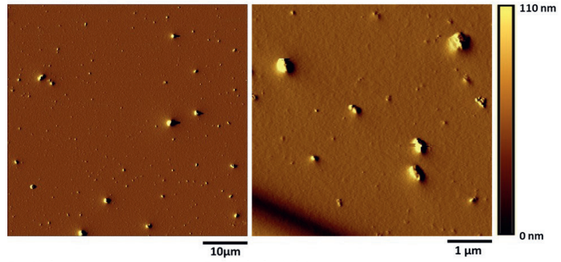
Encapsulation Efficiency and Loading Capacity



A Encapsulation efficiency (primary y-axis; bar chart) and loading capacity (secondary y-axis, dot chart) of nab-paclitaxel Biotest HSA in comparison to nab-paclitaxel recombinant HSA. **B** Encapsulation efficiency (primary y-axis; bar chart) and loading capacity (secondary y-axis; dot chart) of nab-paclitaxel Biotest HSA samples 1-3 and nab-paclitaxel recombinant HSA samples 1-3. A and B: No significant differences were observed.

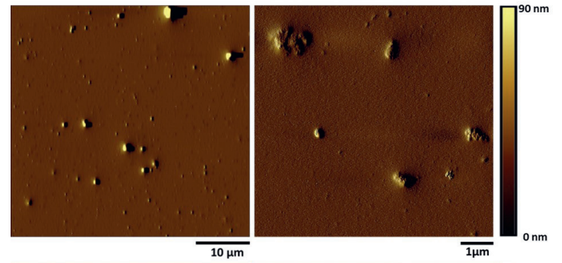
Atomic Force Microscopy-Imaging

A Biotest HSA



Particle sizes: 40 - 200 nm, Particle heights: 30 - 110 nm

B Recombinant HSA



Particle sizes: 50 - 250 nm, Particle heights: 30 - 90 nm

Representative Atomic Force Microscopy (AFM)-images of dried nanoparticles of Biotest (A) and recombinant HSA (B) samples.
Reference: Biotest AG | Data on File, DoF_0009, 2022.

Results

Particle size and particle size distribution:

The results show that both Biotest HSA and recombinant HSA enabled the preparation of NPs in the size range of approx. 130-140 nm with a narrow particle size distribution, which correlates with the marketed product Abraxane®. Biotest HSA, being a natural product, proofed to be a suitable material for the reproducible preparation of nab-paclitaxel as variations in particle size among different batches are not significant and differ only slightly to those of recombinant HSA.

Zeta potential:

The zeta potential, as an indicator of physical stability, is in the range of moderate colloidal stability (i.e., 10-20 mV) for both candidates. A slight difference was observed to recombinant HSA, but since an obligatory lyophilization step follows in each case to assure storage stability of the final product, an almost equal performance of the natural product can be concluded.

Encapsulation efficiency and loading capacity:

Both HSA sources achieved equivalent success, showing a paclitaxel encapsulation efficiency of around 98%. Accordingly, comparable results for loading capacity were observed. With around 9 % paclitaxel loading, the results are in line with the characteristics of the marketed product.

Atomic Force Microscopy (AFM)-imaging:

The results of the AFM investigations showed that both Biotest HSA and recombinant HSA had similar particle sizes and morphology. Due to the preparation method, the particle sizes differed slightly from examinations in the aqueous phase (i.e., dynamic light scattering).