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Risperidone-loaded surface-modified albumin nanocarriers for intranasal drug delivery

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Background: Risperidone is a first-line drug used in central nervous system-associated disorders, limited by the blood-brain barrier (BBB), hindering its permeation and bioavailability, which creates a significant need for enhancement of permeated concentration to the brain to achieve an effective dosage with as few excipients as possible. These targets can be achieved via the application of fine-engineered human serum albumin nanoparticles (HSA-NPs) due to their bioavailability and biodegradable properties; however, limitations are also present in the form of their limited encapsulation capability and targetability. In this ongoing research, we are optimizing and characterizing the HSA-NPs by the application of polymers to enhance these absent properties of HSA-NPs and to open the intranasal route to enhance the effective brain targeting of our model drug.

Methods: A modified coacervation method was employed to synthesize risperidone-loaded HSA-NPs (RIS-NPs) using Poloxamer 407 (P407). To determine the optimal formulation, a 2^3 factorial design has been set for the determination of HSA and polymer concentrations optimal for our DDS. The colloidal characterization of NPs was measured via dynamic light scattering. Drug binding was measured by HPLC after centrifugation at 4°C and 14,000 rpm for 15 min. The *in vitro* drug release studies were conducted in dialysis bags (molecular weight cut-off: 12 – 14 kDa) and were carried out at nasal conditions and simulated blood conditions.

Results: The characterization studies showed a clear effect on size based on the concentrations of HSA and P407. Most of the formulations were acceptable; however, higher concentrations showed aggregation. The drug binding efficiency shows no clear correlation and is approximately 60% which correlates with the literature data, so no alterations were observed. The drug release studies revealed a close-to-burst-like drug release profile. The formulations with 30 mg/ml HSA concentrations provided a higher overall solubility than the initial, with the respective values varying between 80% to 100%.

Conclusion: RIS-NPs were successfully prepared and characterized and showed an improved pharmacokinetic profile based on our drug release studies. The modification of HSA-NPs with P407 was also favourable, as it contributed to the improvement of drug release under nasal conditions, followed by a steady profile.