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	Hasan Can Hoser (Anadolu University, Türkiye)*; A. Alper Ozturk (Anadolu University, Türkiye)
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	Pinar Kocabay (Ankara University, Türkiye)*; Ahmet Cetinkaya (University of Health Sciences, Türkiye); Esen Bellur Atici (Deva Holding, Türkiye); Sibel A. Ozkan (Ankara University, Türkiye)

Development and Characterization of Eudragit RS 100-Based Nanoparticles Stabilized by Poloxamer 188 via Double Emulsion Solvent Evaporation Method: Impact of Formulation Parameters and Brimonidine Tartrate Loading

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H.C. Hoser[1], A.A. Ozturk[1].
(1)Anadolu University, Faculty of Pharmacy, Department of Pharmaceutical Technology, Eskişehir, Türkiye.

Keywords: *Brimonidine Tartrate, Double Emulsion Solvent Evaporation, Eudragit RS 100, Nanoparticles, Ocular Formulation*

Introduction: Nanoparticles (NPs) are promising drug delivery carriers due to their potential to enhance bioavailability, extend circulation time, and enable controlled release. The double emulsion solvent evaporation (DESE) technique is particularly suitable for encapsulating active pharmaceutical ingredients (APIs). Eudragit RS100 (ERS), a cationic polymethacrylate, is commonly used in NP formulations owing to its pH-independent solubility and permeability. This study aimed to develop and optimize ERS-based NPs using DESE and to investigate the effects of key formulation parameters—surfactant type and concentration, and probe sonication time—on particle size (PS), polydispersity index (PDI), and zeta potential (ZP). Additionally, the encapsulation efficiency of a model hydrophilic drug, brimonidine tartrate (BT), used in ocular glaucoma treatment, was evaluated [1-3].
Materials and Methods: A total of 29 nanoparticles (22 blank and 7 BT-loaded) were prepared using the W1/O/W2 DESE method. Each formulation contained 60 mg of ERS, with methanol or acetone as the organic phase. The aqueous phases included either PVA or Poloxamer 188 (P188) (0.5–1.5% w/v), and selected formulations contained 20 mg Span 60 for enhanced emulsion stability. Emulsification was performed via probe sonication (30–120 s, 60% amplitude). PS, PDI, ZP were characterized by DLS, and BT-loaded NPs were compared with their blank counterparts to assess the effect of drug loading [1-3].
Results: First of all, when methanol was used as the organic solvent, the NP structure could not be obtained. When PVA was used as a stabilizer, acetone as the organic solvent failed to produce stable NPs. These systems showed incomplete or irregular NP formation, high PDI values, and signs of aggregation or sedimentation. Conversely, NPs employing P188 in both the W_1 and W_2 phases produced stable and uniform NPs, especially when acetone was used as the organic phase and Span 60 was included. These successful blank NPs displayed PSs ranging from 97.1 to 189.1 nm, with PDI values below 0.574, suggesting a narrow PS distribution. Moreover, ZPs were consistently positive, ranging from +16.3 to +25.1 mV, indicating excellent electrostatic stability and surface charge appropriate for interaction with negatively charged mucosal membranes. Among these, the V-Blank-NP demonstrated the most favorable properties, with a PS of 177.7±0.8 nm, a PDI of 0.326±0.032, and a ZP of +20.5±0.2 mV. The BT-loaded NPs, which included BT(6 mg), exhibited a moderate increase in PS and a slight increase in PDI. The positive ZP was maintained, with values ranging between +11.3 and +19.4 mV, confirming that drug incorporation did not significantly compromise colloidal stability. The best-performing BT-loaded NP was V-BT-NP, which exhibited a PS of 180.2±3.4 nm, a PDI of 0.369±0.031, and a ZP of +19.1±0.6 mV.
Conclusion: This study successfully demonstrates the design, development, and optimization of positively charged ERS based NPs prepared using the DESE technique. Our findings indicate that P188 is a superior stabilizer compared to PVA in producing stable NPs with desirable physicochemical properties. Acetone was identified as a more appropriate solvent than methanol and Span 60 contributed to further enhancing emulsion stability and particle uniformity. Importantly, BT was effectively loaded into the NP system without significant disruption to PS, homogeneity, or surface charge. The optimized NP, V-BT-NP, demonstrated excellent potential for further development in ocular or mucosal drug delivery applications, particularly for hydrophilic, cationic active pharmaceutical ingredients.

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References

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