

TRANSLATIONAL FORMULATION OF MICRONEEDLE DRUG DELIVERY SYSTEMS: CHALLENGES AND ACTIVE STRATEGIES

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Microneedles are an emerging technology initially developed for minimally invasive cutaneous delivery of therapeutic molecules that were not capable of penetrating the skin. Their use quickly expanded to being used for other applications, such as ocular, gastrointestinal, mucosal, and buccal drug delivery, as well as sampling and sensing the skin interstitial fluid (1). In particular, dissolvable microneedles (DMN) offer an attractive delivery strategy for drugs and vaccines due to several advantages compared with solid or hollow microneedles. However, the translation of DMN from research laboratories to successful medicinal products is proved to be very challenging and demanding task due to several crucial factors that must be considered (2). This presentation will provide insight into these factors and an overview of materials and methods used for DMN fabrication along with their feasibility at industrial scale. In addition, safety and regulatory aspects for DMN as potential medicinal products will also be considered.

Literatura

1. Moore LE, Vucen S, Moore AC. Trends in Drug-and Vaccine-Based Dissolvable Microneedle Materials and Methods of Fabrication. *Eur J Pharm Biopharm.* 2022; 173, 54-72.
2. Avcil M, Çelik A. Microneedles in Drug Delivery: Progress and Challenges. *Micromachines.* 2021; 12(11):1321.

TRANSLACIONA FORMULACIJA MIKROIGALA KAO SISTEMA ZA ISPORUKU LIJEKA: IZAZOVI I AKTIVNE STRATEGIJE

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Mikroigle predstavljaju novu tehnologiju koja je u početku razvijena za minimalno invazivnu dostavu terapijskih molekula koje nisu mogle prodrijeti u kožu. Njihova upotreba brzo se proširila i za druge primjene, kao što je oftalmološka gastrointestinalna, mukozna i bukalna isporuka lijeka, kao i uzorkovanje i ispitivanje intersticijalne tečnosti u koži (1). Rastvorljive mikroigle nude posebno atraktivnu strategiju isporuke lijekova i vakcina zbog nekoliko svojih prednosti u poređenju s čvrstim ili šupljim mikroiglama. Međutim, pokazalo se da je translacija rastvorljivih mikroigala iz istraživačkih laboratorija u uspješne ljekovite proizvode vrlo izazovan i zahtjevan zadatak zbog nekoliko ključnih faktora koji se moraju uzeti u obzir (2). Ova prezentacija će pružiti uvid u pomenute faktore, kao i pregled materijala i metoda korištenih za izradu rastvorljivih mikroigala, te mogućnost njihove izvodljivosti na industrijskom nivou. Osim toga, sigurnost i regulatorni aspekti mikroigala kao potencijalnih medicinskih proizvoda ce takođe biti razmatrani.

Literatura

1. Moore LE, Vucen S, Moore AC. Trends in Drug-and Vaccine-Based Dissolvable Microneedle Materials and Methods of Fabrication. *Eur J Pharm Biopharm.* 2022; 173, 54-72.
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