BUDAPEST UNIVERSITY OF TECHNOLOGY AND ECONOMICS
FACULTY OF CHEMICAL TECHNOLOGY AND BIOTECHNOLOGY
GEORGE A. OLAH DOCTORAL SCHOOL

Alternating current electrospinning in pharmaceutical technology

Summary of PhD Theses

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1. Introduction

The pharmaceutical industry has arrived to a paradigm shift due to the growing demand for well controllable, economical continuous production lines which can replace conventional batch-based production. The implementation of such systems is cumbersome due to the lack of fully continuous tools – especially when it comes to drug formulation – with good compatibility when linked together with other processing methods. Furthermore, the number of newly developed active substances with poor water solubility is increasing. Electrospinning (ES) might be a feasible technique to tackle these challenges. On one hand, electrospinning is able to prepare polymeric micro- and nanofibers with huge surface area leading to the immediate drying of the product resulting in the amorphization of the incorporated drug. This way amorphous solid dispersions can be made, thus the dissolution of the poorly soluble substances can be greatly enhanced. On the other hand, electrospinning is a truly continuous process, therefore it can be applied as part of continuous production lines.

Based on the type of the high voltage as the drawing force, ES can be categorized into direct current and alternating current methods. The main drawback of the direct current method is its low productivity and difficult scale-up. In contrast, alternating current electrospinning is a novel method with multiple times higher productivity even at laboratory-scale capable to maintain good fiber quality. Alternating current electrospinning enables the modification of frequency and waveform which might be crucial factors affecting both productivity and fiber morphology.

Based on the aforementioned the question arises whether it is possible to process important pharmaceutical polymers using alternating current electrospinning, even at industrial productivity. Another aim of the doctoral research was to develop amorphous solid dispersions of poorly water-soluble drugs with modified dissolution in order to control their bioavailability.

2. Scientific background and objectives

Up until today the pharmaceutical industry is mainly based on batch technologies because of the strict regulations and the long and expensive authorization of new processes [1]. However, the increasing development costs and the intense competition encourage manufacturers to adopt more economic processes with special focus on product quality [2]. Due to the advantages of Quality by Design (QbD) and Process Analytical Technology (PAT) methods the application of continuous production lines is becoming more feasible therefore regulatory authorities are trying to make it easier for the manufacturers to introduce continuous technologies.

Besides the changing mindset from batch to continuous production another main challenge of the pharmaceutical industry is to ensure proper bioavailability. The increasing number of poorly water-soluble drugs among the newly developed candidates dates back to the early 1990's [3]. Before that time lead optimization had been based on the investigation of aqueous solutions of drug candidates, thus poorly soluble drugs dropped out in the early phase of the development. In contrast, nowadays high throughput screening systems are used and the molecules are dissolved in dimethyl sulfoxide which is a much better solvent than water, therefore less water-soluble molecules have started to appear in marketed products. This phenomenon has amplified the importance of the development of formulation techniques.

The most common methods for enhancing the solubility of poorly soluble drugs are micronization, nanonization, modification of crystal habit, preparing polymorphs, pseudopolymorphs, complexation and solubilization [4]. Besides their advantages, all of these techniques have their drawbacks which can mostly be handled by preparing amorphous solid dispersions (ASDs). ASDs are solid preparations consisting of at least two components, usually a drug dispersed in a polymer in an amorphous form. Due to the much higher energy state of the amorphous drug compared to the crystalline form multiple times higher drug concentration can be achieved meaning higher bioavailability levels. The number of marketed ASDs reached 25 in 2018 and keeps growing [5].

The use of ES enables the amorphization of the drug accompanied with the high surface area of the fibers both enhancing the dissolution properties. ES has gained great attention due to the ability to form large surface area fibrous ASDs from polymeric solutions and melts under the drawing force of the electrostatic field. Single needle direct current electrospinning (DCES) is the most common method for preparing nanofibrous ASDs, however its productivity is quite low for industrial applications. Trying to overcome this hurdle needleless or free surface

methods have been developed, but the difficulty with controlling the liquid jets results in fluctuating fiber quality and productivity. Moreover, in pharmaceutical development mostly volatile solvents are used (methanol, ethanol, dichloromethane, etc.), therefore the solution can easily dry on the free surface ceasing the fiber formation. Better results could be achieved through the combination of the centrifugal force and the electrostatic field with a reported maximum of 1500 mL/h at 40,000 rpm [6]. Corona electrospinning is a similar method with lower productivity but simpler setup [7]. The slowly rotating corona spinneret (~100 rpm) with a narrow, annular orifice provides the continuous, consistent feeding of the solution. The annulus is surrounded by a metal electrode having sharp edge from the outside promoting fiber formation. The productivity can be increased up to 120 mL/h using a direct current power source.

Novel alternating current electrospinning (ACES) provides multiple times higher productivity compared to DCES by simply replacing the power source. During ACES multiple Taylor cones are formed on the surface of the droplet leaving the spinneret compared to DCES where only one Taylor-cone is formed. Based on recent articles we concluded that the conductivity of the electrospinning solutions may have a significant effect on the ACES processability of the different polymers. Despite that, none of these researches have investigated the role of conductivity thoroughly which would be essential for the industrial introduction of ACES. Furthermore, most of the articles have reported increased productivity compared to DCES but in none of these cases has a scaled-up ACES method been developed.

ACES was first used for enhancing the bioavailability of a poorly soluble drug by our research group [8]. In that work with polyvinylpyrrolidone K90 (PVPK90), which is one of the most easily processable polymer with DCES, only poor quality fibers could be produced with limited productivity. According to that observation the ACES processability of polymers is not as clear as with DCES, therefore it requires further investigations. The question has also arisen whether the quality of the fibers and the amorphous form of the drug can be maintained despite the higher productivity of ACES.

The application of an alternating current power source enables the modification of both frequency and waveform which might be of crucial role regarding productivity and fiber morphology. Nevertheless, these important matters had not been clarified earlier.

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3. Methods

3.1. Experimental methods

- Direct current electrospinning

  NT-35 high voltage transformer, SEP-10S Plus syringe pump, single needle spinneret (ID: 1 mm, OD: 2 mm)
- Alternating current electrospinning

  FME-24 high voltage transformer, Harvard Apparatus Model 33 type twin syringe pump, single needle spinneret (ID: 1 mm, OD: 2 mm)
- Direct current corona electrospinning

  NT-65 high voltage transformer, SEP-10S Plus syringe pump, corona spinneret (OD: 110 mm)
- Alternating current corona electrospinning

  TUR PEO 8/100 A high voltage transformer, Harvard Apparatus Model 33 type twin syringe pump, corona spinneret (OD: 110 mm)
- Modified frequency and waveform alternating current electrospinning

  Feeltech FY2200S signal generator, 0-250 V_{RMS} signal amplifier, FME-24 high voltage transformer, Harvard Apparatus Model 33 type twin syringe pump, single needle spinneret (ID: 1 mm, OD: 2 mm)
- Melt extrusion

  MiniLab HAAKE Rheomex CTW5 extruder

3.2. Characterization methods

- Scanning electron microscopy (SEM) and fiber diameter analysis

  JEOL JSM-6380LA type Scanning electron microscope, fiber measurement algorithm
- Energy-Dispersive X-ray Spectroscopy (EDS)

  JEOL JSM-6380LA type Scanning electron microscope coupled with the energy-dispersive X-ray detector of the equipment
- Surface tension measurement

  Pendant drop test with self-developed apparatus
- Electric conductivity measurement

  Consort C860 conductivity meter

- Kinematic viscosity measurement

  Modified Ostwald viscometer
- Differential scanning calorimetry (DSC)

  Setaram DSC 92 apparatus
- X-ray powder diffraction (XRPD)

  X'Pert Pro MDP PANanlytical X-ray diffractometer
- Raman microspectroscopy

  Horiba Jobin Yvon Labram Raman spectrometer
- Transmission Raman microspectroscopy

  Kaiser RamanRxn2® Hybrid analyzer coupled with PhAT (Pharmaceutical Area Testing) probe
- *In vitro* dissolution tests

  Pharmatest PTWS 600 USP dissolution tester, USP II (paddle)

4. Results and discussion

- We successfully managed to process hydroxypropylmethylcellulose (HPMC), as one of the most important carriers in marketed ASDs, with ACES. The poor electrospinnability of HPMC could be overcome by adding small amounts of well-electrospinnable polyethylene oxides (PEOs) to the spinning solution. The optimized composition was proved to be suitable for preparing excellent quality placebo and drug-loaded HPMC fibers with 20% and 40% spironolactone (SPIR) content with increased productivity compared to DCES.
- The next phase of the doctoral work was to prepare drug-loaded fibers with pH dependent dissolution made of hypromellose acetate succinate (HPMCAS) using ACES. As HPMCAS could not be processed with ACES alone (Figure 1. a), high molecular weight PEOs were added to the solution in order prepare good quality fibrous mats. By applying PEOs the quality of the fibers somewhat improved, yet large droplets and beads remained observable (Figure 1. b). The addition of sodium dodecyl sulfate (SDS) to the HPMCAS-PEO solution yielded and droplet-free excellent quality fibers with ACES (Figure 1. c). The investigation of viscosity, surface tension and conductivity of the solutions showed that neither viscosity nor surface tension changed significantly after the addition of SDS but conductivity was multiple times higher. The same results were obtained after replacing SDS to simple salts ($CaCl_2$, NH_4OAc) verifying the importance of the optimization of solution conductivity during ACES. Finally, enhanced dissolution could be achieved with SPIR-loaded HPMCAS fibers compared to the crystalline drug and the marketed SPIR tablet.

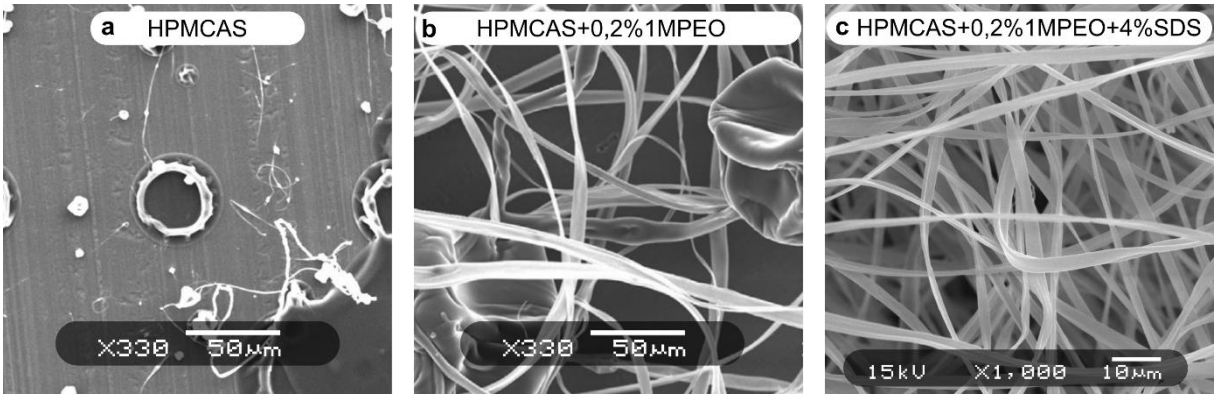

Figure 1. HPCMAS-based samples prepared with ACES.

- The next goal was to investigate the new Eudragit® FS (EudFS) anionic terpolymer. It is only soluble above pH=7,4 making it an excellent excipient for targeted drug delivery in the colon. EudFS had not been processed with ACES before but it turned out to be easily electrospinnable with ACES since excellent quality fibers could be prepared without adding any other excipient

to the EudFS solution. 10% and 20% SPIR-loaded fibers were prepared for further experiments and the same compositions were melt extruded as comparison. With X-ray powder diffraction (XRPD) and energy dispersive X-ray spectroscopy (EDS) significant amount of crystalline traces could be detected in the melt extruded samples with higher drug loading or lower processing temperatures (Figure 2.). *In vitro* dissolution measurements showed pH-dependent release of SPIR: in the first period in acidic medium no significant drug release was observed, but after increasing the pH to 7,4 enhanced drug release took place.

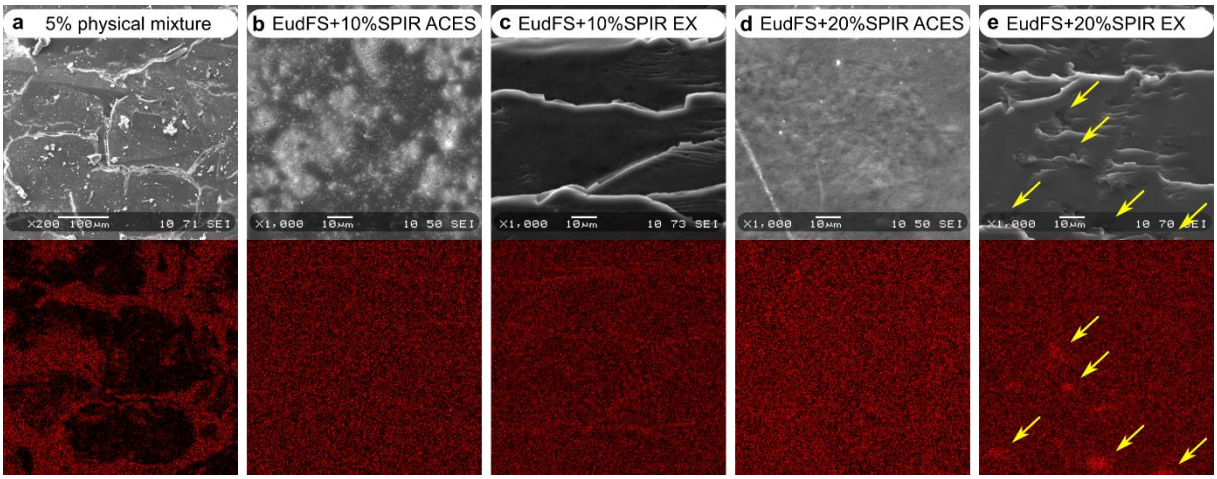

Figure 2. SEM images and EDS mapping of (a) 5% SPIR-loaded physical mixture, (b, c) 10% and (d, e) 20% SPIR-loaded ACES fibers and extrudates. The inhomogeneities of S atoms of SPIR are highlighted with yellow arrows.

- By applying an alternating current power source the modification of frequency and waveform become possible in contrast to DCES. Neither the effect of frequency nor waveform has been investigated before, yet it could affect both productivity of ACES and the morphology of the product. PVPVA64, one of the most important matrix polymer of marketed ASDs was chosen as carrier. PVPVA64 has been used on several occasions with DCES for enhancing the bioavailability of poorly water soluble drugs, however it had not been processed with ACES before. During the first ACES experiments only poorly fibrous samples were obtained with large droplets and beads. Based on our earlier experiences the optimization of solution conductivity with SDS and the addition of PEOs to the PVPVA64 solution resulted in the production of bead and droplet-free, excellent quality fibrous mats. The effect of frequency on ACES was investigated using sinusoidal waveform in the range of 40 to 250 Hz. The ACES process could be operated at all frequency levels, but the maximum feeding rate of 30 mL/h could not be further increased and the different frequencies did not change fiber morphology significantly. Besides sinusoidal, ACES experiments could also be carried out with square, triangle and saw tooth waveforms but it did not improve fiber morphology or the productivity

of the method (Figure 3.). Overall, the optimal condition of sinusoidal waveform with 50 Hz frequency proved to be feasible for preparing PVPVA64 fibers with ultrafast drug release using ACES.

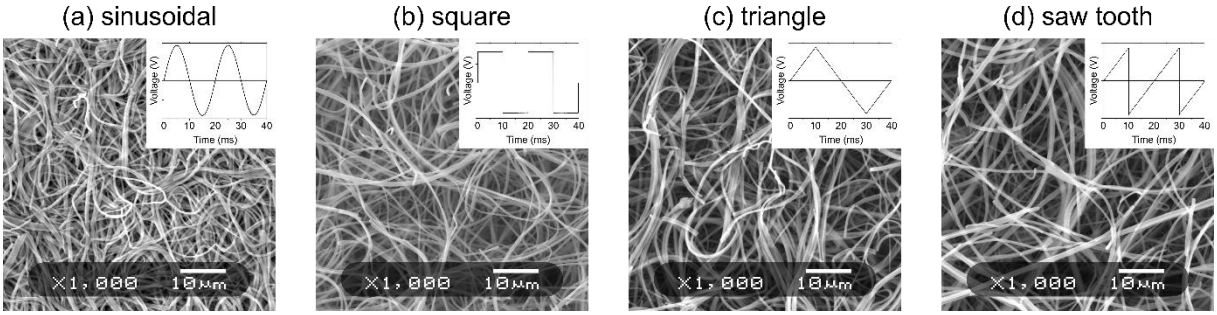

Figure 3. SEM images of ACES fibers prepared at 50 Hz with (a) sinusoidal, (b) square, (c) triangle and (d) saw tooth waveforms.

- Exploiting the maximum productivity of ACES the method was combined with a corona spinneret (C-ACES, Figure 4.). PVPK90 was selected as carrier, a hydrophilic polymer with poor ACES processability based on earlier experiments [8]. After the optimization of polymer concentration and solution conductivity with SDS excellent quality fibers could be obtained with ACES. Using a corona spinneret 120 times higher productivity was achieved compared to the laboratory-scale single needle DCES. 20% SPIR-loaded fibers could be prepared with C-ACES maintaining the same excellent fiber morphology and amorphous drug content based on solid phase analyses. The i*n vitro* dissolution tests showed similarly ultrafast drug release from both ACES and C-ACES fibers, thus the higher productivity did not affect the quality of the products.

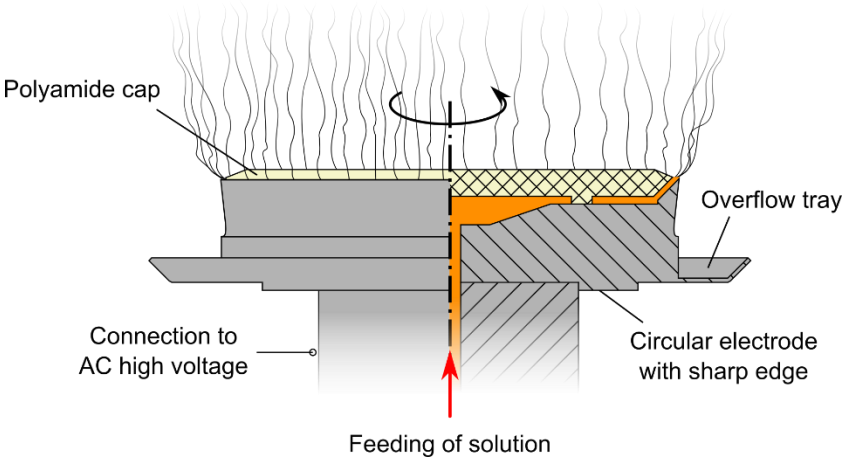

Figure 4. The schematic drawing of the C-ACES method with the corona spinneret (OD=110 mm) coupled with AC high voltage. The application of a grounded surface is also recommended for proper fiber formation (not shown here).

5. Theses

1. Hydroxypropylmethylcellulose (HPMC 2910 5 mPa·s), one of the most important polymeric carriers of marketed amorphous solid dispersions was processed for the first time with alternating current electrospinning. The insufficient electrospinnability of the polymer was overcome by introducing well electrospinnable high molecular weight polyethylene oxides (100 kDa, 1 MDa, 4 MDa PEOs) as secondary polymers to the composition. Spironolactone-loaded fibers were prepared by applying the novel alternating current electrospinning method with multiple times higher productivity compared to the conventional direct current method. Enhanced drug release could be observed from the electrospun fibers due to the amorphous form of the drug and the large surfaces of the fibers. [I]

2. Poorly electrospinnable hydroxypropylmethylcellulose acetate succinate (HPMCAS) was processed for the first time using alternating current electrospinning with multiple times higher productivity compared to direct current electrospinning. In order to overcome the poor processability, small amounts of high molecular weight PEOs (100 kDa, 1 MDa) were applied with HPMCAS. In addition, the vital role of the optimization of solution conductivity was proven in the case of alternating current electrospinning. In vitro dissolution tests showed targeted liberation from the spironolactone-loaded fibers at the pH of the small intestine (pH=6,8). [II]

3. Eudragit FS (EudFS), an anionic methacrylate terpolymer, was processed for the first time with direct current electrospinning. It was also verified for the first time that EudFS can be smoothly processed using alternating current electrospinning with different solvents without the need for any additives at multiple times higher productivity compared to direct current electrospinning. Using the new alternating current method spironolactone-loaded EudFS fibers were prepared with colon-targeted enhanced release based on the in vitro dissolution tests. [III]

4. The effect of frequency and waveform on fiber morphology and productivity of alternating current electrospinning was investigated for the first time. It was revealed that alternating current electrospinning can be operated using square, triangle and saw tooth waveforms besides sinusoidal in the range of 40 Hz to 250 Hz, however these factors did not have significant effect on either the productivity or the morphology of the products. A novel composition was developed for the experiments based on PVPVA64, one of the most frequently applied polymeric carrier in marketed amorphous solid dispersions. After the optimization of the

composition with PEOs and adjusting the conductivity excellent quality fibers were prepared ensuring ultrafast drug release. [IV]

5. A novel scaled-up electrospinning method, corona alternating current electrospinning was developed. Combining a corona spinneret rotating at a relatively low speed (100 rpm) with alternating current electrospinning two orders of magnitude higher productivity could be achieved (from 10 mL/h to 1200 mL/h) compared to single needle direct current electrospinning. A composition of PVPK90 was developed with the optimization of solution conductivity. The higher productivity of corona alternating current electrospinning did not deteriorate the quality of the drug-loaded fibers, ultrafast drug release could be achieved. Based on these finding the new method can be used for the scaled-up production of amorphous solid dispersions satisfying both quality and quantity requirements. [V]

2. Possible fields of application

The introduced electrospinning methods may be of great use for the formulation of poorly water-soluble drugs on laboratory-scale facilitating the early phase of the drug development process.

Electrospinning is being investigated by numerous international pharmaceutical companies.

Corona alternating current electrospinning is a pilot-sized method for the preparation of drug-loaded fibrous mats. Its productivity may be further increased after the optimization of the equipment making it suitable for industrial applications.

The introduced electrospinning methods may serve as the formulation part of continuous production lines.

Electrospun fibers may be used as an alternative delivery form instead of tablets, for example in the form of orodispersible mats.

3. Publications

Publications related to the PhD theses

(Citations retreived from Google Scholar, 2021.02.17.)

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