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Research Article

Effects of Spray Drying Temperature on Dry Emulsion Properties and Aceclofenac Entrapment Efficiency

Efectos de la temperatura de secado por aspersión en las propiedades de la emulsión seca y la eficiencia de captura de aceclofenaco

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ABSTRACT

Introduction: Aceclofenac (ACE), a BCS class II non-steroidal anti-inflammatory drug, has limited bioavailability due to poor aqueous solubility.

Objective: To investigate the effects of spray drying temperature on the physicochemical properties and entrapment efficiency of ACE in dry emulsions.

Methods: Dry emulsions were prepared by spray drying an oil-in-water emulsion containing maltodextrin, HPMC E6, and Aerosil 200 at temperatures ranging from 110°C to 160°C. The powders were characterized for moisture content and water activity using a rapid moisture analyzer and a water activity meter, respectively. Powder yield, bulk density, and particle size were determined using standard gravimetric and sizing methods. Aceclofenac entrapment efficiency was assessed by UV spectrophotometry. FTIR spectroscopy was used to evaluate drug-excipient interactions, and *in vitro* drug release was assessed using the USP 24 paddle method.

Results: The dry emulsion powder formed at 130°C had a high yield (53.5%), good particle integrity, and small powder particle size. With the spray drying temperature increasing from 110°C to 160°C, the entrapment efficiency of ACE in dry emulsion powder decreased from 78.09% to 70.52%.

Conclusions: Spray drying temperature has a significant impact on the physicochemical properties and entrapment efficiency of aceclofenac in dry emulsions. Higher temperatures led to decreased entrapment efficiency. The formulation dried at 130°C showed optimal yield, particle integrity, and size. Thus, 130°C is the most suitable temperature for producing effective aceclofenac-loaded dry emulsion powders.

Keywords: aceclofenac; dissolution; dry emulsion; spray drying.

RESUMEN

Introducción: El aceclofenaco (ACE) es un fármaco antiinflamatorio no esteroideo de la clase II del Sistema de Clasificación Biofarmacéutica (BCS); presenta biodisponibilidad limitada por su baja solubilidad acuosa.

Objetivo: Investigar los efectos de la temperatura de secado por atomización en las propiedades fisicoquímicas y la eficiencia de encapsulación de ACE en emulsiones secas.

Métodos: Se prepararon emulsiones secas mediante secado por atomización de una emulsión aceite-en-agua con maltodextrina, HPMC E6 y Aerosil 200 a temperaturas entre 110 °C y 160 °C. El polvo obtenido se caracterizó para el contenido de humedad y actividad acuosa, mediante un analizador rápido de humedad y un medidor específico. Se determinó el rendimiento, la densidad a granel y el tamaño de las partículas por métodos gravimétricos y de análisis de tamaño. La eficiencia de encapsulación se evaluó por espectrofotometría UV. Las interacciones fármaco-excipiente se analizaron mediante espectroscopía FTIR. La liberación *in vitro* del fármaco se estudió con el método del vaso *paddle* de la USP 24.

Resultados: El polvo de emulsión seca formado a 130 °C mostró un alto rendimiento (53,5 %), buena integridad de las partículas y tamaño pequeño. A medida que aumentó la temperatura de secado, la eficiencia de encapsulación de ACE disminuyó del 78,09 % al 70,52 %.

Conclusiones: La temperatura de secado por atomización impacta significativamente en las propiedades fisicoquímicas y la eficiencia de encapsulación de aceclofenaco. Las temperaturas más altas reducen la eficiencia de encapsulación. La formulación secada a 130 °C mostró óptimo rendimiento y tamaño.

Palabras clave: aceclofenaco; disolución; emulsión seca; secado por atomización.

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INTRODUCTION

Aceclofenac [(2-(2,6-dichlorophenyl) amino) phenylacetoxy acetic acid] is a non-steroidal anti-inflammatory drug (NSAID) commonly used to treat osteoarthritis, rheumatoid arthritis, dental pain, and other rheumatoid conditions.(1) Its therapeutic effect is primarily achieved through the inhibition of inflammatory mediators, including prostaglandin E2, tumor necrosis factors, and interleukins (IL-1β, IL-2).(2,3)

Additionally, aceclofenac exhibits chondroprotective properties by promoting the synthesis of glycosaminoglycans.(3,4) The drug exerts its action through preferential inhibition of cyclooxygenase-2 (COX-2) after conversion into an active metabolite, which contributes to its improved safety profile compared to conventional NSAIDs and selective COX-2 inhibitors.(2,3,4,5)

Aceclofenac, an aryl acetic acid derivative, is classified as a BCS class II drug due to its low solubility in water but high permeability.(6) It rapidly and effectively absorbed following oral administration, with a mean plasma half-life of approximately 4 hours. However, its high concentration resulting from rapid absorption may lead to adverse effects on the gastrointestinal tract.(7)

Various technological approaches have been developed to enhance the bioavailability of drugs, particularly for BCS class II compounds. For poorly water-soluble active substances, bioavailability can be improved by increasing dissolution rates through methods such as particle size reduction, preparation of water-soluble complexes, use of surfactant systems, incorporation into liposomes, and formulation as solid dispersions.[8]

Dry emulsions are particularly appealing as they are physically and microbiologically stable solid formulations. Similar to oil-in-water (O/W) emulsions, dry emulsions are promising drug delivery systems for lipophilic and poorly soluble active ingredients, as well as for compounds requiring protection from light, oxidation, or hydrolysis.[9] In addition to offering effective protection of the active ingredient, dry emulsions should ensure homogeneous dispersion of the drug. To maintain stability during storage, dry emulsions require minimal water content and low water activity, which prevent issues such as wall collapse or sticking.

Given these benefits, the objective of this study was to formulate and characterize dry emulsions containing aceclofenac, with a specific focus on evaluating the physicochemical properties of the formulations obtained at different drying temperatures and determining the entrapment efficiency of aceclofenac.

METHODS

Solubility of aceclofenac in oils and surfactants

The solubility study of ACE in various oils and surfactants was conducted to evaluate its solubility profile. Briefly, 0.5 g of ACE was added to 3 g of each of the following: castor oil, olive oil, sweet almond oil, coconut oil, Tween 80, Cremophor RH40, and Span 80. The mixtures were stirred at 37°C for 24 hours to ensure equilibrium. Afterward, each sample was centrifuged at 12,000 rpm for 10 minutes. The resulting supernatant was filtered using a 0.45-µm membrane filter, appropriately diluted with the corresponding organic solvent, and analyzed by UV-spectrophotometry at 276 nm to determine the aceclofenac content.[10]

Preparation of dry emulsion

Based on the solubility study results (Fig. 1), castor oil was selected as the oil phase, with Cremophor RH40 and Tween 80 as surfactants. The dry emulsion was prepared by spray-drying liquid emulsions using solid carriers, including maltodextrin, HPMC E6, and Aerosil 200, in a 2:2:1 ratio (8.6% w/w of the formulation).[11]

The aqueous phase was prepared by dissolving the carriers and Tween 80 in water, while the oil phase was prepared by dissolving aceclofenac in castor oil (4.5 g) and Cremophor RH40 (4.5 g). The oil phase was homogenized at 100 rpm for 2 hours, followed by sonication for 1 hour. The two phases were combined and emulsified using a homogenizer at 24,000 rpm for 5 minutes to achieve uniform droplet size. The resulting emulsion was spray-dried using a spray dryer at inlet temperatures of 110, 120, 130, and 160°C with a feed rate of 3 mL/min. The dry emulsion powders were collected, stored in airtight containers, and reconstituted in deionized water (1:10 w/v) for further analysis.

Characterization of spray-dried emulsion powder

Moisture content and water activity

The moisture content of the dry emulsion powder was determined using a rapid moisture analyzer. The water activity of the dry emulsion powder was measured at 25°C using a water activity meter.

Yield and bulk density

The yield of the dry emulsion powder was calculated as the ratio of the collected powder to the total soluble solids in the feed solution. Bulk density was measured using a 10 mL graduated cylinder. The mass of the empty cylinder (H1) was recorded, followed by filling it with the dry emulsion powder to a known volume (V). The total mass of the filled cylinder (H2) was then measured, and bulk density was calculated using equation.[12]

$$\text{Bulk density (g/ml)} = \frac{\text{H2} - \text{H1}}{\text{V}}$$

Particle size distribution

The particle size of the dry emulsion samples was measured using a Zetasizer Nano analyzer. To prevent multiple scattering, the emulsion sample was diluted 1000-fold with deionized water at 25°C prior to analysis.

Entrapment efficiency of ACE

Entrapment efficiency (EE%) was assessed via UV-spectrophotometry at 275 nm in phosphate buffer (pH 6.8) with 10% methanol.[13] A stock solution of aceclofenac (100 µg/mL) was prepared and diluted to 2–25 µg/mL for calibration. Dry emulsion powders equivalent to 100 mg of aceclofenac were extracted with 20 mL methanol and diluted to 100 mL with phosphate buffer (pH 6.8). A 1 mL aliquot was further diluted to 10 mL with the same buffer, and absorbance was recorded at 275 nm. The procedure was repeated for pure aceclofenac. Absorbance values were used to calculate drug content, and the method was validated for linearity, accuracy, and precision.

$$\text{Entrapment efficiency \%} = \frac{\text{Actual quantity of drug determined}}{\text{Theoretical quantity of drug}} \times 100$$

Fourier-Transform Infrared (FTIR) Analysis

FTIR spectra were obtained using a spectrometer (FTIR 4700, Jasco, Japan). Measurements were performed in the spectral range of 4000–400 cm^{-1} with 24 scans at a resolution of 4 cm^{-1}. Pure ACE and DE-ACE were analyzed directly in powder form, and the spectra were normalized using Spectra Manager™ software.

In Vitro Release Studies

The *in vitro* release profile of ACE from dry emulsion powders (F3) and pure ACE was evaluated using the USP 24 paddle method (100 rpm, 37.0 ± 0.5 °C). Dry emulsion powder equivalent to 10 mg ACE and 10 mg pure ACE were weighed and placed in dialysis bags (Dialysis membrane, MWCO: 14000, Biosharp, China) and immersed in 900 mL of phosphate buffer (pH 6.8), which served as the release medium. Samples (5 mL) were collected at intervals of 5, 10, 15, 20, 30, 40, 50, and 60 with the withdrawn volume replaced by fresh medium.[1] The collected samples were filtered through 0.45 µm membranes and analyzed for ACE concentration using UV spectroscopy at 275 nm.

RESULTS

Solubility Studies

Solubility studies identified suitable oils and surfactants to maximize ACE drug loading and ensure emulsion stability. ACE exhibited the highest solubility in castor oil (57.78 mg/g), followed by sweet almond oil (10.37 mg/g) and coconut oil (8.2 mg/g). Among surfactants, cremophor RH40 showed the highest solubility (322.36 mg/g), followed by Tween 80 (314.66 mg/g) (Fig. 1). Therefore, castor oil was chosen as the oil phase, with cremophor RH40 and Tween 80 as surfactants for emulsion preparation.

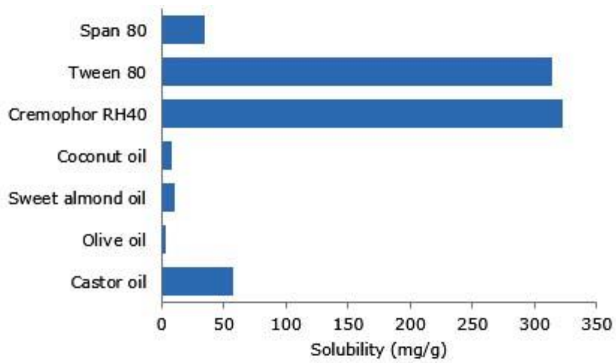

Fig. 1 - Solubility of aceclofenac in different oils and surfactants.

Effect of drying temperature on the physical properties of dry emulsion powder

Dry emulsion powder moisture content and water activity

Table 1 showed the influence of inlet temperature on the moisture content and water activity of spray-dried dry emulsions.

Table 1 - Results of the physical parameters of dry emulsion powder at different inlet temperature

Inlet temperature (ºC)	Batch code	Moisture content (%)	Water activity	Powder yield (%)	Bulk density (g/mL)
110	F1	4.03 ± 0.53	0.56 ± 0.03	36.7 ± 0.34	0.46 ± 0.03
120	F2	3.41 ± 0.11	0.42 ± 0.01	43.9 ± 0.25	0.42 ± 0.02
130	F3	3.38 ± 0.47	0.41± 0.05	53.5 ± 0.45	0.39 ± 0.02
160	F4	3.25 ± 0.38	0.39 ± 0.04	50.2 ± 0.38	0.35 ± 0.01

The inlet temperature ranged from 110°C to 160°C across four batches (F1 to F4). A clear trend is observed where increasing the inlet temperature results in a reduction in both the moisture content and water activity of the dry emulsions. Specifically, the moisture content decreased from 4.03 ± 0.53% (F1) at 110°C to 3.25 ± 0.38% (F4) at 160°C. Similarly, the water activity followed a decreasing trend, starting from 0.56 ± 0.03 (F1) at 110°C and reaching 0.39 ± 0.04 (F4) at 160°C.

Yield and bulk density

Table 1 showed the powder yield increased significantly as the inlet temperature increased from 110°C to 130°C, reaching its peak at 53.5 ± 0.45% (F3). However, at 160°C (F4), the yield slightly decreased to 50.2 ± 0.38%. The bulk density exhibited a decreasing trend with increasing inlet temperature, starting from 0.46 ± 0.03 g/mL (F1) at 110°C and dropping to 0.35 ± 0.01 g/mL (F4) at 160°C.

Z-average, polydispersity index, and entrapment efficiency of dry emulsion powder

In table 2, the Z-average particle size demonstrated a non-linear dependence on inlet temperature during the spray-drying process.

Table 2 - Z-average, polydispersity index, and entrapment efficiency of dry emulsion powder

Inlet temperature (ºC)	Batch code	Z-average (nm)	Polydispersity index (PI)	Entrapment Efficiency (%)
110	F1	127.5	0.396	78.09 ± 0.34
120	F2	126.4	0.358	72.44± 0.25
130	F3	101.9	0.329	76.20± 0.45
160	F4	139.0	0.303	70.52 ± 0.38

At 110°C (F1), the particle size was 127.5 nm, decreasing slightly to 126.4 nm at 120°C (F2) and significantly to 101.9 nm at 130°C (F3). However, it increased to 139.0 nm at 160°C (F4). The polydispersity index decreased steadily from 0.396 at 110°C (F1) to 0.303 at 160°C (F4), indicating improved particle size uniformity (table 2). Entrapment efficiency (EE%) varied with temperature (table 2). The highest EE% (78.09 ± 0.34%) was observed at 110°C (F1), dropping to 72.44 ± 0.25% at 120°C (F2). At 130°C (F3), EE% partially recovered to 76.20 ± 0.45% but declined again to 70.52 ± 0.38% at 160°C (F4), likely due to thermal degradation or volatilization of the encapsulated material.

Fourier-transform infrared spectroscopy (FT-IR)

The FT-IR spectra of individual components, their physical mixture, and the DE-ACE (F3) are shown in figure (Fig. 2). Aceclofenac displayed peaks at 3319.86 cm^{-1} (N-H stretching), 1712 cm^{-1} (carbonyl stretching), and 1589.06–1451.86 cm^{-1} (aromatic C=C stretching).[14] HPMC E6 showed characteristic bands at 3466.42 cm^{-1} (O-H stretching), 2935.13 cm^{-1} (C-H stretching), and 1059.69 cm^{-1} (C-O stretching).[15] Maltodextrin exhibited peaks at 3398.92 cm^{-1} (O-H stretching) and 1147–1076 cm^{-1} (C-O stretching).[16] Aerosil 200 revealed bands at 3433.64 cm^{-1} (O-H), 1629 cm^{-1} (H-O-H bending), and 1104, 808.03 cm^{-1} (Si-O vibrations).[17] In formulation F3, the disappearance of the characteristic peaks of aceclofenac at 3319.28 cm^{-1} (N-H) and 1716.75 cm^{-1} (carbonyl) suggests the amorphous transformation of aceclofenac during the dry emulsion preparation process.

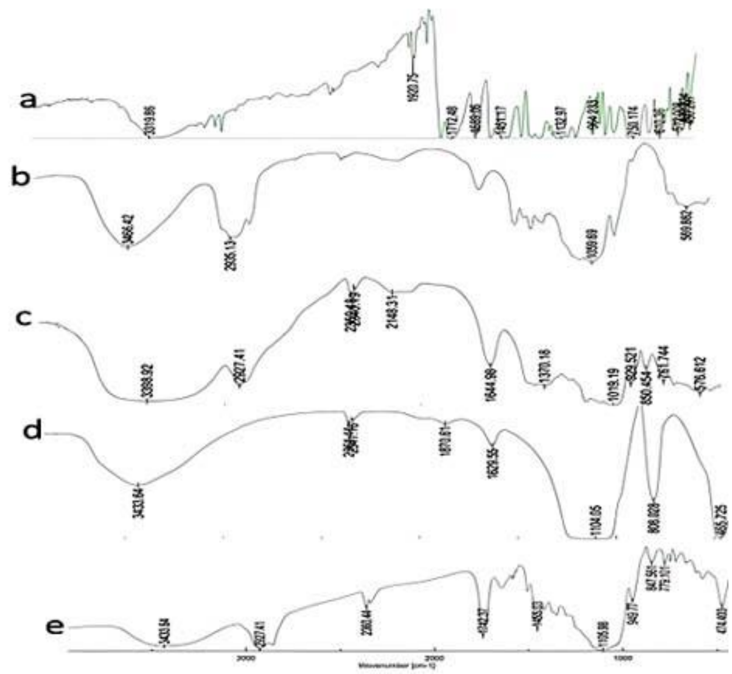

Fig. 2 - FTIR spectrum of ACE (a), HPMC E6 (b), maltodextrin (c), aerosil 200 (d), and DE-ACE (e).

In vitro dissolution test

The dissolution profiles of the F3 formulation and pure ACE powder into phosphate buffer (pH 6.8) showed in figure (Fig. 3).

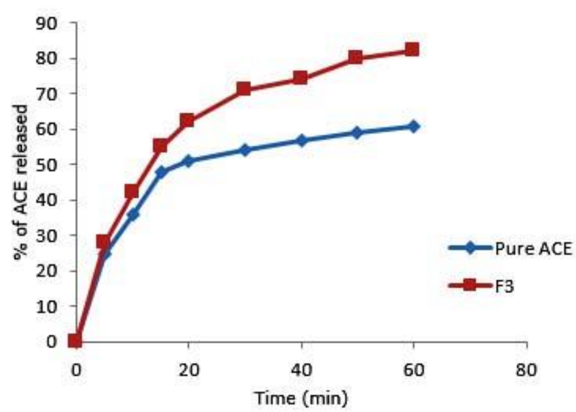

Fig. 3 - The dissolution profiles of aceclofenac and DE-ACE (F3).

The drug release rate of pure ACE was slower than that of the F3 formulation; it increased gradually over the first 20 minutes but remained below 50% after 60 minutes. On the other hand, the F3 formulation had a significantly improved release, releasing more than 60% of the aceclofenac in the first 20 minutes and almost 80% by the 60-minute point.

DISCUSSION

Dry emulsions are innovative lipid-based solid systems that enhance the bioavailability of poorly soluble active pharmaceutical ingredients while addressing the inherent physical instability of liquid emulsions.(18) These systems can reconstitute into o/w emulsions upon contact with aqueous media or within the biological environment, offering superior physical and microbiological stability.(19) Their versatility in dosage forms, such as reconstitutable powders, capsules, and tablets, makes them a promising platform for drug delivery applications.(20)

Dry emulsions can be prepared through techniques like spray drying, freeze-drying, and solvent evaporation.(21) Among these, spray drying is particularly advantageous due to its efficiency, scalability, and ability to preserve the stability of active compounds. This method transforms liquid emulsions into stable powders by rapidly removing the aqueous phase, maintaining the integrity of sensitive components.(22) Spray drying is influenced by several parameters, with the inlet temperature being a critical factor.(22)

In this study, the inlet temperature significantly impacts the properties of dry emulsion powders, including moisture content, water activity, particle size, and entrapment efficiency. At moderate drying temperatures (130°C), moisture on the dry emulsion surface diffuses outward more efficiently, resulting in reduced moisture content. However, excessively high temperatures (160°C) cause rapid evaporation of surface water, forming a hardened shell that prevents internal moisture migration. This imbalance can lead to defects such as shell expansion and fragmentation.(23) Likewise, the drying temperature plays a critical role in influencing the water activity of the dry emulsion powder. As shown in the results (table 1), water activity progressively declines with an increase in drying temperature.(22)

Regarding the effect of inlet temperature on the powder yield and bulk density, increasing the temperature from 100°C to 130°C reduces moisture content and improves yield. However, further elevation to 160°C decreases yield. Therefore, 130°C was the optimal drying temperature for producing high-yield powder. Bulk density declines with higher temperatures due to increased evaporation rates, leading to porous structures. This is consistent with findings that higher temperatures decrease particle density, resulting in hollow particles and reduced bulk density.(24)

Particle size is also affected by drying temperature (table 2). At lower temperatures (110°C), incomplete drying results in larger, irregular particles due to adhesion and aggregation. Under optimal conditions (130°C), a balance between evaporation rate and moisture migration produces uniform particles with minimal aggregation, averaging 101.9 nm in size.(25) However, at elevated temperatures (160°C), unbalanced water evaporation leads to dry emulsion expansion and rupture, increasing the particle size to 139.0 nm.(22)

Finally, the entrapment efficiency decreases with rising temperatures due to chemical degradation and structural damage to the microcapsule shell. Efficiency drops from 78.09% at 110°C to 70.52% at 160°C, reflecting increased degradation and particle surface cracks (table 2).

In summary, the preparation of aceclofenac dry emulsion using the spray drying method was successfully achieved. At a drying temperature of 130°C, the resulting dry emulsion exhibited favorable properties, including low moisture content (3.38%), high powder yield (53.5%), small particle size (101.9 nm), and uniform morphology. The entrapment efficiency of ACE reached 76.20% at this temperature, and *in vitro* dissolution studies demonstrated a significantly enhanced release rate compared to pure ACE. These results indicate that the dry emulsion formulation of ACE via spray drying is a promising strategy for improving its dissolution rate and potentially enhancing its oral bioavailability.

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Conflict of interest

The authors have no conflicts of interest.

Authorship contribution

Conceptualization: *Van Thu Nguyen.*

Data curation: *Van Thu Nguyen, Duc Thinh Pham.*

Formal analysis: *Van Thu Nguyen, Duc Thinh Pham.*

Research: *Van Thu Nguyen, Duc Thinh Pham.*

Methodology: *Van Thu Nguyen, Duc Thinh Pham.*

Supervision: *Van Thu Nguyen, Duc Thinh Pham.*

Writing –original draft: *Van Thu Nguyen, Duc Thinh Pham.*

Data Availability Statement

The study data are considered confidential by the authors and therefore cannot be published or shared publicly. They are stored in a private repository maintained by the authors, and access can only be granted with their permission via email.

Supplementary file: Research materials, instruments, and results (PDF): Available from: https://revmedmilitar.sld.cu/index.php/mil/libraryFiles/downloadPublic/53