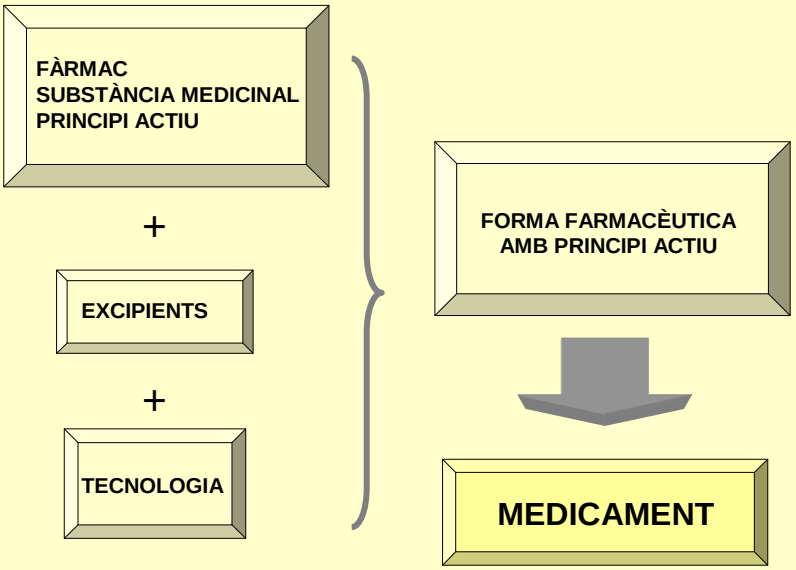
DISSENY I FORMULACIÓ DE MEDICAMENTS: NOVES FORMES FARMACÈUTIQUES

Forma farmacèutica o forma galènica: és la disposició individualitzada a que s'adapten les substàncies medicinals i excipients per a constituir un **MEDICAMENT**.



Disseny i formulació de medicaments

Recerca aplicada

Obtenció medicament

- **SEGUR**
- **EFICAÇ**
- **DE QUALITAT → ESTABLE**

FASES DE LA RECERCA EN TECNOLOGIA FARMACÈUTICA PER A LA OBTENCIÓ D'UN MEDICAMENT

1- Caracterització del principi actiu. Estudis de preformulació.
2- Estudis de formulació.
3- Estudis d'optimització de la tècnica d'elaboració.
4- Caracterització de la formulació definitiva:
5- Estudis de transposició a escala industrial.
6- Estudis d'estabilitat accelerada i a llarg termini segons ICH.
7- Estudis clínics.

CARACTERITZACIÓ DEL PRINCIPI ACTIU. ESTUDIS DE PREFORMULACIÓ.

- Característiques organolèptiques.
- Tipus de cristal·lització; polimorfisme. Difracció raig X.
- Espectofotometria IR.
- Ressonància magnètica nuclear (RMN).
- Solubilitat: diferents dissolvents, en funció pH.
- Puresa: aigua, metalls pesants, dissolvents residuals, impureses estructurals (CCF, UV, HPLC).
- Grandària partícula: comptador làser, anàlisi d'imatges, etc.
- Estabilitat front temperatura, dissolució àcida, dissolució alcalina, peròxids, permanganat, llum UV, llum visible, humitat.
- Estudis reològics, si cal: densitat, capacitat de flux, velocitat de lliscament, angle de repòs, capacitat de compressió, etc.
- Estudis de compatibilitat amb excipients (DSC, HPLC).

ESTUDIS DE FORMULACIÓ = INVESTIGACIÓ GALÈNICA

- Quina forma farmacèutica és la més adequada?
- Quins excipients s'han d'utilitzar?
- Quina tecnologia de fabricació es pot fer servir?

CONDICIONARAN LES CARACTERÍSTIQUES DEL MEDICAMENT I PER TANT LA SEVA BIODISPONIBILIDAT

INVESTIGACIÓ GALÈNICA. OBJECTIU

Aconseguir una formulació correcta que vehiculitzi la substància medicamentosa per fer possible la seva administració en una dosis determinada i per la via d'administració desitjada, aconseguint l'òptima biodisponibilitat

MEDICAMENT SEGUR, EFICAÇ, ESTABLE I DE QUALITAT

INVESTIGACIÓ GALÈNICA

Elecció
forma farmacèutica

Via d'administració

- **Acció farmacològica**
- **Característiques del fàrmac:**
  - **-físico químiques**
  - **-biodisponibilitat**
- **Comoditat d'administració**

ESTUDIS DE FORMULACIÓ

- Selecció d'excipients
- Selecció tècnica d'elaboració
- Disseny formulació base

SELECCIÓ D'EXCIPIENTS EN FUNCIÓ DE:

•MOLÈCULA PA
•ESTUDIS DE PREFORMULACIÓ PA

DISSENY DE LA FORMULACIÓ BASE

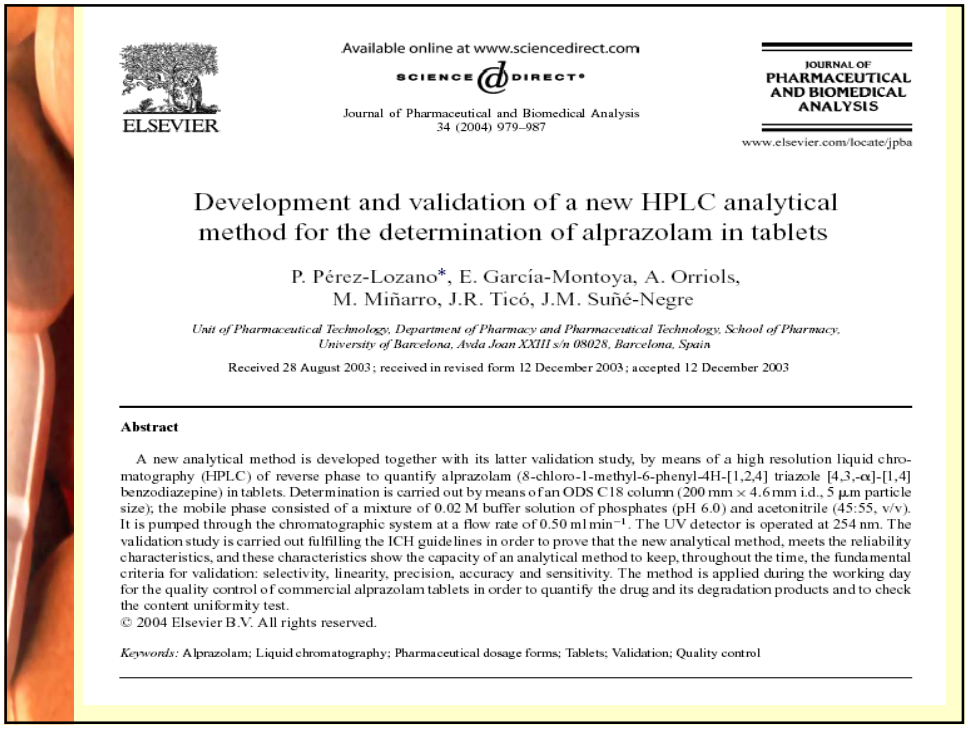
- Dissenyar la fórmula més simple
- Utilitzar estàndards bibliogràfics
- Executar experimentalment la formulació
- Avaluar experimentalment l'adequació a objectius (assaigs control de qualitat de la forma farmacèutica)
- Modificar la fórmula en funció d'objectius no complerts
- Estudiar les variables tecnològiques en funció dels objectius no complerts
- Poden utilitzar-se tècniques estadístiques de planificació d'experiències

ESTUDIS D'OPTIMITZACIÓ DE LA TÈCNICA D'ELABORACIÓ

- Utilitzar formulació definitiva
- Estudiar condicions tecnològiques
- Estudiar reproductibilitat 3 lots galènics

CARACTERITZACIÓ DE LA FORMULACIÓ DEFINITIVA

- Establiment assaigs control de qualitat.
  - –Farmacèutics (friabilitat, resistència ruptura,…)
  - –Biofarmacèutics (disgregació, dissolució,…)
- Posada a punt metòdica analítica per producte acabat (HPLC).
  - –Identificació p.a. i substàncies relacionades
    - Impureses
    - Productes degradació
  - –Quantificació p.a. i substàncies relacionades.



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JOURNAL OF PHARMACEUTICAL AND BIOMEDICAL ANALYSIS
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Development and validation of a new HPLC analytical method for the determination of alprazolam in tablets

P. Pérez-Lozano*, E. García-Montoya, A. Orriols, M. Miñarro, J.R. Ticó, J.M. Suñé-Negre

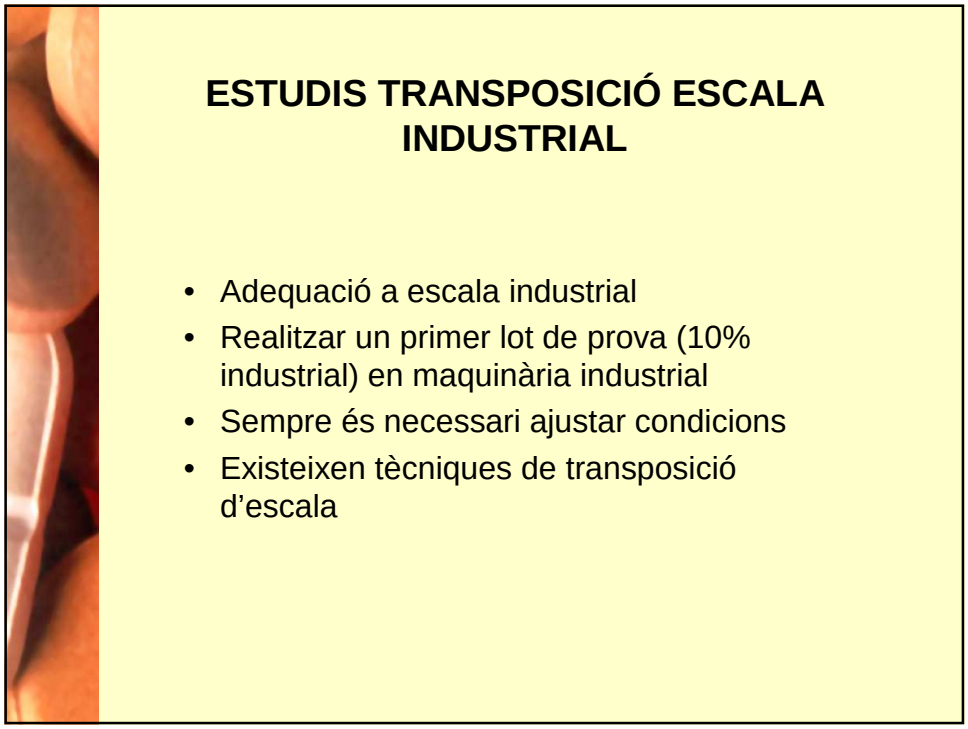
Unit of Pharmaceutical Technology, Department of Pharmacy and Pharmaceutical Technology, School of Pharmacy, University of Barcelona, Avda Joan XXIII s/n 08028, Barcelona, Spain

Received 28 August 2003; received in revised form 12 December 2003; accepted 12 December 2003

Abstract

A new analytical method is developed together with its latter validation study, by means of a high resolution liquid chromatography (HPLC) of reverse phase to quantify alprazolam (8-chloro-1-methyl-6-phenyl-4H-[1,2,4] triazole [4,3,-α]-[1,4] benzodiazepine) in tablets. Determination is carried out by means of an ODS C18 column (200 mm × 4.6 mm i.d., 5 μm particle size); the mobile phase consisted of a mixture of 0.02 M buffer solution of phosphates (pH 6.0) and acetonitrile (45:55, v/v). It is pumped through the chromatographic system at a flow rate of 0.50 ml min^{-1}. The UV detector is operated at 254 nm. The validation study is carried out fulfilling the ICH guidelines in order to prove that the new analytical method, meets the reliability characteristics, and these characteristics show the capacity of an analytical method to keep, throughout the time, the fundamental criteria for validation: selectivity, linearity, precision, accuracy and sensitivity. The method is applied during the working day for the quality control of commercial alprazolam tablets in order to quantify the drug and its degradation products and to check the content uniformity test.

Keywords: Alprazolam; Liquid chromatography; Pharmaceutical dosage forms; Tablets; Validation; Quality control



ESTUDIS TRANSPOSICIÓ ESCALA INDUSTRIAL

- Adequació a escala industrial
- Realitzar un primer lot de prova (10% industrial) en maquinària industrial
- Sempre és necessari ajustar condicions
- Existeixen tècniques de transposició d'escala

ESTUDIS D'ESTABILITAT DEL MEDICAMENT

- Segons ICH.
- Estabilitat accelerada (zona climàtica 2):
  - 40 ºC ± 2 ºC / 75 % ± 5 % HR (6 mesos)
  - 30 ºC ± 2 ºC / 65 % ± 5 % HR (12 mesos)
- Estabilitat a llarg termini (zona climàtica 2):
  - 25 ºC ± 2 ºC / 60 % ± 5 % HR (màxim 60 mesos)

Application of a Validated Method in the Stability Study of Colistin Sulfate and Methylparaben in a Veterinary Suspension Formulation by High-Performance Liquid Chromatography with a Diode Array Detector

Authors: Pérez-Lozano, Pilar; García-Montoya, Encarna; Orriols, Anna; Miñarro, Montse; Ticó, Josep Ramon; Suñé-Negre, Josep Maria

Source: Journal of AOAC International, Volume 90, Number 3, May 2007, pp. 706-714(9)

Publisher: AOAC International

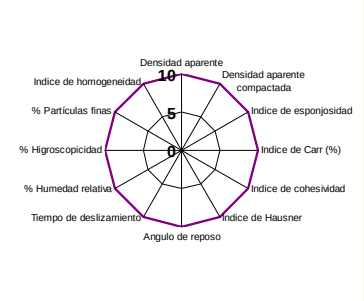
Abstract:

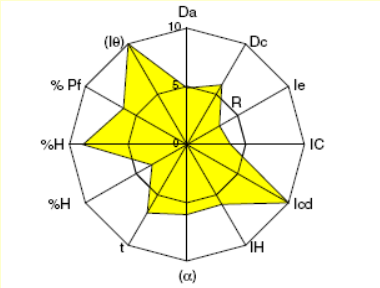
A methodology following International Cooperation on Harmonization for Veterinary Products (VICH) guidelines for the stability evaluation of colistin sulfate in a nonaqueous suspension pharmaceutical dosage form for veterinary use (via their drinking water) is described. This method monitors the percentage of colistin sulfate during the stability study of the preparation in drinking water and establishes the shelf life of the final product by a new high-performance liquid chromatography method which was developed and validated for the simultaneous determination of colistin sulfate [colistin A (Polymixin E_1) and colistin B (Polymixin E_2)] and methylparaben (Nipagin) using a diode array detector (DAD). The method uses a Kromasil C18 column and isocratic elution. The mobile phase consisted of an acetonitrilesodium sulfate anhydrous solution (25 + 75) pumped at a flow rate of 1.5 mL/min. The DAD was set at 215 nm. The validation study was carried out according to the VICH guidelines in order to prove that the new analytical method meets the reliability characteristics, which include the fundamental criteria for validation: selectivity, linearity, precision, accuracy, and sensitivity. The method was applied during the quality control or stability studies of the suspension dosage form in order to quantify the drug (colistin) and preservative, and proved to be suitable for rapid and reliable quality control.

LINIA RECERCA:

Disseny sistemes experts per a preformulació i formulació de medicaments

DIAGRAMA SeDeM:





Es defineix un perfil per a la substància pulverulenta en funció de les seves característiques físiques relacionades amb:

- Densitat
- Compressibilitat
- Lliscament / fluïdesa
- Humitat / higroscopicitat
- Mida de partícula

Es determinen experimentalment 12 paràmetres físics de la substància, que proporcionen un determinat perfil.

Coneixent el perfil, poden corregir-se aquells paràmetres deficients

Facilitat per a que el laboratori formuli.
Criteri per escollir l'excipient que millor s'adapti a la formulació.

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European Journal of Pharmaceutics and Biopharmaceutics 64 (2006) 351–359
European Journal of Pharmaceutics and Biopharmaceutics
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Research paper

A new expert systems (SeDeM Diagram) for control batch powder formulation and preformulation drug products

Pilar Pérez [a], Josep M. Suñé-Negre [a], Montserrat Miñarro [a,*], Manel Roig [a], Roser Fuster [a], Encarna García-Montoya [a], Carmen Hernández [b], Ramón Ruhí [b], Josep R. Ticó [a]

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Available online 6 July 2006

Abstract

The new SeDeM Method is proposed for testing the batch-to-batch reproducibility of the same active pharmaceutical ingredient (API) in powder form. The procedure describes the study of the galenic properties of substances in powder form in terms of the applicability of direct compression technology. Through experimental determination of the SeDeM Method parameters, and their subsequent mathematical treatment and graphical expression (SeDeM Diagram), three batches of the same API were analysed to determine whether it was suitable for direct compression. Batch-to-batch reproducibility of the results was verified. It was concluded that the SeDeM Method is suitable for testing batch-to-batch reproducibility of characteristics in powdered APIs substances. The results obtained confirm that the SeDeM Method is a useful, effective tool for drug-preformulation studies providing the pharmacotechnical data required when formulating a drug in tablet form. In addition, the results were effective for defining the most appropriate manufacturing technology.

Keywords: Expert system; Preformulation; Formulation; Bulk density (Da); Tapped density (Dc); Inter-particle porosity (Ie); Angle of repose (α); Flowability (t''); Particle size (%PI); Direct compression (DC)

LINIA RECERCA:

Noves formes farmacéutiques

- Comprimits matricials hidròfils SR.
- Pellets d'alliberació prolongada.
- Comprimits osmòtics
- Gels termorreversibles o bioadhesius SR

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The use of the SeDeM diagram expert system for the formulation of Captopril SR matrix tablets by direct compression

J. Saurí[a], D. Millán[b], J.M. Suñé-Negre[a,c], P. Pérez-Lozano[a,c], R. Sarrate[a], A. Fàbregas[a], C. Carrillo[a], M. Miñarro[a,c], J.R. Ticó[a,c], E. García-Montoya[a,c,*]

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SeDeM
Diagram expert system
Preformulation
Direct compression
Quality by Design (ICH Q8)
Index good compression (IGC)
Captopril
Slow release

ABSTRACT

The SeDeM diagram expert system has been used to study excipients, Captopril and designed formulations for their galenic characterization and to ascertain the critical points of the formula affecting product quality to obtain suitable formulations of Captopril direct compression SR matrix tablets.

The application of the SeDeM diagram expert system enables selecting excipients with in order to optimize the formula in the preformulation and formulation studies.

The methodology is based on the implementation of ICH Q8, establishing the design space of the formula with the use of experiment design, using the parameters of the SeDeM diagram expert system as system responses.

(19) Europäisches Patentamt / European Patent Office / Office européen des brevets

(11) EP 2 444 067 A1

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A61K 31/351 *(2006.01)* ***A61K 47/46*** *(2006.01)*

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BA ME

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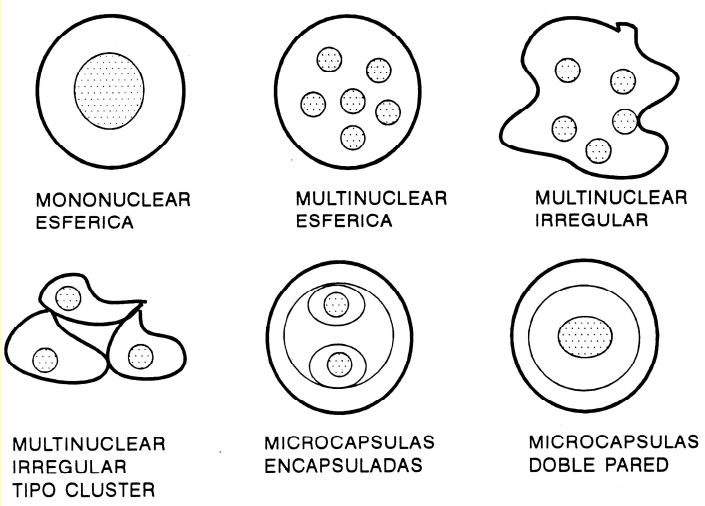
(54) **Anhydrous gel comprising mupirocin**

(57) Anhydrous topical gel composition of mupirocin or its salts comprising: a) a lipophilic base selected from the group consisting of petrolatum, medium-chain triglycerides, isopropyl myristate and mixtures thereof; b) a bioadhesive selected from the group comprising polyvinylpyrrolidone and polymethacrylates; and c) a solvent selected from the group comprising ethanol, propanol, and isopropanol; which is stable and shows an increased residence time of the active ingredient in the skin, resulting in an improved clinical effect in the treatment of bacterial skin infections while maintaining the safety profile of the commercial pharmaceutical product.

LINIA RECERCA:
MICRO I NANOENCAPSULACIÓ

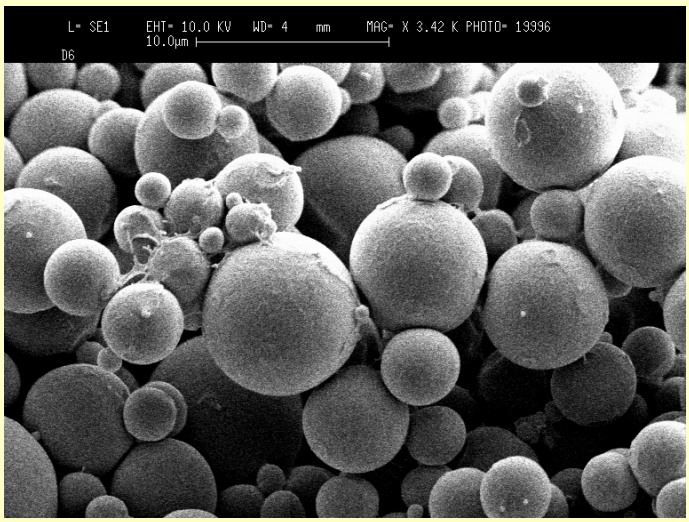
OBJECTIUS:

- Protecció p.a.
- Protecció del pacient
- Modificar característiques organolèptiques p.a.
- Modificar estat físic p.a.
- Modificar solubilitat p.a.
- Modificar densitat p.a.
- **Modificar alliberació p.a.→ ACCIÓ CONTROLADA**
- **Dirigir p.a. a cèl·lula / teixit diana.**



LINIA RECERCA:
MICRO I NANOENCAPSULACIÓ

- Nucli
- P.a.
  - Líquid o sòlid
  - Sol o formulat
- Coberta :
  - Substàncies filmògenes (polímers)
  - Dissolvents
  - Plastificants
  - Tensioactius
  - Impermeabilitzants
  - Reticulants
  - altres



Parasitol Res (2008) 102:1243–1247
DOI 10.1007/s00436-008-0901-z

ORIGINAL PAPER

In vitro evaluation of the effectiveness and cytotoxicity of meglumine antimoniate microspheres produced by spray drying against *Leishmania infantum*

G. Pujals · J. M. Suñé-Negre · P. Pérez · E. García · M. Portus · J. R. Tico · M. Miñarro · J. Carrió

Received: 16 January 2008 / Accepted: 22 January 2008 / Published online: 17 February 2008

Abstract The aim of the present study was to evaluate the in vitro activity and cytotoxicity of meglumine antimoniate microspheres produced by spray drying on *Leishmania infantum* and the effect of the excipients used in them. The parasite strain shows sensitivity to the meglumine antimoniate microspheres prepared. All the antimony IC_{50} values from encapsulated meglumine antimoniate (3.80±0.34 to 9.53±0.70 μg SbV/ml for promastigotes assay) are considerably lower compared to the mean value of IC_{50} in Glucantime solution (112±12.74 μg SbV/ml). Interesting IC_{50} values for the excipient chitosan (112.64±0.53 mg/ml for promastigotes and 100.81±26.45 mg/ml for amastigotes) were obtained (without cytotoxic activity), whereas the rest of the excipients did not show any activity. This new delivery system could offer a new pharmacological tool for the treatment of leishmaniosis that reduces the doses required, lowering toxic side effects because of meglumine antimoniate.

Introduction

Leishmaniosis is a worldwide health problem that affects more than 12 million people. In the Mediterranean region, visceral leishmaniosis and cutaneous leishmaniosis are caused by *Leishmania infantum*, a common coinfection in people infected with human immunodeficiency virus, and dogs are considered to be the main reservoir. Leishmaniosis is still considered a category I disease by the Special Programme for Research and Training in Tropical Diseases. For the last 60 years, the pentavalent antimonials, sodium stibogluconate and the meglumine antimoniate (MGA), have been considered first-line drugs for the treatment of leishmaniosis. They have several disadvantages such their intramuscular route and toxic effects. Treatment failures with those drugs are becoming a common problem in endemic areas with the emergence of drug resistance (Farault-Gambarelli et al. 1997; Lira et al 1999). Neither the traditional second-line drugs such as pentamidine and amphotericine B, which are more toxic and difficult to administer, nor the recent oral agent miltefosine provides a clear alternative for the treatment of visceral leishmaniosis (Guerin et al. 2002). For this reason, we considered it to be of interest to continue searching for new options for treatment with alternative drug delivery systems, such as antimonial biodegradable microspheres to target the macrophages and reduce their toxicity. Another possible improvement would be to increase oral drug absorption using a mucoadhesive biopolymer. The aim of this study was to determinate the in vitro drug sensitivity of *L. infantum* (both promastigote and amastigote stages) to MGA microspheres produced by spray drying and the effect of their excipients on parasites.

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Unit of Pharmaceutical Technology, Facultat de Farmàcia, Universitat de Barcelona, Avda. Joan XXIII s/n, 08028 Barcelona, Spain

M. Portus · J. Carrió (✉)
Laboratory of Parasitology, Facultat de Farmàcia, Universitat de Barcelona, Avda. Joan XXIII s/n, 08028 Barcelona, Spain
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Materials and methods

Parasite strains and cultures

The *L. infantum* strain MCAN/ES/92/BCN83 (BCN83), isolated from bone marrow from an asymptomatic dog was

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DNA delivery via cationic solid lipid nanoparticles (SLNs)

Carolina Carrillo [a,*], Noemí Sánchez-Hernández [b], Encarna García-Montoya [c], Pilar Pérez-Lozano [c], Josep M. Suñé-Negre [c], Josep R. Ticó [c], Carlos Suñé [b], Montserrat Miñarro [c]

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Keywords:
Non-viral vectors
Lipoplexes
Gene therapy
Solid lipid nanoparticles
Cationic nanoparticles
Drug delivery systems

ABSTRACT

In recent years the use of solid lipid nanoparticles (SLNs) as transport systems for the delivery of drugs and biomolecules has become particularly important. The use of cationic SLNs developed by the technique of microemulsion, which are complexed with DNA in order to study their application as non-viral vectors in gene therapy, is reported. The nanoparticles are characterized by scanning electron microscopy and transmission electron microscopy (SEM and TEM), atomic force microscopy (AFM) and differential scanning calorimetry (DSC). Furthermore, the process of lyophilization of the samples and their stability was studied. The nanoparticles obtained presented a particle size of 340 nm with a positive surface charge of 44 mV and the capability of forming lipoplexes with DNA plasmids was stated.

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International Journal of Pharmaceutics

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Pharmaceutical nanotechnology

Impact of physical parameters on particle size and reaction yield when using the ionic gelation method to obtain cationic polymeric chitosan–tripolyphosphate nanoparticles

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[a] Service of Development of Medicines (SDM), Faculty of Pharmacy, University of Barcelona, Avda. Joan XXIII, s/n 08028 Barcelona, Spain
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ARTICLE INFO

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Available online 19 February 2013

Keywords:
Nanoparticles
Chitosan–tripolyphosphate
Cationic
Polymeric
Ionic gelation

ABSTRACT

Ionic gelation is the most frequently used method to obtain chitosan–tripolyphosphate nanoparticles due to its simplicity and because it does not generate waste solvents in the samples prepared.

This paper presents a study of the physical factors involved in this method for obtaining nanoparticles in order to determine which of them significantly influences the particle size of polymeric nanoparticles made from low-molecular-weight chitosan, without any additional chemical treatment, with the aim of standardising and optimising the method conditions, in addition to establishing the reaction yield.

The results indicate that stirring speed during ionic gelation reaction is decisive for the size of the nanoparticles obtained. Furthermore, it thus follows that the stirring speed during ionic gelation significantly affects reaction yield, and therefore, by manipulating this parameter a greater proportion of nanoparticles of a given size range can be obtained.

US 20100159017A1

(19) **United States**

(12) **Patent Application Publication**
GAMON et al.

(10) **Pub. No.: US 2010/0159017 A1**

(43) **Pub. Date: Jun. 24, 2010**

(54) **COMPOSITION OF BIOCOMPATIBLE MICROPARTICLES OF ALGINIC ACID FOR THE CONTROLLED RELEASE OF ACTIVE INGREDIENTS BY INTRAVENOUS ADMINISTRATION**

(75) Inventors: **Salvador GRANCHA GAMON**, Granollers (ES); **Anna Nardi Ricart**, St. Joan Despi (ES); **Josep Maria Suñe Negre**, Barcelona (ES); **Josep Ramón Tico Grau**, Barcelona (ES); **Montserrat Miñarro Carmona**, Barcelona (ES)

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(73) Assignee: **GRIFOLS, S.A.**, Barcelona (ES)

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(22) Filed: **Dec. 9, 2009**

(30) **Foreign Application Priority Data**

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A61K 38/17	(2006.01)
A61P 7/04	(2006.01)
A61P 5/00	(2006.01)
A61K 38/36	(2006.01)
B29B 9/00	(2006.01)

(52) **U.S. Cl.** **424/493**; 514/2; 514/12; 514/8; 264/7

(57) **ABSTRACT**

The invention relates to a biocompatible composition which comprises microparticles of alginic acid or its salts and an active ingredient. More particularly, the invention relates to microparticles for the encapsulation of an active ingredient to be administered intravenously to a patient who needs it. These microparticles are of a combination of size sufficient to increase the half-life or survival of the active ingredient in blood, with a low uptake in the liver and a fast cell clearance when administered intravenously.