LAPaL
THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

Developed by

medicines patent pool

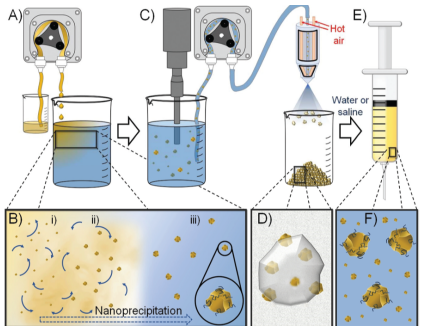
UNIVERSITY OF LIVERPOOL

CELT

Supported by

Unitaid
SAVE LIVES FASTER

leap



Scalable process to achieve LA injectable delivery of insoluble medicines

Verified by the innovator, on May 2023

Developer(s)

Centre of Excellence for Long-acting Therapeutics - University of Liverpool
https://www.liverpool.ac.uk/centre-of-excellence-for-long-acting-therapeutics/

United Kingdom

The team is a multidisciplinary collaboration of materials chemists and pharmacologists. Their research focuses on developing and delivering new LA technologies and candidate LA therapeutics for a range of diseases. Also, the team is driving the conversation around LA opportunities to encourage uptake and build awareness

Sponsor(s)

None

None

Partnerships

None

None

Technology information

Type of technology

Aqueous drug particle suspension

Administration route

Subcutaneous, Intramuscular

Development state and regulatory approval

Active Pharmaceutical Ingredient (API)

Niclosamide

Development Stage

Pre-clinical

Regulatory Approval

Not provided

Description

Nanoprecipitation technology to form redispersible solid drug nanoparticles (SDN) formulations that may be stored as solids, reconstituted with water and utilised as long-acting injectables to provide extended drug exposure, of otherwise highly insoluble drugs.

Technology highlight

This technology broadens the use of a highly insoluble drug molecule and generates high injectable concentrations of particles in an aqueous medium and to achieve extended release of medicines. The drug has very low bioavailability but IM injection leads to prolonged plasma exposure

Technology main components

Polymer (eg. hydroxypropyl methylcellulose), Surfactant (eg. Tween 20, Pluronic (r) F127), Sugar (eg. sucrose) Nanoprecipitation into water from Class3 solvents

Information on the raw materials sourcing, availability and anticipated price

readily available and low-price materials - selected from the FDA CDER list of Inactive Ingredients

Delivery device(s)

No delivery device

APIs compatibility profile

API desired features

Water-soluble molecules

Water-insoluble molecules

Small molecules

Niclosamide, nitazoxanide, atovaquone

Additional solubility data

Not provided

Additional stability data

Not provided

API loading: Maximum drug quantity to be loaded

50-75 wt%

API co-administration

1 single API :

LogP

Not provided

Scale-up and manufacturing prospects

Scale-up prospects

The process is highly scalable

Tentative equipment list for manufacturing

spray-dryer

Manufacturing

Not provided

Specific analytical instrument required for characterization of formulation

dynamic light scattering (eg. Malvern Panalytical ZetaSizer Ultra Proton Correlation Spectroscope)

Clinical trials

Not provided

Excipients

Proprietary excipients used

No proprietary excipient used

Novel excipients or existing excipients at a concentration above Inactive Ingredients Database (IID) for the specified route of administration

No novel excipient or existing excipient used

Residual solvents used

No residual solvent used

Additional features

Other features of the technology

- Biodegradable
- Non-removable
- Room temperature storage
- At least 1 year shelf life

Release properties

Extended drug exposure for > 1 month from single administration

Injectability

injectable (IM or SC) - reconstitutable solid at the point of need

Safety

No safety issues identified during preclinical work

Stability

Drug substance is stable to terminal sterilisation by irradiation

Storage conditions and cold-chain related features

No cold chain requirement

Potential application(s)

Therapeutic area(s)

COVID 19

Other(s) : "Niclosamide has numerous claimed effects, including influenza, oncology, and antibacterial benefits"

Use case(s)

Pre-Exposure Prophylaxis (PrEP)

Post-Exposure Prophylaxis (PEP)

Treatment

Use of technology

Ease of administration

- Administered by a community health worker
- Administered by a nurse
- Administered by a specialty health worker

Frequency of administration

Monthly

User acceptance

Not provided

Targeted user groups

Age Cohort

- Adults

Genders

- All

Pregnant individuals

Unspecified

Lactating individuals

Unspecified

Healthy individuals

Unspecified

Comment

Not provided

Potential associated API(s)

Niclosamide

Class(es)

antiparasitic

Development stage

Pre-clinical

Clinical trial number(s)

Not provided

Foreseen/approved indication(s)

Prophylaxis and7or therapy of SARS-CoV2

Foreseen user group

Not provided

Foreseen duration between application(s)

1 month

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Not provided

Patent info

Description

The present invention relates to solid compositions of pharmaceutically active compounds, aqueous dispersions derived from these compositions and processes for the preparation of these solid compositions and dispersions. The present invention also relates to pharmaceutical compositions derived from these solid compositions and dispersions, and their use in the treatment and/or prophylaxis of helminthic, protozoal, and viral infections.

Brief description

Not provided

Representative patent

WO2022101623 (A1)

Category

Process

Patent holder

University of Liverpool

Exclusivity

No exclusivity or licence in place

Expiration date

May 14, 2034

Status

Filed

Supporting material

Publications

** Hobson JJ , Savage AC , Dwyer AB , Unsworth C , Massam J , Arshad U , Pertinez H , Box H , Tatham L , Rajoli RKR , Neary M , Sharp J , Valentijn A , David C , Curley P , Liptrott NJ , McDonald TO , Owen A , Rannard SP . Scalable nanoprecipitation of niclosamide and in vivo demonstration of long-acting delivery after intramuscular injection. Nanoscale. 2021 Apr 7;13(13):6410-6416. doi: 10.1039/d1nr00309g. Epub 2021 Mar 25. PMID: 33885522. **

The control of COVID-19 across the world requires the formation of a range of interventions including vaccines to elicit an immune response and immunomodulatory or antiviral therapeutics. Here, we demonstrate the nanoparticle formulation of a highly insoluble drug compound, niclosamide, with known anti SARS-CoV-2 activity as a cheap and scalable long-acting injectable antiviral candidate.

Additional documents

No documents were uploaded

Useful links

There are no additional links

Access principles

Collaborate for development

Consider on a case by case basis, collaborating on developing long acting products with potential significant public health impact, especially for low- and middle-income countries (LMICs), utilising the referred to long-acting technology

Not provided

Share technical information for match-making assessment

Provide necessary technical information to a potential partner, under confidentiality agreement, to enable preliminary assessment of whether specific medicines of public health importance in LMICs might be compatible with the referred to long-acting technology to achieve a public health benefit

Not provided

Work with MPP to expand access in LMICs

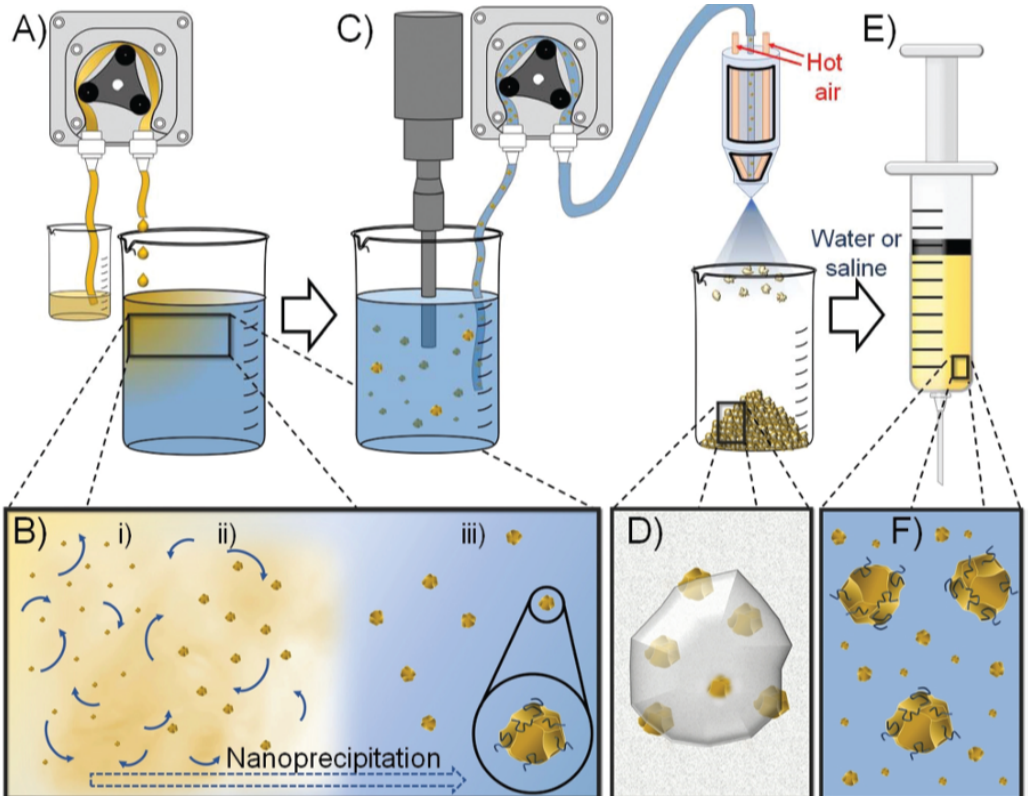
In the event that a product using the referred to long-acting technology is successfully developed, the technology IP holder(s) will work with the Medicines Patent Pool towards putting in place the most appropriate strategy for timely and affordable access in low and middle-income countries, including through licensing

Not provided

Comment & Information

The CELT team at Liverpool are keen to work with partners who wish to scale and distribute products derived from the technology

Illustrations



Schematic Overview of the nanoprecipitation and spray drying process

Royal Society of Chemistry