

CYNDEA PHARMA

ABOUT US

Cyndea Pharma is an independent Spanish laboratory specializing in the development and production of generic formulations, based in steroid active ingredients (corticosteroids and sex hormones), all of which is done in the latest state-of-the-art high containment facilities.

Our goal is to become a leader in the development & manufacturing of woman's health related medicines.

Our mission:

- To provide a **long term partnership** throughout the entire development-to-production cycle.
- Provide **innovative solutions** and **niche products**.
- Develop & manufacture **high quality** pharmaceuticals.
- Offer a **competitive pricing** structure.
- Enforce the highest **safety and environmental-responsibility standards**.



Shareholders:

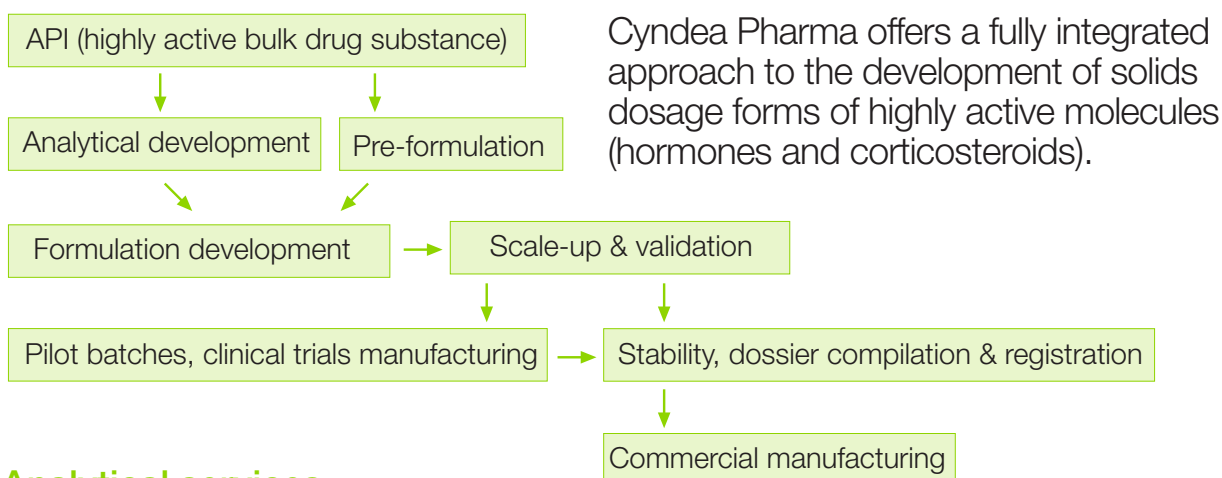


World leader in API steroids.
Extensive expertise in the development & registration of APIs for regulated markets.
High potential in Intellectual Property & Research.



Spanish leader in the generic formulations market.
Consolidated expertise in the development and manufacturing of generic formulations.
Operational excellence.

QUALITY BY DESIGN PHARMACEUTICAL DEVELOPMENT SERVICES



Analytical services:

R & D Personnel:

- Employees: (60% University Graduate).

R&D Laboratory capabilities:

- Equipped with Chromatography Techniques (HPLC, GC) and Conventional Techniques (PSD, DSC, UV, IR, In vitro dissolution...).
- Stability chambers (ICH conditions).
- High containment isolator for the handling of potent drugs (hormones).

Development and validation of analytical methods.

Extensive ICH compliance stability studies.

Formulation services:

- Solid dosage forms.
- Licensed GMP pilot plant for highly potent solid dosage form.
- Pilot plant with batch sizes ranging from 0,5-10 Kg.
- Specific experience in formulating highly potent molecule solid dosage forms.

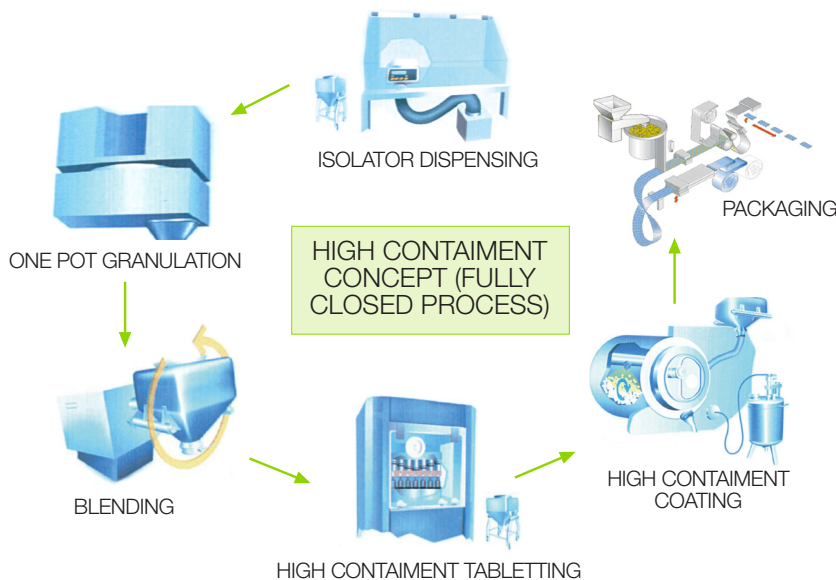


QUALITY BY DESIGN CONTRACT MANUFACTURING SERVICES

Cyndea offers contract manufacturing services for highly active molecules in solid dosage forms.

Cyndea can meet your outsourcing needs for both potent & conventional solid dose drugs.

Cyndea offers **segregated manufacturing premises** for highly active molecules, with a state-of-the-art GMP facility designed to comply with the most demanding environmental and safety regulations.



The plant:

- Two segregated manufacturing areas for oral tablets:
 - Line 1: Sex hormones. Dedicated line
 - Line 2: Slightly potent molecules (Corticosteroids & others).
- Packaging areas.
- Warehouse.
- GMP Pilot Plant.
- GLP QC Laboratories.
- GLP R&D Laboratories.

Manufacturing facilities:

- Personnel: 30% highly-qualified
- Production capacity:
 - Line 1: Hormones line capacity ranges from 23 Kg to 75 Kg.
 - Line 2: Corticosteroids & others line capacity ranges from 100 to 200 Kg.

QUALITY BY DESIGN QUALITY ASSURANCE

Personnel: 40% highly-qualified

QC and Micro Labs capabilities:

- Equipped with Chromatography Techniques (HPLC, GC) and conventional techniques (PSD, DSC, UV, IR, in vitro dissolution...).
- High containment isolator for potent drugs.
- Bio-safety cabinet class II.

Certifications:

- GMP certification granted by Spanish Health Authorities
- Next steps: ISO 9001 and FDA



QUALITY BY DESIGN OUR PRODUCTS

Woman's health related products (hormones)

- Contraceptives.
- Hormonal therapies.

Corticosteroids

- Dermatological treatments.
- Auto- immune disease.

Products ready for registration (Licensing-out)

- Desogestrel 75 mcg (Cerazette ®)
- Dienogest 2 mg + Ethinyl Estradiol 30 mcg (Valette ®)
- Prednisone 2,5 mg, 5 mg, 10 mg & 30 mg (Dacortin ®)

Products under development:

- Levonorgestrel 0,10 mg + Ethinyl Estradiol 20 mcg (Loette ®)
- Chlormadinone acetate 2 mg + Ethinyl Estradiol 30 mcg (Belara ®)
- Desogestrel 0,150 mg + Ethinyl Estradiol 20 mcg (Mercilon ®)
- Drospirenone 3 mg + Ethinyl Estradiol 30 mcg (Yasmin ®)
- Drospirenone 3 mg + Ethinyl Estradiol 20 mcg (Yasminelle ® and Yaz ®)

Future developments

- Dienogest + Estradiol Valerate (Multiphasic pill, Qlaira ®)
- Norgestimate 0,25 mg + Ethinyl Estradiol 35 mcg (Cilest ®)
- Gestodene 60 mcg+ Ethinyl Estradiol 15 mcg (Mirelle ®)

Business development:

Cyndea is interested in developing a partnership for new highly active molecules pharmaceutical dosage forms: vaginal rings, patches, soft capsules, gels, implants and sprays.

® Reference product.