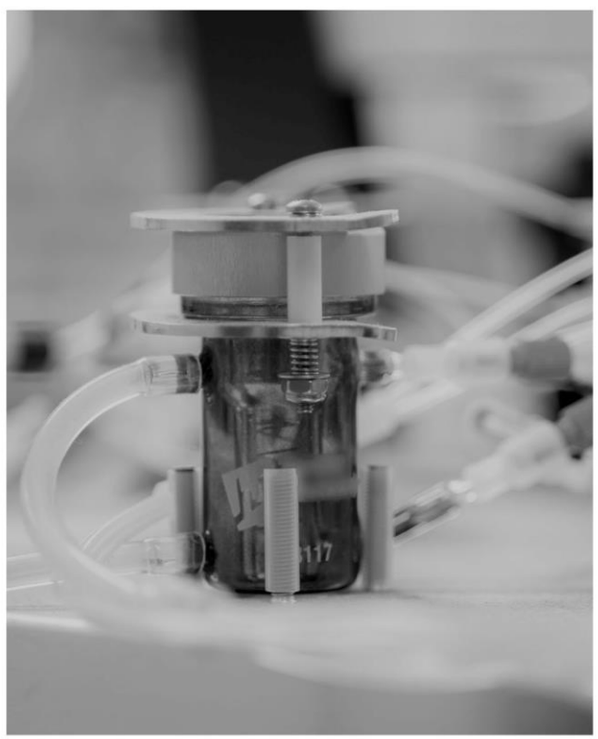


groupeparima

REACH THE WORLD.

ABOUT US

Groupe PARIMA is a Contract Development & Manufacturing Organization (CDMO).

Specialized in the development and manufacturing of non-sterile pharmaceutical products such as:

- **Liquids**
- **Semi-solids**
- **Suspensions**

Some Numbers

135

employees

29

years in business

72

products in commercial production

24

active development projects

50 million units

Annual Capacity

Facility - 67,000 sq. ft. - 6,250 m^2

Authorizations

Health Canada
Santé Canada

FDA

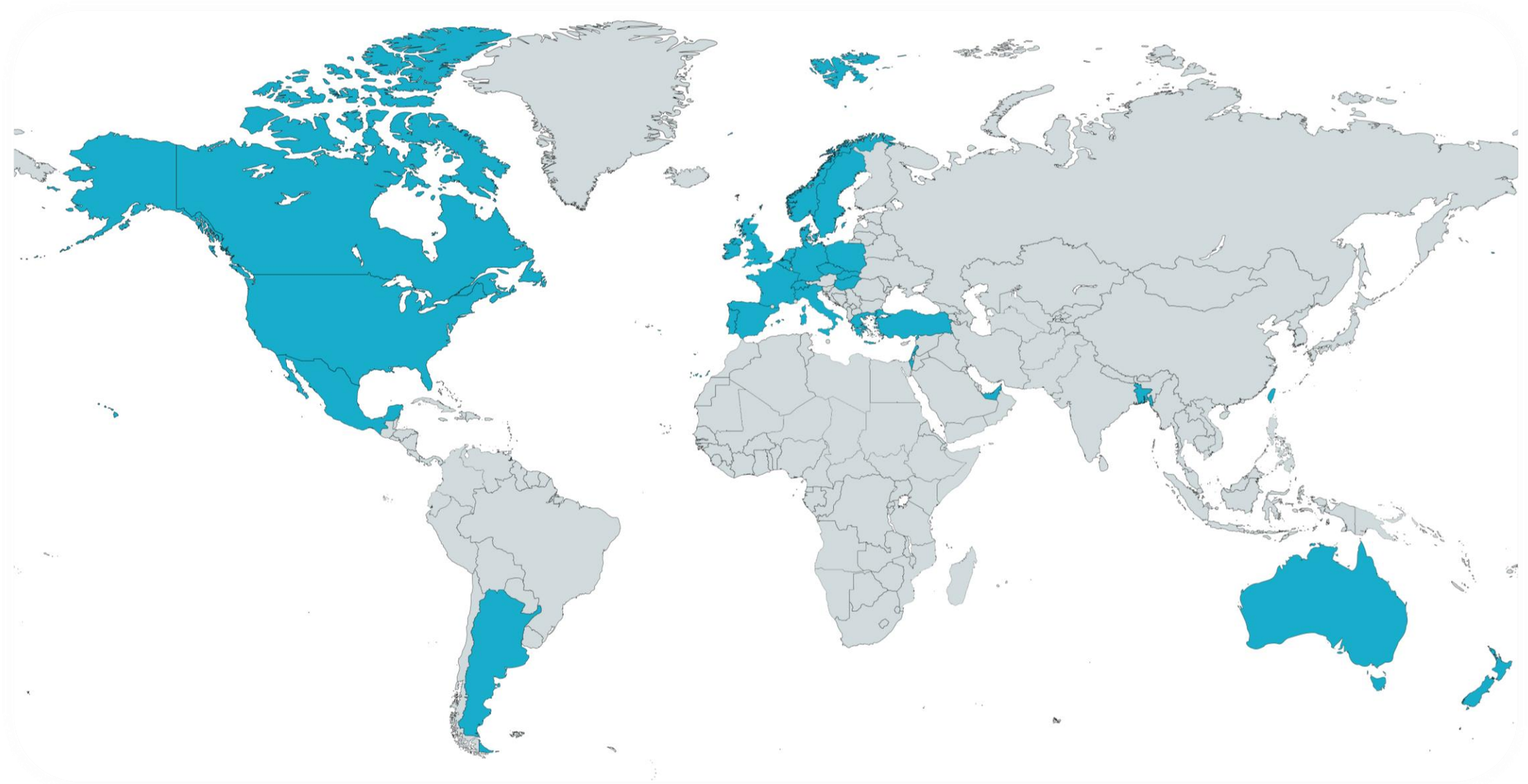
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Republic of Turkey
Ministry of Health
Turkish Medicines and Medical Devices Agency

Products Distributed in 28 Countries



Reach the World.

Clients are small biotechs to large pharmas

On-Site Services

Product Development

Commercial Manufacturing and Packaging

Laboratory Testing

Product Development Services

Early Development

- Formulation development
- Process development and optimization
- Analytical development and validation

Scale-Up and Clinical Supply

- Process scale-up
- Clinical lots manufacturing
- Analytical validation

Preparation for Commercialization

- Site transfers
- Process validation
- Cleaning validation
- Analytical validation

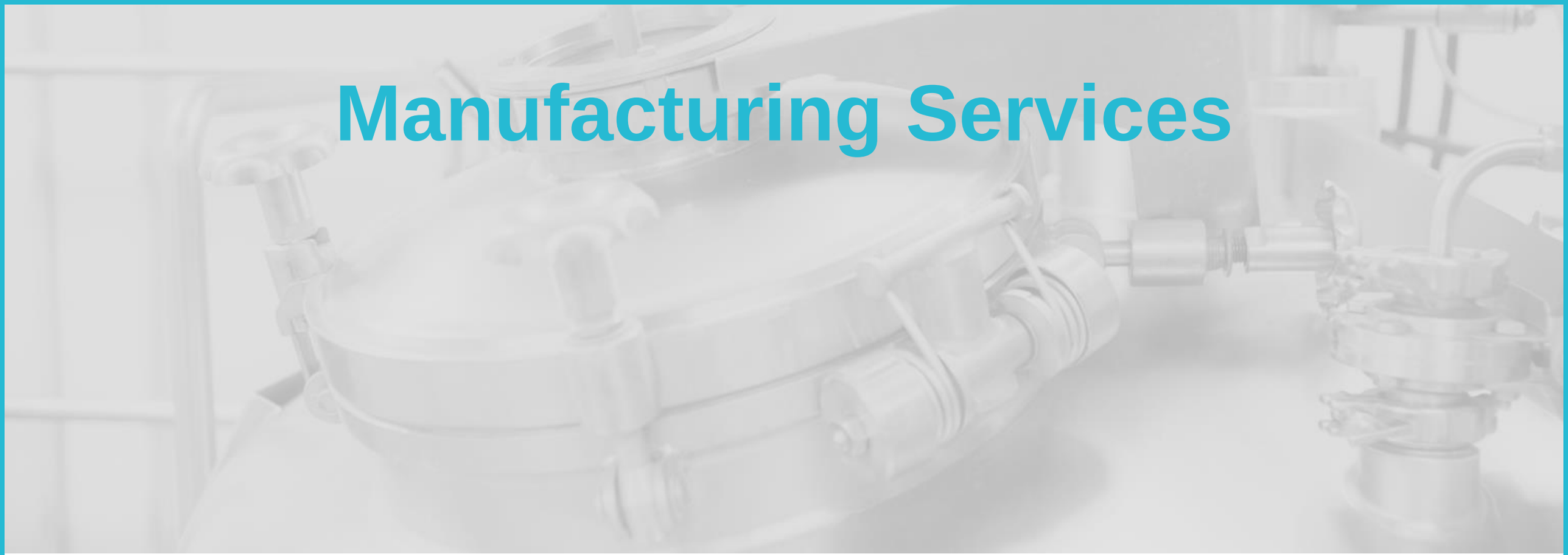
Expertise with (pre)-IND activities, NDA [505(b)(1) & 505(b)(2)] ANDA and Orphan drug projects

Commercial Manufacturing and Packaging Services

Turn-key service to free-up your resources

- Handling of supply for API, excipient and packaging
- Complete release testing
- Audit and supplier qualification
- Established relationships with transporters and 3PL

Manufacturing Services



- Creams
- Lotions
- Gels
- Ointments
- Explosion Proof Capabilities (e.g., high alcohol products)
- Solutions
- Suspensions

Manufacturing Capabilities

5

Manufacturing suites

Lotion, Cream and Ointment

- 5 to 2,500 kg

Lotion

- 5 to 4,000 kg

Cleanser and various liquid

- 5 to 3,800 kg

High alcohol solutions

- 10 to 1,600 kg

Clinical and scale-up batches

- 2 to 110 kg

Packaging Services

- Primary packaging
- Secondary packaging
- Kit preparation
- Serialization
- Cold-chain products
- Light and oxygen sensitive products

Packaging Services

10 packaging lines

- **Airless Pumps**
- **Bottles and Jars (Plastic, Glass)**
- **Metered-Dose Sprays (Nasal / Sublingual)**
- **Pump Sprays**
- **Sachets (Single and Double)**
- **Stick Packs**
- **Syringe applicators**
- **Tubes (Plastic, Laminate, Metal)**

Analytical Services

- **API and raw materials**
- **Packaging materials**
- **Bulk**
- **Finished products**

- **Stability testing**

Standard conditions
- Standard (25 °C/ 60% RH)
- Intermediate (30 °C/65% RH)
- Accelerated (40 °C/ 75% RH)

IV-B area
- 30 °C/75% RH

Cold-chain products
- 2-8 °C
- - 20 °C

Semi-permeable containers
- 25 °C/ 40% RH

In-House Analytical Laboratory

- **GC, HPLC, UPLC and LCMS**
- **Physical testing (viscosity, pH, specific gravity, etc)**
- **Microbiology (USP<51>, <61>, <62>)**
- **Droplet size, particle size**
  - Malvern Mastersizer 3000, SprayTech, Microscopy
- **IVRT**
  - Franz-cells (Hanson Microette)

Specialized Analyses Supported Through Qualified Labs

- **Elemental impurities**
- **IVPT**
- **Leachables/Extractables**
- **Metered-dose spray characterization**
- **Nitrosamine**

Quality Assurance

- **Oversight commercial production and product development GMP activities**
- **Audits: remote or in-person**
  - Records reviews done through Firmex from client location
- **Direct Client access to eQMS available**
- **Supplier qualification**

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