

FILLING YOUR NEEDS



# ROMMELAG CDMO CAPABILITIES



## PRODUCT CHARACTERISTICS

## BATCH SIZE

## PRIMARY PACKAGING/FILLING



### AQUEOUS

- ▽ Sterile / non-sterile products
- ▽ Foamy products
- ▽ Highly alcoholic products (up to 70 %)

- ▽ Up to 20,000 l depending on fill volume and product characteristics
- ▽ Bulk autoclaving within tank possible up to 3,000 l
- ▽ Batch sizes only limited through tank dimensions. Multiple tank connections possible
- ▽ (Sterile) Filtration or aseptic filling only

- ▽ 0,04 ml – 1,200 ml with LDPE
- ▽ A more limited range with HDPE
- ▽ (principally 5 ml – 1,000 ml possible) and PP (5 ml – 500 ml)
- ▽ Coloured polymers and resin blends (typically HDPE / LDPE) possible
- ▽ Filling under nitrogen possible
- ▽ Terminal sterilization possible
- ▽ Microdosing and defined drop size possibilities
- ▽ Multidose capabilities
- ▽ Insert technology for stopper, cap, dropper, brush or similar insertion directly in the BFS process available



### OILY

- ▽ Sterile / non-sterile products

- ▽ Usually up to 3,000 l – larger sizes to be discussed



### EMULSIONS

- ▽ Sterile / non-sterile products

- ▽ With homogenization (high shear) 50 l – 1,200 l
- ▽ Bulk autoclaving within tank possible
- ▽ High pressure homogenisation (typical for micro-emulsions) not available



### SUSPENSIONS

- ▽ Sterile / non-sterile products
- ▽ Recirculation to be implemented

- ▽ 50 l – 1,200 l with homogenization (high shear)
- ▽ Bulk autoclaving within tank possible
- ▽ Use of sterile API currently possible up to 500 l



### GELS/FLUENT VISCIOUS

- ▽ Sterile / non-sterile products
- ▽ Viscosity up to 150,000 cps

- ▽ 50 l – 1,200 l with homogenization (high shear)
- ▽ Bulk autoclaving within tank possible
- ▽ Use of sterile API currently possible up to 500 l
- ▽ Product must be fluent for filling

- ▽ Up to 100 ml
- ▽ With HDPE and PP a more limited range
- ▽ Coloured polymers and resin (typically HDPE/LDPE) blends possible
- ▽ Terminal sterilization possible
- ▽ Typically 0.5 g – 5 g with LDPE
- ▽ Speciality are vaginal and rectal applicators

## CDMO SERVICES

- Regulatory support for registration dossiers
- Support for:
  - Development
  - Laboratory scale batches
  - Functional hand-filled ampoules
  - Scale-up batches
  - Pilot batches
  - Optimization of formulations
  - Risk assessments
  - Validation (cleaning, filter, process, microbiological, Autoclave)
  - Stability studies
- Inhouse BFS-container development/ 3D prints
- Extractables study for primary resins
- Stability and registration batches
- Clinical batches
- Regulatory support for registration dossiers
- Full scale commercial batches
- BFS Test Kit
- Partner Laboratories for:
  - Analytical method development
  - Leachables



## SPECIAL PRODUCT GROUPS



### BIOLOGICALS

- ▽ Proteins / Peptides (synthetic and recombinant)
- ▽ Mono- and polyclonal antibodies, DNA, RNA
- ▽ Cytokines
- ▽ Vaccines, incl. "live" viruses and genetically modified organisms up to Bio Safety Level 2

### NARCOTICS

- ▽ Sedatives, Anesthetics, Anti-Convulsiva

### BLOOD PRODUCTS

- ▽ Plasma constituents

### IMMUNO-SUPPRESSANT

- ▽ Glucocorticoids, Receptor Antagonists

### HORMONES

- ▽ Diverse except for sexual hormones

### ANTIBIOTICS

- ▽ Diverse, except  $\beta$ -lactam Antibiotics

### PHYTOPHARMA-CEUTICALS

- ▽ Diverse plant extracts, except highly alcoholic

### HOMEOPATHIC DRUGS

- ▽ Diverse, incl. potentiation

### VET. MED. DRUGS

- ▽ Diverse but with ANVISA restrictions



### DIETARY SUPPLEMENTS

- ▽ Sterile / non-sterile products



### COSMETICS

- ▽ Sterile / non-sterile products



### TECHNICAL PRODUCTS

- ▽ Motor Oils
- ▽ Detergents and Cleaning Agents
- ▽ Pheromones and similar products
- ▽ Chemicals
- ▽ Fertilizers and further agricultural products
- ▽ Aquaristic products
- ▽ Diverse further non-pharma liquids



Apart from the product groups listed above, standard products such as eye and ear drops (single as well as multi-use) the latter including non-preserved products, rinsing solutions, parenterals, orals, etc. with fill volumes between 40 $\mu$ l and 1200ml can be manufactured.

Please note that we do not have any own products or product registrations and thus cannot offer manufacture of private label products.

## SECONDARY PACKAGING

### FOR ALL ITEMS excl. TECHNICAL PRODUCTS

- ▽ Embossing of data on containers
- ▽ Container labelling
- ▽ Shrink sleeves
- ▽ Pouching in aluminium or other foil, also with nitrogen
- ▽ Packaging in cardboard boxes with leaflets / inserts
- ▽ (Bulk) Packaging in shipper cartons or any other shipper
- ▽ Ink jetting of pouches and cardboard boxes
- ▽ Serialization / Aggregation
- ▽ UDI

### FOR TECHNICAL PRODUCTS

- ▽ Container labelling
- ▽ Limited pouching in aluminium foil
- ▽ Packaging in cardboard boxes with leaflets / inserts
- ▽ (Bulk) Packaging in shipper cartons
- ▽ Serialization / Aggregation



## QUALITY CONTROL

- ▽ General chemical and physical testing
- ▽ ID and analytic assays (compendial or transferred methods)
- ▽ Bioburden
- ▽ Sterility
- ▽ Further testing procedures (e.g. molecular biological methods, method development and validation) possible
- ▽ Microbial Identification
- ▽ Endotoxins

## ADDITIONAL GENERAL SERVICES

- ▽ Cold storage
- ▽ Market release



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