

FILLING YOUR NEEDS



ROMMELAG CDMO CAPABILITIES



PRODUCT CHARACTERISTICS

BATCH SIZE

PRIMARY PACKAGING/FILLING



AQUEOUS

- ▽ Sterile / non-sterile products
- ▽ Foamy products

- ▽ 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) 90 l – 1,200 l
- ▽ Bulk autoclaving within tank possible
- ▽ High pressure homogenisation (typical for micro-emulsions) not available



SUSPENSIONS

- ▽ Sterile / non-sterile products
- ▽ Recirculation available

- ▽ 90 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

- ▽ 90 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
- ▽ Speciality are vaginal and rectal applicators

CDMO SERVICES

- Analytical method validation / transfer / verification
- 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 hormones

ANTIBIOTICS

- ▽ Diverse, except β -lactam Antibiotics

PHYTOPHARMACEUTICALS

- ▽ Diverse plant extracts

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 μ 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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