FILLING AND PACKAGING LINES

- FILLING MACHINES FOR BAGS AND BOTTLES
- STRETCH-BLOW-MOLDING MACHINES FOR PP BOTTLES
- PHARMACEUTICAL CONVEYORS & TURNTABLES
- FORM-FILL-SEAL EQUIPMENT FOR PP BAGS
- BAGS OVERWRAPPING MACHINES
- WASHING, CAPPING & STOPPERING SYSTEMS
- CONNECTORS AND PLUG ASSEMBLING MACHINES
- BAGS INSPECTION LINES

BRAM-COR®
PHARMACEUTICAL TECHNOLOGIES
BRAM-COR pharmaceutical bags or bottles filling machines are intended for automatic, semiautomatic or manual use, for different bags or plastic/glass bottle sizes, according to various production needs from min. 50 ml.

Our equipment ensures trouble-free operation, with reduced maintenance costs and long-term reliability. Complete bottle lines are integrated with washing machines, capping and crimping machines, labelling lines and belt conveyors. Our Filling & Packaging lines:

- FILLING MACHINES FOR BAGS (MANUAL, SEMIAUTOMATIC AND AUTOMATIC)
- BAGS MAKING MACHINES
- FORM-FILL-SEAL EQUIPMENT FOR PP BAGS
- VISUAL INSPECTION LINES FOR BAGS
- BAGS OVERWRAPPING MACHINES
- MACHINES FOR ASSEMBLING PLUGS AND CONNECTORS FOR BAGS
- FILLING MACHINES FOR BOTTLES
- WASHING, STOPPERING, CAPPING MACHINES FOR BOTTLES
- STRETCH-BLOW-MOLDING MACHINES FOR PP BOTTLES
- COMPLETE INTEGRATED LINES INCLUDING CIP/SIP SKIDS
<table>
<thead>
<tr>
<th>BFIL</th>
<th>Filling Machines for Bags</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>FFIL</td>
<td>Filling Machines for Bottles</td>
<td>6</td>
</tr>
<tr>
<td>SBM</td>
<td>Stretch-Blow-Molding Machines for Bottles</td>
<td>8</td>
</tr>
<tr>
<td>NTOS</td>
<td>Pharmaceutical Conveyors &amp; Turntables</td>
<td>9</td>
</tr>
<tr>
<td>NTE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TARO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP</td>
<td>Form-fill-Seal Machines for Polypropylene Bags</td>
<td>10</td>
</tr>
<tr>
<td>TFKPK</td>
<td>Overwrapping Machines</td>
<td>12</td>
</tr>
<tr>
<td>FLPK</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GHA</td>
<td>Washing, Capping &amp; Stoppering Systems</td>
<td>13</td>
</tr>
<tr>
<td>SCP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASSE</td>
<td>Connectors and Plug Assembling Machines</td>
<td>14</td>
</tr>
<tr>
<td>VIS</td>
<td>Bags Inspection Lines</td>
<td>15</td>
</tr>
</tbody>
</table>
BRAM-COR manufactures bags linear filling equipment Mod. BFIL according to CGMP regulations. The equipment is completely validateable with all parts in contact with the fluids in AISI 316L mirror polished stainless steel and with PLC controlled electronics. On request it is possible to modify the software and thus the operation of the machine according to each specific requirement including vacuum extraction, gas or sterile air injection, etc. Three different ranges of equipment are available:

BFIL T: Manual Bags Filler
BFIL S: Semiautomatic Bags Filler
BFIL A: Automatic Bags Filling & Capping machine
EASY CLEANING AND DIFFERENT BAG FORMAT

One of the most important innovations of the BFIL filling equipment is the hydraulic circuit: since it is completely linear and steady, the cleaning and sterilization processes are simplified, ensuring a perfect sterilization of the equipment. A special drop grill to collect any droplet or leakage of solution is installed on each model. Each BFIL equipment can be integrated with a devoted CIP/SIP station. The dosage precision varies according to the adopted flowmeter and can reach ±0.1%. The volume of the bag can range from 50 up to 5000 ml.

SMOOTH OPERATION

The capping process of the BFIL S and BFIL A models is automatic and avoids the uncomfortable operation of manually inserting the plugs into the filling pipe. The feeding of the plugs can be both manual or automatic, through vibrators, the capacity of which depends on the kind of plug used. A wide range of optional extras, such as dedicated sterile laminar air flow hoods, integrated conveyor belts, ink jet printers are available for all BFIL models. Each BFIL station only requires one operator. Up to 4 different BFIL A stations can be integrated in one line, reaching an overall capacity of around 6000 bags/h of 500 ml.
FFIL FILLING MACHINES FOR BOTTLES

The FFIL pharmaceutical linear filling machine for bottles by BRAM-COR represents an evolution in the systems of filling for pharmaceutical rigid vessels, combining:

- Maximum reliability
- High precision in metering
- Low maintenance costs
The process has been designed in order to offer the maximum functional easiness:

- The bottles are fed through a special sanitary belt
- A mechanical system provides for the correct positioning of each bottle under the filling system
- Special slides drive the filling nozzles onto the bottles reducing
- The nozzles have a special design avoiding the production of foam even at high filling speed
- The mass flow-meters provide for the metering of the solution with high precision and reliability, allowing a perfect sterilization in place through pure steam
- The nozzles raise and the separators move in order to let the bottles feed

The FFIL filling machine in standard version is designed for bottles from 50 upto 1000 ml with capacities upto 12.000 bph.
SBM STRETCH-BLOW-MOLDING MACHINES

The SBM machine is an automatic equipment suitable to produce pharmaceutical grade bottles in POLYPROPYLENE (PP) starting from preforms, through a Stretch-Blow-Molding Process, derived by a tight control of the irradiation and thermal transfer of the preforms.

BRAM-COR integrates the SBM machine, through belt conveyors and buffer systems, with Washing / Filling / Stoppersing / Capping / Labelling machines, installing therefore full automatic lines with proper Laminar Air Flow protection. Machines for injection molding of preforms and hangers with due molds can also be supplied to complete the line. The PP is a Medical Grade raw material suited to the Medical and Hospital Field, according to the European Pharmacopoeia.

Starting from preforms duly designed by BRAM-COR to fit the market needs, our SBM lines reach capacities from 1500 to max. 12000 bph and volumes from min. 50 to max. 1000 ml.

PHARMACEUTICAL PP BOTTLES

The SBM bottles offer extraordinary features of:
- Total transparency (and possibility of inspection with automatic visual inspection systems)
- Good moisture barrier
- Perfect resistance to sterilization in autoclave @121°C
- Good oxygen barrier
- Light weight
- Possibility of traditional rubber capping (low cost connector), or of PP stopper
- No waste of raw material
- Cheapest possible cost per unit if compared to BAGS or BFS (blow fill seal) bottles
BRAM-COR customized belt conveyors are designed to satisfy any requirement in the handling of pharmaceutical containers throughout the drug packaging process. Feedlines and output lines to and from production equipments can be specifically dimensioned for different container tipologies, such as glass bottles, PP bottles, small and large volume BAGS.

**HANDLING DRUG CONTAINERS**

Suitable materials, sanitary and safety concerns are the baseline for the design of our belt conveyors:

- First-class, easy-to-clean product handling components
- Sanitary belts
- Stainless steel frame
- Adjustable frame support components
- Sheltered moving parts
- Smooth product flow
- Emergency push button

Conveyor lines can be fitted with our stainless steel rotating (or turn) tables Mod. TARO, in order to suit different machines and uniform the flow of containers.
POP FORM-FILL-SEAL MACHINES
FOR POLYPROPYLENE BAGS

BRAM-COR PVC-free machines POP2 (producing bags with PIPES) or POP1 (producing bags with BOAT PORT connectors) are designed to produce I.V. solution bags, in format from 50 ml up to 5000 ml, turning a non-PVC film into a finished infusional bag, filled, sealed and printed.

BRAM-COR offers equipment with capacities ranging from 1500 upto 6000 bags per hour depending on the bag format. Key factors for productivity are packing material quality, utilities compliance to specifications and operating level.
HIGH TECHNOLOGY IN I.V. SOLUTION BAGS

The main features of these equipments are:

- Compact structure and high production efficiency
- Production of several formats, according to specification for bag forming

Full automation is ensured by a PLC controller and SCADA supervisor. Product critical parameters (such as temperature of film welding electrodes) are monitored and alarmed in the different production stations, from film feeding to bags forming and bags filling. In-line quality control is ensured by advanced Process Analytical Technologies. Unqualified soft bags are memorized and rejected. The filling station is prepared for CIP and SIP system, to save cleaning time and assure sterilization effect. During CIP all the parts in contact with drugs are thoroughly cleaned.
The purpose of TFK (vacuum thermoforming) and FLPK (flow-pack overwrapping) OVERWRAPPING MACHINES is to provide a protecting packaging of the pharmaceutical product (i.e. PVC or PP bags, pharmaceutical accessories, bottles, etc) in a plastic or plastic/paper pouch. BRAM-COR assists the Customer in selecting the proper and most suitable process for his plant. Manual or automatic models are available and each model can be equipped according to the specific options:

- L-shape sealing bar
- Side-continuous sealing head
- Thermoshinking tunnel

**MAIN FEATURES OF OVERWRAPPING MACHINES**

- Increased operator safety and safe-handling of the products
- Ability to work with all kinds of film on the market
- Temperature precise control of sealing tool
- High pressure uniformity along sealing profile
- Fast reel loading
- Scrap-film collecting-rewinding automatic systems
- Positioning of the bags regulated by photocells
- Sealing bars adjustable height
- Reduced maintenance
- PLC control of all process parameters (temperatures, triangle opening film)

The packaged product can be sterilized in autoclave by using proper multilayer film.
CAPPING & STOPPERING SYSTEMS

As a functional completion to our bottles filling lines, the CAPPING MACHINES of BRAM-COR ensure a full-automatic sealing operation. Special optical sensors provide fault detection and smooth product flow. Product critical parameters are constantly checked and alarmed. Transparent panels provide clear visibility of the operation. Moving parts are protected by stainless steel panels and all mechanical details are carefully designed to enhance productivity.

CAPPING/CRIMPING AND SEALING LINES FOR PHARMACEUTICAL BOTTLES AND CANISTERS

With Alu Caps: Pressurized capping for rubber closures & rotating head crimping machine for aluminum ferrules.

With Euro Cap or other plastic plugs: by heat-sealing.

With Screw Caps for canisters: closing by rotating system with or without plastic or aluminum sheet sealing on the container mouth.
ASSE CONNECTORS AND PLUGS ASSEMBLING MACHINES

ASSE is a unique equipment developed by BRAM-COR for a full automated assembly of connectors and plugs for intravenous, intrarenal or blood bags. The equipment consists in multistation assembling transfer with rotary table and feeding groups through vibrators, with a capacity of about 1000-5000 connectors per hour. Suitable for pharmaceutical industries to reduce production costs by in-sourcing plugs manufacturing.

ASSEMBLING INFUSIONAL BAG PORTS

The machine has a TIG welded 304 stainless steel frame, covered by stainless steel plate. Its rotary table, in anodised aluminium alloy, is driven by a motor controlled by an inverter. All the mechanical parts in contact with the connectors and the components to be assembled are made in stainless steel wherever possible, otherwise in aluminium alloy treated with niploy, or in plastic material suitable for the pharmaceutical sector. The pneumatic components are supplied by primary companies and the cylinders and electro-valves are according to ISO dimensions. The machine is controlled by a last generation PLC, operated through a HMI panel. On the panel it is possible to drive all the controls, to change the parameters, to evidence the alarms. The machine is equipped with a complete side protection covering the handling areas. The covers have safety electric connections.
Parenterals should be manufactured and inspected to ensure the highest quality, meeting the requirements set forth in the United States Pharmacopoeia (USP) Chapter <1> Injections.

DETECTION OF PARTICULATE MATTER

As they are typically injected, parenterals have the potential to go directly into the bloodstream which can result in adverse reactions to contamination and particulates. Particulate matter in finished pharmaceuticals can come from multiple sources, such as the ingredients in the drug product, processing equipment, or the container closure system. As a final step in the manufacturing process of parenterals, visual inspection is necessary to reduce or eliminate the risk of non-conformities in the released products. The special features of a filled bag (soft, warm, potential risk of air intrusion, etc) make it very difficult to inspect automatically those products and therefore most of the I.V. fluid companies perform that task in a manual or semi-automatic way. Particulate matter in parenteral solutions can be detected through BRAM-COR systems with black/white background for human inspection:

- Manual Visual Inspection desks
- Semi automatic Visual Inspection Lines
A full understanding of the drug production process is the key concept for correct design. BRAM-COR engineering focuses on fluid drugs sterile production processes, such as parenteral solutions, oral solutions, ophtalmic solutions. The definition, assessment and monitoring of critical parameters directly affecting product quality are the baseline for the application of suitable Process Analytical Technologies for in-line and at-line quality control. BRAM-COR work breakdown structure consists in following main activities:

- Design
- Construction (mechanical, electro-pneumatic, SW configuration)
- Testing
- Documentation
- Installation
- Validation
- Assistance

Every process follows rigorous cGMP-compliant Standard Operative Procedures. Specification, construction and verification steps within the lifecycle are carried out according to GAMP “V-model”, considering risk assessment, architecture of system components, functional specification, sanitization and validation issues with special overview to a sustainable maintenance of the system.

WORLDWIDE SERVICES

We are currently delivering our machines and building complete water treatment systems and preparation lines all over the world. Top quality GMP equipment must necessarily be integrated through a proper high level of professional services including: Technical Documentation, Factory Acceptance Test, Installation, Commissioning, Site Acceptance Test & Start-up, Training, Validation, After Sales Service. Our worldwide network of skilled agents and our affiliated companies ensure assistance to our Clients in over 50 countries, from the very beginning of a pharmaceutical project throughout decades after start-up. Our After Sales Dept. grants punctual and quick deliveries of spares and ongoing technical support.