

# PHARMACEUTICAL GREEN SYSTEMS

*Bram-Cor  
electric heating  
eco-systems*

PRODUCING

**WFI** WATER FOR INJECTION

**PS** PURE STEAM



**BRAM-COR**  
PHARMACEUTICAL TECHNOLOGIES



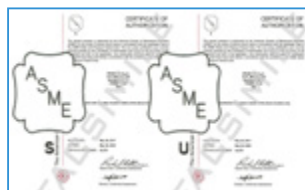
# WATER TREATMENT SYSTEMS WITH ELECTRIC HEATING

BRAM-COR **Pharmaceutical Water Treatment Systems**, designed to produce compendial Water for Injection (WFI) and Pure/Clean Steam (PS / CS) are also available with ***electric heating***, extremely interesting feature for all those situations in which the energy given by fossil fuels is problematic.

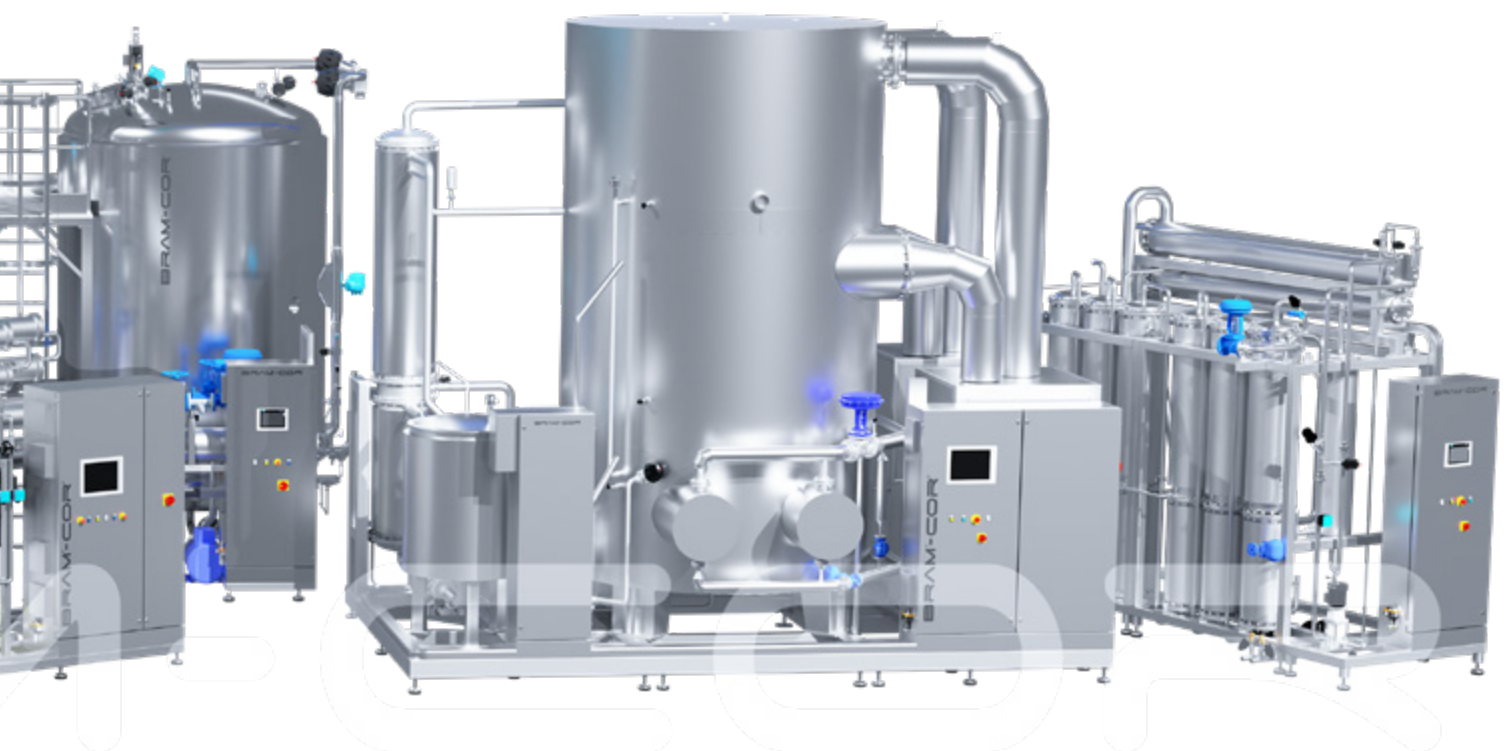
Pre-treatment options, monitoring of critical parameters, regulatory requirement for product quality, consumptions, microbiological control, operation and maintenance requirements, lifecycle costs are taken into considerations in the design of all processing steps, from feed water to the point of use.

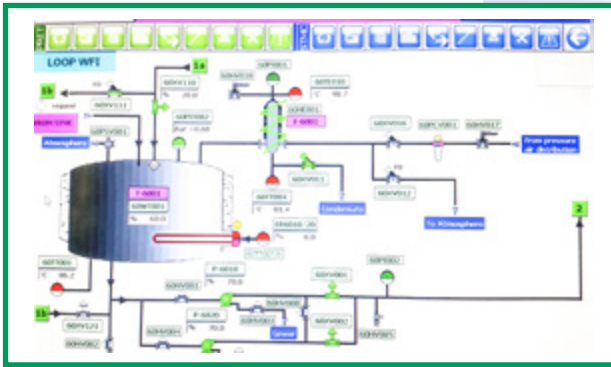


<b>STMC</b>	<b>VAPOR COMPRESSION DISTILLERS</b>	<b>3</b>
<b>SMPT</b>	<b>MULTIPLE EFFECT DISTILLERS</b>	<b>4</b>
<b>CPSG</b>	<b>PURE STEAM GENERATORS</b>	<b>5</b>
<b>DPSG</b>	<b>SINGLE EFFECT DISTILLERS</b>	<b>6</b>
<b>KOMB</b>	<b>WFI + PS GENERATORS</b>	<b>6</b>



Boilers and pressure vessels in BRAM-COR water treatment and processing systems are ASME certified ("S" and "U" stamp).



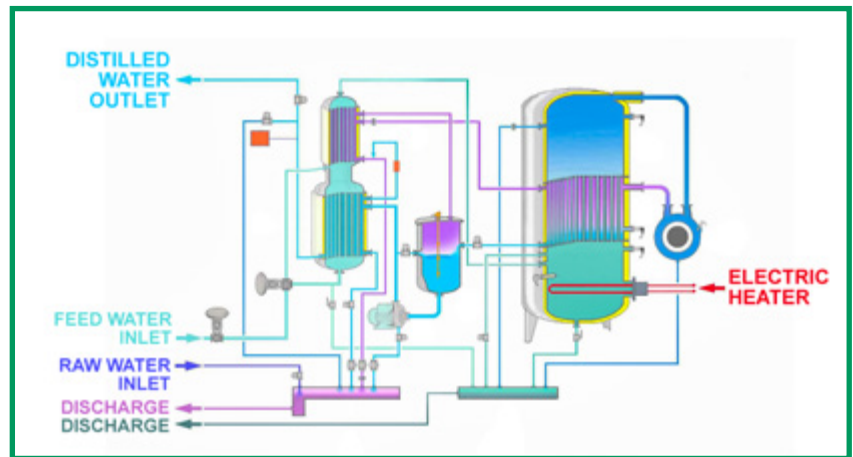


# STMC VAPOR COMPRESSION DISTILLERS

BRAM-COR STMC EL Vapor Compression Distillers produce compendial distilled water for pharmaceutical applications, such as I.V. solutions, injectables, washing systems and special solutions where both quality factors, such as the elimination of the pyrogens and of the chlorine solvents with low molecular weight, and economical factors, as well as the low production costs, are critical for the success of the pharmaceutical process.

## ELECTRIC HEATING CAPACITIES RANGE

From 20 to 3,000 lph, with single or double compressor.



The STMC distiller, made in certified AISI 316L SS, can produce both cold distillate at a temperature and hot distillate with huge savings of energy costs and with no need of cooling water. The design, construction and documentation strictly complies with cGMP and FDA regulations, ensuring an easy certification by the relevant authorities. In detail:

- All internal parts in contact with distillate are mirror-polished
- AISI 304 frame, insulation sheating and control board
- All hydraulic connections are sanitary tri-clamp or flange connection
- All gaskets are made in PTFE, all weldings are T.I.G. (Tungsten Inert Gas)



A full automation ensures easy operation and total monitoring of critical parameters, by means of certified in-line instruments and of a careful alarm policy. Access policy and records can be managed according to 21 CFR PART 11.

BRAM-COR STMC distillers are also available in steam heated and electric/steam heated versions.

# SMPT MULTIPLE EFFECT DISTILLERS

BRAM-COR **Multiple Effect Distillers** are designed and manufactured according to cGMP to produce compendial Water for Injection. Each unit contains a number of boiling columns (or effects), with the first column producing Pure Steam, which is either condensed in the following columns decreasing the operational costs, or used as PS.

Condensation is achieved by means of the thin-falling film system. The process is repeated in each column; the higher the number, the lower the consumption of the equipment.

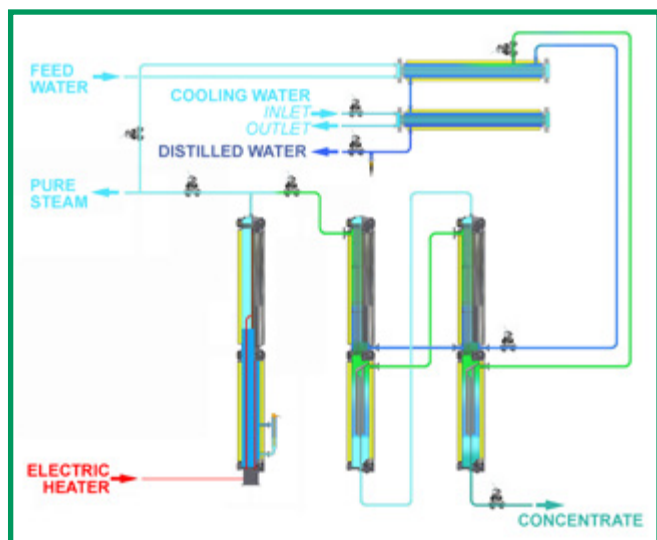
## ELECTRIC HEATING CAPACITIES RANGE

From 50 to 3,000 lph, with three-eight columns MED configurations.

A special baffle-separator installed at the bottom of each column separates the steam generated by the evaporation process from water drops and entrained substance in the steam itself. The result is a pure, "dry", pyrogen-free steam, condensed in compendial Water for Injection. Pressure vessels are designed according to PED regulation, and the equipment features:

- Double tube sheet heat exchangers
- Certified AISI 316L SSI mirror-polished and passivated product contact surfaces
- AISI 304 frame, insulation sheating and control board
- PTFE gaskets
- Pneumatic valves with PTFE membranes and AISI 316L SS body
- ASTM C-795-compliant insulation

BRAM-COR **SMPT** equipment is also available in **steam** heated versions (From 50 to 15,000 lph, with three-ten columns configurations).



# CPSG PURE STEAM GENERATORS

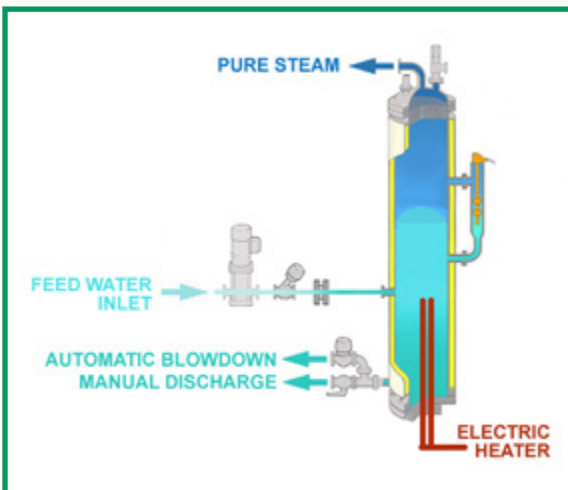


BRAM-COR **CPSG Pure Steam Generators** produce dry, saturated steam, suitable for sterilization of pharmaceutical production plants, for direct contact with active pharmaceutical ingredients, for parenteral and non-parenteral dosage form applications.

The steam, when condensed, meets USP requirements for Water for Injection. The steam is purified using a demister and gravity separation methods.

## CAPACITIES RANGE

From 20 to 500 Kg/h



cGMP and PED standards are baseline criteria in **CPSG** design and construction. In detail:

- The evaporation column is designed to minimize steam speed to avoid the entrainment of water droplets, which are separated from the steam by means of a special separator.
- An electrical heater provides heating of pre-treated feed water above the boiling temperature, generating Pure Steam which expands into the evaporation column.
- Pure Steam pressure is maintained by an electronic control system, modulating the power of electrical heating. The system shall be fed with Purified Water or WFI.

BRAM-COR **KPSG Kettle Pure Steam Generators** provided with a horizontal evaporation chamber with kettle end, are also available for special space needs. BRAM-COR **CPSG/KPSG** are also available in **steam** heated versions (From 20 to 5,000 Kg/h).



# DPSG SINGLE EFFECT DISTILLERS

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**PS & WFI** from a single effect distiller: **DPSG** equipment is both a **Single Effect Distiller** and a **Pure Steam Generator**. This equipment produces dry, saturated steam to be used as sterilizing agent. The Pure Steam, when condensed through a double tube sheet condenser, meets the requirements of international pharmacopoeias for Water for Injection. The system can therefore provide a simultaneous production of Pure Steam and Water for Injection.

The steam is purified using a demister and gravity separation methods. The equipment is made in AISI 316L SS for all parts in contact with the process fluid and steam, and it is designed according to European PED pressure regulation. All pipes are orbital welded when possible, with inert gas protection. Moreover:

- Active surfaces are passivated.
- The parts in contact with the pure steam are polished ( $Ra \leq 0.5 \mu m$ )
- The Skid is in stainless steel AISI 304 satin finished
- The Control Cabinet is in stainless steel AISI 304 satin finished

BRAM-COR **DPSG** equipment is also available in steam heated versions.



# KOMB COMBINED WFI+PS GENERATORS

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BRAM-COR **KOMB** is a unique equipment for the simultaneous production of WFI and PS, combining the double functions of a multiple effect distiller and of a Pure Steam generator on a single skid, shrinking space needs.

A central **plc** controls the two units, providing separate or concurrent outlet of Water For Injection or/and Pure Steam.

BRAM-COR **KOMB** equipment is also available in **steam** heated versions.



## BRAM-COR KEY DESIGN CONCEPTS

BRAM-COR engineering focuses on liquid and sterile drugs and low, medium and high viscosity production processes, such as parenteral solutions, oral solutions, ophthalmic and oncology solutions, low, medium and high viscosity emulsions, such as ointments, creams and cosmetic preparations.

BRAM-COR work flow structure consists of the following main activities: **Design, Construction (mechanical, electro-pneumatic, software configuration), Testing, Documentation, Installation, Validation, Assistance.** Every step of the assembly follows rigorous quality approved processes and procedures.

Specification, construction and verification steps within the lifecycle are carried out according to GAMP, considering risk assessment, architecture of system components, functional specification, sanitization and validation issues with special overview to include sustainability and maintenance of the system.



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## BRAM-COR 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.

