BRAM-COR Water Treatment Systems

CPSG PURE STEAM GENERATORS

A clear vision about pure steam generation in pharmaceutical environment

BRAM-COR
PHARMACEUTICAL TECHNOLOGIES

CPSG *Generator*

PHARMACEUTICAL PURE STEAM.

EVERY DAY READY FOR ALL BIOPHARMA.

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 centrifugal and gravity separation methods.

The **CPSG** unit can be fed with **Purified Water** or **WFI** and are heated using industrial steam; however heating can also be achieved using superheated water, or with direct electrical power supply.

Capacities range:
from 20 to 8,000 Kg/h

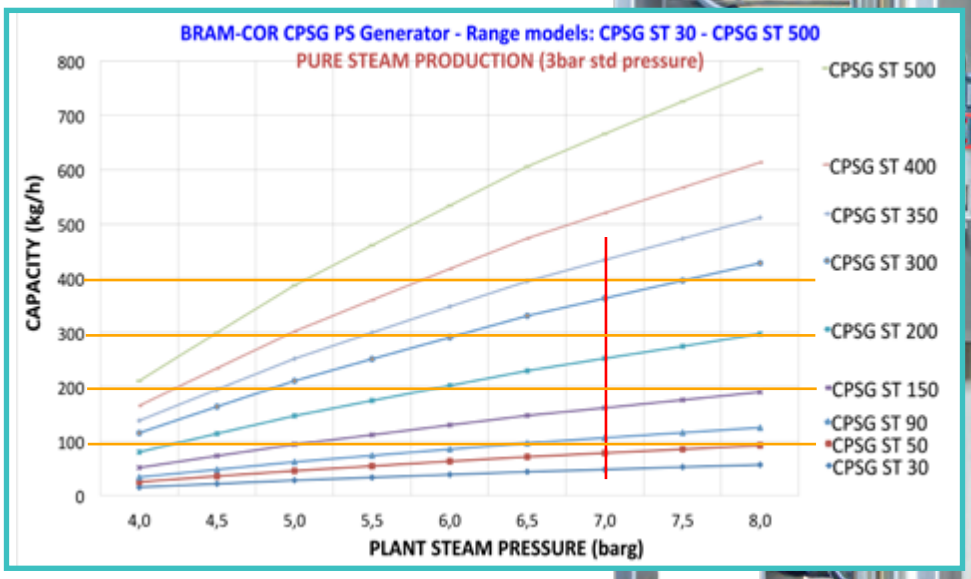
Destination of use	**Production of dry, saturated steam, suitable for sterilization of pharmaceutical production plants, for direct contact with active pharmaceutical ingredients, for parenteral and non-parenteral dosage form applications. The steam, when condensed, meets USP requirements for Water for Injection.**
Technology	**The unit contains one boiling column (or effect) producing pure steam.**
Technical features	**• cGMP design and construction**
	• All product contact surfaces in AISI 316 L stainless steel
	• Jackets, frame and control board in AISI 304 stainless steel
	• All welding is performed by certified welders
	• Gaskets in EPDM or PTFE or Silicone
	• Pneumatic valves with Teflon/PTFE membranes and AISI 316 L SS polished body
	• ASTM C-795 – compliant insulation
	• Instruments: conductivity meter, pressure transducers, temperature probes & level transmitter
	• Adjustable feet
	• Available in steam, electrically operated model, or superheated water
Control system	**Automation unit: integrated 24 v dc power supply. HMI: Siemens Touch-screen SCADA system for compliance to 21 CFR PART 11 . Allen-Bradley Rockwell Automation available on request. Functions operated by the PLC: • Automatic Sequences (Level control, production) • Control Functions (PID valve control, etc.) • Input of measured values and setting of limits • Output of digital commands and analog values**
Optionals	**• Quenched waste water collector & cooler with spray valve • Pure Steam Condenser including conductivity instrument for measuring Pure Steam quality • Digital Recorder • VPN Router for Tele-assistance**

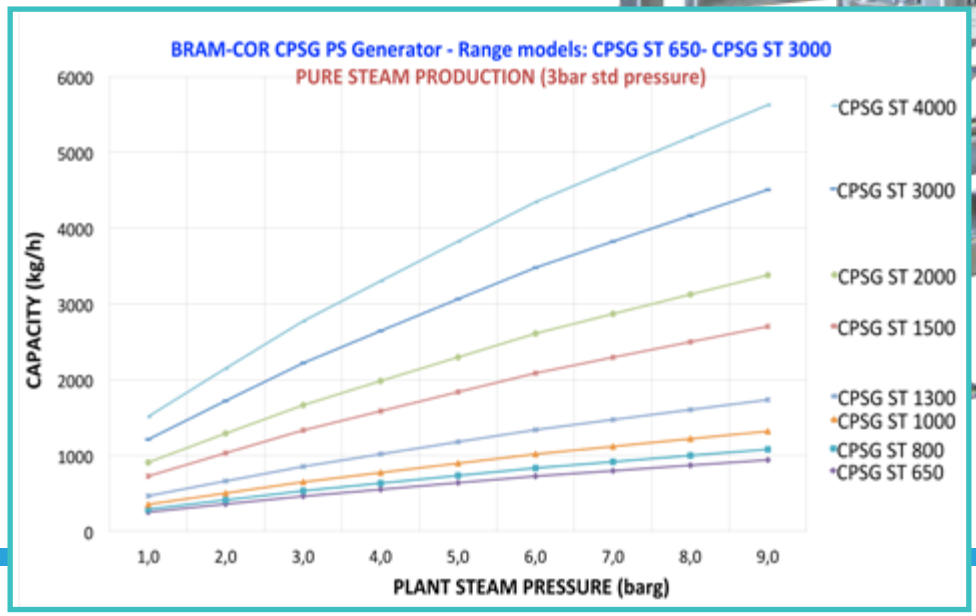
CPSG *Quality range*

BRAM-COR MANUFACTURING EXCELLENCE IN EVERY STANDARD

CUSTOMIZED DESIGN AND FABRICATION FOR ANY APPLICATION

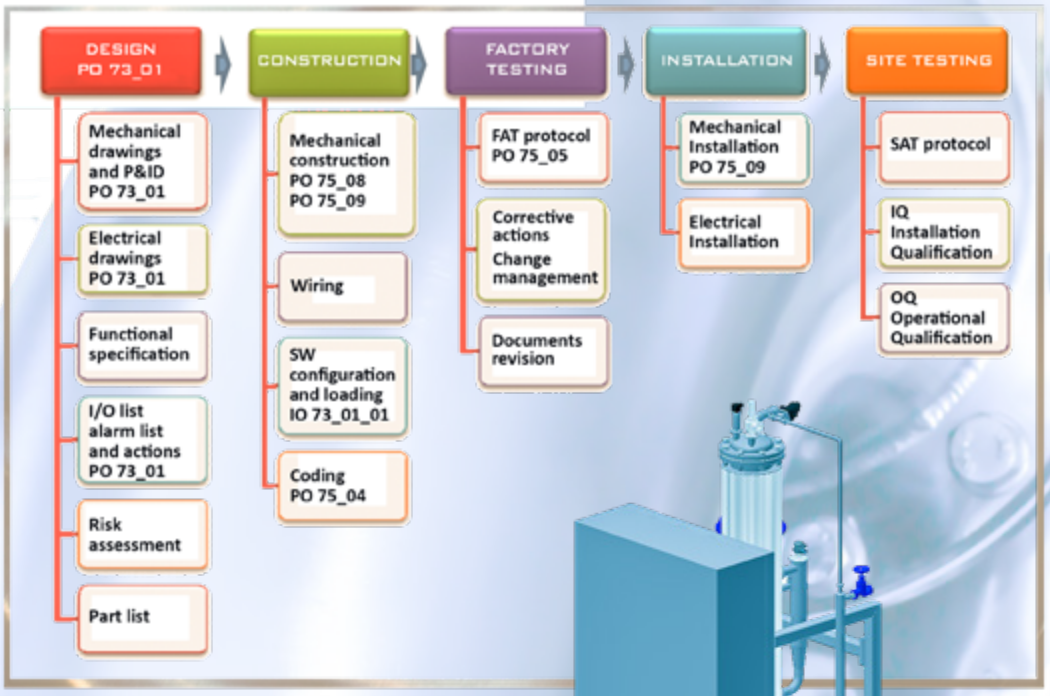
CPSG quality range. BRAM-COR provides the highest quality: **cGMP** and **PED** standards are the baseline criteria for our design and construction of all **CPSG models**: full traceability, certified material and instruments, welds made by qualified welders.





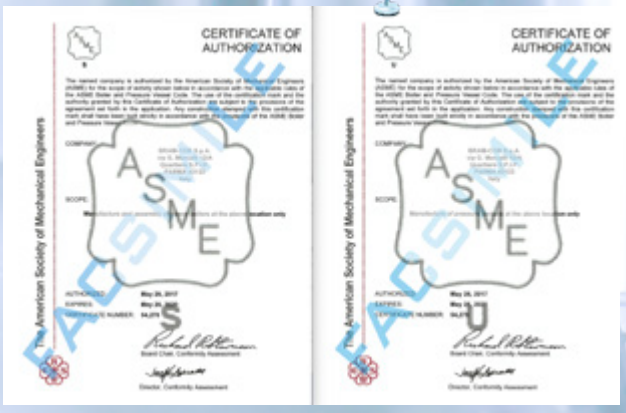
Project steps

Design specifications are collected in the Design Qualification Protocol (DQ). Customer's approval of the DQ is the starting point for production activities according to Bram-Cor Quality System Procedures.



DOCUMENT	CONTENTS IN BRIEF
TECHNICAL DOCUMENTATION (for each plant)	DRAWINGS
	COMPONENTS DOCUMENTATION
	VALVES DOCUMENTATION
	INSTRUMENTS DOCUMENTATION
	HARDWARE DOCUMENTATION
	SOFTWARE DOCUMENTATION
	WELDING DOCUMENTATION
	USE AND MAINTENANCE MANUAL
	OPERATING MANUAL
	SPARE PARTS LIST
TECHNICAL DOSSIERS (for stainless steel components built in Bram-Cor)	PRODUCT DESCRIPTION
	DRAWING
	MATERIAL CERTIFICATES
	WELDING DOCUMENTATION
	PICKLING AND PASSIVATION CERTIFICATE
	NON-DESTRUCTIVE TESTS REPORT
	HYDRAULIC PRESSURE TEST REPORT

DOC. TYPE	CONTENTS IN BRIEF
F.A.T. PROTOCOL FACTORY ACCEPTANCE TEST	TEST PRE-REQUISITES
	MECHANICAL COMPONENTS ACCEPTANCE TEST
	ELECTRICAL HARDWARE ACCEPTANCE TEST
	SOFTWARE ACCEPTANCE TEST
	FUNCTIONAL TEST
	FAT REPORT APPROVAL
	DEVIATION REPORT
S.A.T. PROTOCOL SITE ACCEPTANCE TEST	TEST PREREQUISITES
	MECHANICAL COMPONENTS ACCEPTANCE TEST
	ELECTRICAL HARDWARE ACCEPTANCE TEST
	SOFTWARE ACCEPTANCE TEST
	FUNCTIONAL TEST & TRAINING
	SAT REPORT APPROVAL
	DEVIATION REPORT



PURE STEAM (CONDENSATE) - QUALITY CRITICAL ATTRIBUTES

Physical/chemical	EUROPEAN PHARMACOPOEIA	USP PHARMACOPOEIA
Conductivity	Not defined	≤ 1,3 (25°C) µS/cm
TOC	Not defined	≤ 500 ppb
Bacterial count	Not defined	≤ 10 CFU/100 ml
Bacterial endotoxins	Not defined	≤ 0.25 EU/ml

CPSG *Process*

RELIABLE TECHNOLOGY

STAINLESS STEEL CONSTRUCTION, FOR DURABILITY AND LONG LASTING EFFICIENCY.

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.

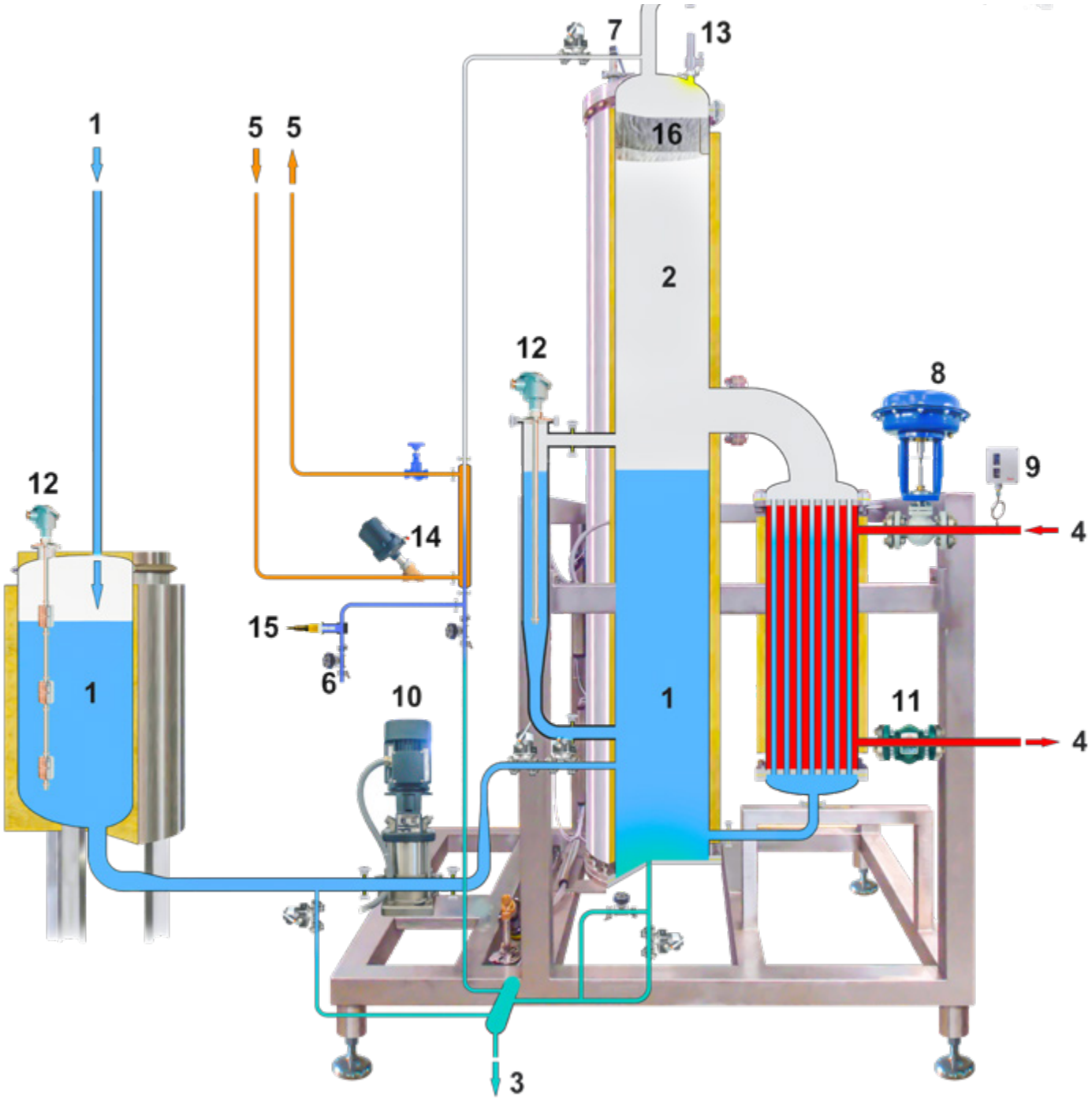
A Double Tube Sheet (DTS) Heat Exchanger provides heating of pre-treated feed water above the boiling temperature, generating Pure Steam which expands into the evaporation column. Heating medium in the DTS Heat Exchanger is typically industrial steam at 100 to 120 psig (7.9 to 2.0 bars).

Pure Steam pressure is maintained by an electronic control system, which modulate the supply steam.

BRAM-COR **KPSG Kettle Pure Steam Generators** provided with a horizontal evaporation chamber with “kettle” end, are also available when there are space height limitations.

PURE STEAM GENERATOR - CPSG DIAGRAM

01 - FEED WATER
02 - PURE STEAM
03 - BLOW-DOWN/DRAIN
04 - INDUSTRIAL STEAM
05 - CHILLED WATER
06 - SAMPLING POINT
07 - PURE STEAM PRESSURE TRANSMITTER
08 - MODULATING VALVE
09 - INDUSTRIAL STEAM PRESSURE SWITCH
10 - SANITARY PUMP
11 - STEAM TRAP
12 - LEVEL PROBE
13 - SAFETY VALVE
14 - PURE STEAM SAMPLING CONDENSER
15 - CONDUCTIVITY METER
16 - DEMISTER



Key design concept

BRAM-COR engineering focuses on liquid/sterile drug and low/medium/high viscosity production processes, such as parenteral solutions, oral solutions, ophthalmic and oncology solutions, viscous emulsions, gel and pharmaceutical creams, 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 "V-model", considering risk assessment, architecture of system components, functional specification, sanitization and validation issues with special overview to include sustainability and maintenance of the system.

Worldwide services

We deliver BRAM-COR machines all over the world and our high quality cGMP equipment is supported through our high level professional services including: Technical documentation, Factory Acceptance Test, Installation, Commissioning, Site Acceptance Test & Start-up, Training, Validation, and After sales service. Our worldwide network ensures assistance to our clients in over 50 countries, from the very beginning of a pharmaceutical project and for decades after start-up. Our ***After sales dept***. provides punctual and quick deliveries of spares and ongoing technical support.

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