TOSOH

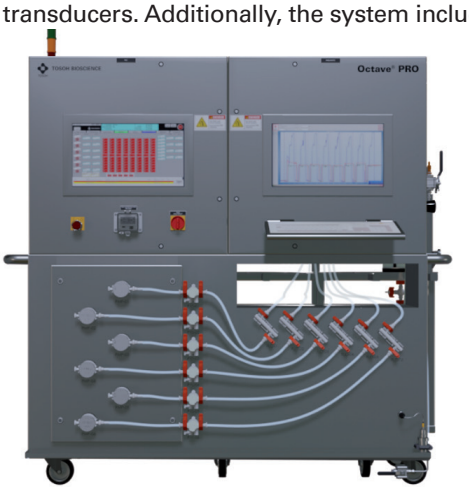
Octave™ PRO Specification Sheet

System Overview

The Octave PRO system from Tosoh Bioscience is a cGMP-ready multi-column chromatography (MCC) system for the purification of biopharmaceuticals at the clinical and commercial scale. The Octave PRO is designed for direct scale-up after process development on the Octave BIO, and both systems offer the same method-execution capabilities. The Octave PRO enables ultimate process versatility and agility to address the most challenging downstream bottlenecks.

The entire flow path of the instrument is single-use, easy to replace and gamma irradiated. The flow path features a biocompatible, pneumatically actuated 104-valve array that directs process fluids through 1 to 8 columns accommodating increasingly intensified upstream titers. Fluid flow is controlled by six independent pumps with a maximum flow rate of 150 L/h, which operate based on real-time data feedback from six integrated flow sensors and six pressure transducers. Additionally, the system includes four sensor towers each containing a dual-channel UV sensor, a conductivity monitor, and a pH sensor housed in a compact single-use cell for fluid stream monitoring. The Octave PRO's three-dimensional design gives it a compact footprint. Pump head fluid connections, HMI keyboard, and touch screen monitor are arranged on the front with column connections to the valve block and outlet line connections to collection vessels on the back.

Tosoh Bioscience's PROController™ software provides automated control of the Octave PRO system using the AVEVA Wonderware Framework for security and data integrity under Good Automatic Manufacturing Practices issue 5 (GAMPV). The application communicates via a supervisory control and data acquisition (SCADA) computer to a programmable logic controller (PLC), which in turn controls the equipment (pumps, valves, sensors, nitrogen supply, power, communication interfaces, etc.). The 21 CFR part 11 compliant software allows for process control in a cGMP environment.



Technical Specifications - System Architecture

Description	Specifications
Dimensions (W / D / H)	213 / 115 / 219 cm, (198 cm without alarm tower)
Weight	450 kg
Operating flow rate	1 – 150 L/hr (2.5 L/min)
Maximum operating pressure	6 bar (87 psi)
Valve Pressure	8 bar (116 psi)
Gas inlet pressure	9 bar (130 psi)
Column Positions/ Connections	1 to 8 columns, ¾ in. sanitary clamps
Valve block	1 single-use assembly containing 104 pneumatic two-way valves

Description	Specifications
Inlet number	6
Outlet number	6
Pumps	6; 4-piston-diaphragm pump, flow rate ranges 1-150 L/h
Flowmeters	6; 1 after each pump, flow rate ranges 0.01-8 L/min
Pressure sensors	6; 1 after each pump, measuring range 1-10 bar
Outlet sensors	4 assignable single-use combination UV/ conductivity/ pH
UV sensors	UV 280 nm & 305 nm
Conductivity sensors	CND range 0–850 mS/cm
pH sensors	pH range 0-14

Single-Use Flowkit

Item	Description
Inlet Connections	6 Aseptiquik® G
Outlet Connection	6 Aseptiquik® G
Pumps	6 Quattroflow® EZ-Set Pump Chamber quaternary diaphragm single-use heads
Pressure sensors	6 single-use gauge tees (TS1, 1 after each pump)
Flow sensors	6 single-use; ultrasonic (1 after each pump)

Single-Use Materials of Construction

Component	Wetted Materials
Pump head	polypropylene (PP), thermoplastic elastomer (TPE), ethylene propylene diene monomer (EPDM)
Pressure adapter	PP, TPE
Flow sensor	PP
Valve block assembly	USP class VI compliant polyetherimide (PEI), polyvinylidene fluoride (PVDF), polyfluoroalkoxy (PFA)
Optical/ conductivity/ pH flow cell	quartz (UV-transparent), EPDM, stainless steel 1.4435 (SS 316L), polyphenylsulfone (PPSU)
Fittings	PEEK, platinum cured silicone, PP
Tubing	¼ in. ID polybraided platinum cured silicone, pump inlet is weldable ¼ in. ID Advantaflex biopharmaceutical grade thermoplastic elastomer (TPE)
Gamma irradiation dose	25-40 kGy

Electrical Requirements

Parameter	North America	EMEA
Voltage	120V; 1 phase	220-240V; 1 phase
Amps	30A	15A
Frequency	60 Hz	50 Hz
Number of Cords	1	1
Type of Plug	NEMA L5-30P, with ground	Must meet local code, with ground

Ordering Information

Systems

P/N	Description
0041200	Octave PRO US, Octave PRO GMP ready multi-column chromatography skid for US region.
0041201	Octave PRO EU, Octave PRO GMP ready multi-column chromatography skid for EU region.
0041202	Octave PRO SU Flowkit, Full single-use flowkit for the Octave PRO.