qEV Zenco Pro (for cGMP-Compliant Environments)

The qEV Zenco is an automated chromatography system developed specifically for purifying samples using the qEV2, qEV10, qEV100 and larger customised qEV columns. To facilitate production in cGMP-compliant environments, we propose the following enhancements to the standard qEV Zenco model, which will form the qEV Zenco Pro. Note that the proposed specifications are subject to change, and we welcome your feedback or any questions you may have.

Table 1: Product Compliance Information for both qEV Zenco Models

Safety	IEC/EN/UL 61010-1, CAN/CSA-C22.2. No. 61010.12
EMC (Electromagnetic compatibility)	IEC/EN 61326-1, US 47 CFR part 15, Subpart B, Class A
Environment	RoSH2&3, REACH, WEEE

Table 2: cGMP Compliance Information for the qEV Zenco Pro

Software	21 CFR part 11
Material specifications of wetted parts (i.e., wetted parts of components that come into direct contact with process fluids or product)	USP class VI or ISO 10993, 21 CFR 177, animal origin free or in compliance with EMA/410/01, Quartz glass, Fused silica, Borosilicate glass to ASTM E483 Type 1 Class A, Stainless steel 316L ASME-BPE

Table 3: Specifications of Key Components

	qEV Zenco (standard)	qEV Zenco Pro (for cGMP-compliant environments)
Regulatory requirements	• See electrical compliance information above	• See electrical compliance and cGMP compliance information above
Shell	• Powder coated steel	• Stainless steel
Device-PC connection	• USB-C	• USB-C
Screen	• No	• Yes
TFF integrated	• No	• No
Inlet valve	• Rotary valves • 8 inlets/1 outlet • OD: 3.175 mm (1/8"); ID: 1.59 mm • PTFE tubing	• Diaphragm valves • 8 inlets/1 outlet • OD: 3.175 mm (1/8); ID: 1.59 mm • PTFE tubing
Pump	• One piston pump • Max operation pressure: 10 bar • Max operation flow: 100 mL/min; • Accuracy: 1.5% • Pre-pump tubing: OD: 3.175 mm (1/8"); ID: 1 mm; PEEK; • Post-pump tubing: OD: 1.6 mm (1/16"); ID: 0.75 mm; PEEK;	• Two peristaltic pumps with the ability to add or remove one during construction. (i.e. 1 of the pumps is modular) • Max operation pressure: 3 bar • Max operation flow: 100 mL/min • Accuracy: 1.5 % • OD 4.8 mm, ID 1.6 mm, silicone tubing

Pressure sensor	• Accuracy: 0.25%	• Accuracy: 0.25%
In-loop air sensor	• No	• Modular. Designed so that the air sensor can be added or removed during construction
Flow direction valve	• Rotary valves	• Diaphragm valves
Post-column conductivity detector	• Range: 0.02 – 200 mS/cm; • Accuracy: ± 2%, min ± 20 µs/cm	• Range: 0.3 – 300 mS/cm, • Accuracy: ± 3% or 0.10 mS/cm
Post-column UV detector	• 1 wavelength (190-400 nm), variable • Accuracy: ±1 nm	• 2 wavelength (190-400 nm), variable • Accuracy: ±1 nm
Outlet valve	• Rotary valves • 8 inlets/1 outlet • OD: 1.6 mm (1/16"); ID: 0.75 mm • PTFE tubing	• Diaphragm valves • 8 inlets/1 outlet • OD: 3.175 mm (1/8"); ID: 1.59 mm • PTFE tubing
Bubble trap	• No	• No
Back pressure valve	• Yes	• Yes
Power supply	• 24 V connection into the unit. • 110 V and 220 V to 24 V power bricks so unit can be plugged into wall socket.	• 24 V connection into the unit. • 110 V and 220 V to 24 V power bricks so unit can be plugged into wall socket.
Fraction collector	• No	• Modular. Designed so that the fraction collector can be added or removed during construction.

Tubing	• Before pump: ID 1 mm; After pump: ID 0.75 mm • PEEK and PTFE non-pharm grade	• ID 1.6 mm for all tubing • PTFE and silicone • Compliance with USP ‹88› Class IV or ISO 10993
Data outputs	• CSV including the following information: Sample ID, column information, fraction id, retention time, plot of UV vs volume. • Include any adjustable parameters • Sample rate: 0.5 samples per second is acceptable	• CSV including the following information: Sample ID, column information, fraction id, retention time, plot of UV vs volume. • Include any adjustable parameters • Sample rate: 0.5 samples per second is acceptable
Mixer	• No	• Yes
RFID compatibility (software)	• Yes	• Yes
Enclosure protective class	• IP21	• IP21

Got questions?

Get in touch for more information about product details, lead times or to request a quote.