



## The SOTAX CP 7-35 Ceramic Piston Pump for Consistent and Accurate Flow Rates and Samples

- ▶ 7 valveless, **self-priming** ceramic piston pump heads ensuring a **consistent and accurate** delivery of media
- ▶ Designed specifically for USP 4 “flow-through” dissolution techniques with flow rates from **4 to 35 ml/min**
- ▶ **Fulfills and exceeds** all USP requirements for pump design
- ▶ **Open concept**, easy access, space-saving design
- ▶ Unique individually **adjustable flow rates** allowing for maximum flexibility in testing
- ▶ Local user interface: control panel with function keys, LCD display, **unique scroll knob** for menu navigation
- ▶ No maintenance and **trouble-free** design
- ▶ Automated **gravimetric calibration** and validation with connected balance and option to print test results

[www.sotax.com](http://www.sotax.com) | e-mail [info@sotax.com](mailto:info@sotax.com)





SOTAX CP 7-35 and automated calibration station

**Validation report SOTAX CP 7-35**

Ceramic Pump: SOTAX CP 7-35 V111.15  
 Serial Number: 06.1.014  
 Date of validation: 09.07.04 14:00  
 Medium: \_\_\_\_\_  
 Size: Density: 1.000 g/cm<sup>3</sup>  
 Pump speed: 100 rpm  
 Acceptance Range: 1.5%

Flow Rate	8ml/min	Flow Rate	16ml/min
Quantity:	1 x 32 ml	Quantity:	1 x 48 ml
1. Reading	Flow Rate Deviation (ml/min) (%)	1. Reading	Flow Rate Deviation (ml/min) (%)
	1. 8.00 0.00		1. 16.07 0.44
	2. 8.00 0.28		2. 16.00 0.00
	3. 8.00 0.00		3. 16.00 0.00
	4. 8.00 0.00		4. 16.00 -0.19
	5. 8.00 0.00		5. 16.00 0.00
	6. 8.00 0.00		6. 16.01 0.19
	7. 8.00 0.28		7. 16.00 0.00
Statistics:	Deviation: Min ±0.00% Max ±0.28%	Statistics:	Deviation: Min ±0.00% Max ±0.44%

  

Flow Rate	25ml/min
Quantity:	1 x 50 ml
1. Reading	Flow Rate Deviation (ml/min) (%)
	1. 25.00 0.00
	2. 25.00 0.00
	3. 25.00 0.20
	4. 25.00 0.20
	5. 25.00 0.20
	6. 25.00 0.20
	7. 25.00 0.20
Statistics:	Deviation: Min ±0.00% Max ±0.20%

Operator: *F. List*  
 Signature: *F. List*

SOTAX CP 7-35 validation report

**Technical data**

<b>Flow unit</b>	<b>7 channels</b>
<b>Flow rate</b>	<b>4–35 ml/min</b>
<b>Drive</b>	<b>Brushless DC 24 V</b>
<b>Cycles</b>	<b>0–300 cycles/min</b>
<b>Reproducibility of the flow rate</b>	<b>99.0 %</b>
<b>Connection</b>	<b>1/4"–28 UNF</b>
<b>Max. Pressure</b>	<b>6.9 bar</b>
<b>Width/depth/height</b>	<b>295/350/500 mm (11.61/13.78/19.68 in)</b>
<b>Weight ca.</b>	<b>25 kg (55.16 lb)</b>
<b>Supported balances</b>	<b>Mettler, Sartorius, Acculab</b>
<b>Power</b>	<b>230 V/50 Hz or 115 V/60 Hz</b>

**Order Information**

<b>Part #</b>	<b>Description</b>
<b>9150</b>	<b>SOTAX CP 7-35</b>
<b>9300</b>	<b>Automated calibration station (balance not included)</b>
<b>Y580-0170</b>	<b>Precision balance Acculab, 6100 g/0.1 g</b>
<b>C100-0051</b>	<b>Label printer EPSON U220PD</b>

**Description**

The SOTAX CP 7-35 pump is equipped with 7 valveless, self-priming ceramic pump heads, ensuring a very high level of consistency and accuracy. Due to design, this pump maintains consistency and efficiency even if it is placed before the filtration. It overcomes problems associated with pumping viscous media. The SOTAX CP 7-35 is constructed with inert material including ceramic heads and pistons with teflon media tubings. The flow rate can now be adjusted automatically from 4 to 35 ml/min using the control panel. An important new parameter of this pump is the fact that the flow rate can now be adjusted channel per channel. This feature is advantageous during the development of a USP 4 dissolution method requiring flow rate studies. For example, the SOTAX CP 7-35 allows to test the 3 recommended USP 4 flow rates (4, 8 and 16 ml/min) during the same test.

Under careful consideration of these USP requirements and recommendations from the pharmaceutical industry, SOTAX has developed the SOTAX CP 7-35 Ceramic Piston Pump especially for the USP 4 "flow-through" dissolution method. Furthermore, the maintenance of such a pump is considerably less due to the use of these valveless ceramic pump heads. Sticking, clogging and tedious maintenance problems have now been eliminated.

**Features**

**USP 4**

In the USP 4 "flow-through" dissolution method, the pump is responsible for ensuring the most important parameter: the flow rate of the media. As per USP requirements, the flow rate must stay constant and precise throughout the duration of the test, even in cases of back pressure created by filter resistance. The USP regulations require a sinusoidal flow profile with a pulse action of 120 +/-10 pulses per minute with typical flow rates of 4, 8 and 16 ml/min within an accuracy of +/-5 %.

**pH change**

The SOTAX CP 7-35 is best utilized with USP 1 or 2 dissolution systems for modified release forms requiring accurate pH change by adding medium automatically during the test. It can now be implemented in any of our automated dissolution systems.

**Automated calibration and validation**

The SOTAX CP 7-35 can be integrated with the automated calibration station, a balance and a printer. The pump automatically checks and if necessary adjusts its flow rate channel per channel based on user-defined volumes. Without the automated calibration station an external balance can be used. Starting the validation the software leads to the complete validation process. The weights reading can then be entered manually. A calibration protocol is automatically generated and can be printed out. The calibration schedule can also be automatically set to expire after a user-defined time.

**Optional accessories**

- ▶ Automated calibration station (balance not included)
- ▶ Precision balance (Mettler, Sartorius or Acculab)
- ▶ Label printer

**Validation and qualification**

The SOTAX CP 7-35 is precisely calibrated in our factory before delivery. The appropriate qualification documentation is supplied with each unit.