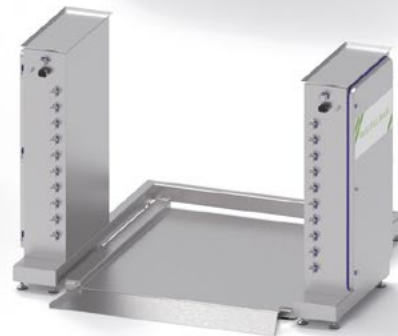


SINGLE USE SUPPORT.

PIONEERING BIOPHARMA



RoSS.FILL

Scale Overview

Automated systems.

Full modularity.


Highest flexibility.

Small Volumes (1 mL - 1000 mL)

HARDWARE

LAB

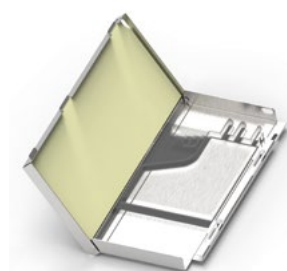
CGT



LAB SCALE / CGT

CONSUMABLE

for up to 12 (lab) or 36 bags (cgt)/ rack at 1 mL to 1000 mL each



Filling of small single-use bags for clinical studies and cell & gene therapies

Large Volumes (1 L - 1000 L+)

BAG

BASE

BOTTLE

BAG

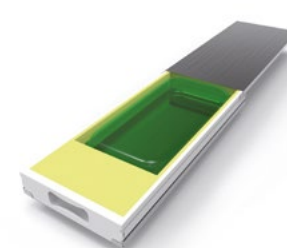
BASE

BOTTLE

for up to 20 bags/rack at 1 L to 20 L each

for up to 20 containers up to 3000 kg gross

for single-use bottles up to 10L







Fully automated bulk drug substance handling with 20 individual weighing scales

Commercialized bulk drug substance process

Hybrid control unit with bottle rack for easy transition to single-use bags

**Only standard configurations are shown. On request, parameters such as max. racks to be connected, pump or pump head, bag sizes, the number of valves or the racks can be customized.*

ONE CONTROL UNIT - SEVERAL OPTIONS



RoSS.FILL offers full flexibility thanks to its **modular design**. The platform's control unit is compatible with various filling racks and can therefore be used universally for filling single-use bags and bottles in all available sizes and from all manufacturers.

- It is even possible to
- **attach multiple racks:** increasing the batch volumes for commercialized production as requested
 - **perform continuous filling due to alternating filling racks:** increased efficiency through unlimited batch volume filling

RoSS.FILL Standard Configurations

TECHNICAL SPECIFICATIONS*

GENERAL INFORMATION	RoSS.FILL Lab Scale	RoSS.FILL CGT		RoSS.FILL Bag	RoSS.FILL Base		RoSS.FILL Bottle
		36 valves	64 valves		1500kg	3000kg	
Field of use	Clinical studies / cell & gene therapies / seed train intensification / low volume BDS	Clinical studies / cell & gene therapies / seed train intensification / low volume BDS		BDS handling	BDS handling / commercialized BDS / bigger volumes, any container		BDS handling
Primary packaging	2D single-use bags	2D single-use bags		2D single-use bags	any (2D single-use bags, 3D single-use bags, drums, moveable racks etc.)		bottles

VOLUMES SPEED QUANTITIES

Bags per rack (valve tower)	12	36	64	20	10		up to 24
Max. number of racks (valve towers)	0	2	2	2	2		up to 2
Max. bags total	12	72	128	40	20		up to 48
Volume or weight per bag	1 to 1000 mL	1 to 1000 mL	1 to 250 mL	1 to 20L	1 to 1500 kg (gross)	1 to 3000 kg (gross)	up to 10 L
Max. volume or weight total (per system run)	12 L	72 L	32 L	800 L	1500 kg (gross)	3000 kg (gross)	up to 320 L
Filling speed	12 x 1000 mL in 0.5 h (24 L/h)	36 x 1000 mL in 1 h (36 L/h)	64 x 250 mL in 0.75 h (21 L/h)	20 x 16 L in 3 h (105 L/h)	20 x 50 L in 4 h (250 L/h)	20 x 50 L in 4 h (250 L/h)	16 x 10 L in 40 minutes (240 L/h)

ACCURACY

Accuracy gravimetric	±2 g (10 - 500 mL) / ±5 g (500 - 1000 mL)	±2 g (10 - 500 mL) / ±5 g (500 - 1000 mL)		±20 g (0.2 kg - 5 kg) / ±25 g (5 kg - 20 kg)	±100 g		±10 g
Accuracy flow sensor	±20 % (1 - 5 mL) / ±10 % (6 - 20 mL)	±20 % (1 - 5 mL) / ±10 % (6 - 20 mL)		not available	not available		not available
Reading	1 g	1 g		1 g	50 g	50 g	1 g
Weighing Class	OIML R60 class C3	OIML R60 class C3		OIML R60 class C3	OIML R60 class C3		OIML R60 class C3

VALVE SET UP

Valves per rack (tower)	12+1	36+2	64+2	20+1	10+1	up to 24
Actuation type	Electric	Electric		Electric	Electric	Electric
Pinch function	Included	Included		Included	Included	Included
Stepper function	Included	Included		Upgrade	Included	Upgrade
Sealer function	Included	Included		Upgrade	Upgrade	Upgrade
Perforation function	Included	Included		Upgrade	Upgrade	Upgrade
Bubble sensors per rack	1	2		1	1	1

* The specified values refer to the standard version; customized changes are possible on request.

RoSS.FILL Standard Configurations

MANIFOLD SET UP	RoSS.FILL Lab Scale	RoSS.FILL CGT		RoSS.FILL Bag	RoSS.FILL Base		RoSS.FILL Bottle
		36 valves	64 valves		1500kg	3000kg	
Max. Pump tubing OD	3/8"	5/8"		5/8"	5/8"		5/8"
Main Manifold OD	3/8"	3/8"		3/8"	5/8"		3/8"
Bag Branches OD	1/4"	1/4"		3/8"	5/8"		3/8"
Manifold Supply	Single Use Support + all other vendors	Single Use Support + all other vendors		Single Use Support + all other vendors	Single Use Support + all other vendors		Single Use Support + all other vendors

DIMENSIONS & WEIGHT (EXCLUDING CU)

Dimensions (LxWxH)	1000 x896 x1671 mm 39.370 x 35.276 x 65.787"	1717 x 770 x 1617 mm / 67.598 x 30.315 x 63.661"	2317 x 770 x 1617 mm / 91,220 x 30,315 x 63,661"	1789 x 932 x 1841 mm 70.433 x 36.693 x 72.480"	1882 (+250)x 1920 x 1477 mm / 74.094 (+9.843) x 75.590 x 58.150"	1882 (+250) x 1920 x 1777 mm / 74.094 (+9.843) x 75.590 x 69.960"	2084 x 843 x 1565 mm 82.047 x 33.189 x 61.614"
Weight	280 kg	420 kg	690 kg	675 kg	280 kg	435 kg	410 kg

CU SPECIFICATIONS

Pump	Watson Marlow 314 DW	Watson Marlow 630	Watson Marlow 630	Watson Marlow 630	Watson Marlow 630
Max. pump speed	350 mL/min (1/8"ID) / 1224 mL/min (1/4"ID)	7200 mL/min (3/8" ID)	7200 mL/min (3/8" ID)	7200 mL/min (3/8" ID)	7200 mL/min (3/8" ID)
Flow sensor	Upgrade	Upgrade	Not available	Not available	Not available
Sample scale	No	Yes	Yes	Yes	Yes
Label printer	Included	Included	Included	Included	Included
Provision for filter	Included	Included	Included	Included	Included

VARIOUS

Designed in accordance with	ASME / CE / UL /ASME-BPE / cGMP / 21 CFR Part 11	ASME / CE / UL /ASME-BPE / cGMP / 21 CFR Part 11	ASME / CE / UL /ASME-BPE / cGMP / 21 CFR Part 11	ASME / CE / UL /ASME-BPE / cGMP / 21 CFR Part 11	ASME / CE / UL /ASME-BPE / cGMP / 21 CFR Part 11
Electrical power supply	230V 50Hz / 115V 60Hz	230V 50Hz / 115V 60Hz	230V 50Hz / 115V 60Hz	230V 50Hz / 115V 60Hz	230V 50Hz / 115V 60Hz
Available as I/O	Yes	Yes	Yes	Yes	Yes
Control system manufacturer	Siemens S7 / Delta V / PCS 7	Siemens S7 / Delta V / PCS 7	Siemens S7 / Delta V / PCS 7	Siemens S7 / Delta V / PCS 7	Siemens S7 / Delta V / PCS 7
Communication	OPC UA interface available	OPC UA interface available	OPC UA interface available	OPC UA interface available	OPC UA interface available
Mobile system	Yes	Yes	Yes	CU-yes / Scale-no	Yes