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# AUSTAR vivafill Aseptic Filling Line



AUSTAR is a technology-based pharmaceutical engineering solution provider with deep understanding of pharmaceutical industry regulations and processes. Integrating global high-quality resources, AUSTAR is committed to helping clients improve pharmaceutical process and operational effectiveness. Through efforts in promoting global drug safety and efficacy to make contribution to human health.

The vivafill series consists of the latest state-of-the-art aseptic filling and closing technology to meet the requirements of the pharmaceutical industry. It is designed, developed and manufactured by AUSTAR in compliance with cGMP and meets the standards of all major regulatory bodies.

## Contents

# vivafill Filling Lin **Rotary Washing** Depyrogenation Liquid Filling Ma Powder Filling M Capping Machine Isolator Turn-Key Solutio

#### AWSTAR | vivafili

ne Overview	02
Machine	- 03
Tunnel	- 04
chine	- 05
lachine	- 07
e	- 09
	- 10
ons	- 11









Cartridges















Other formats



RTU \_\_\_\_





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#### **Core Business**

The flexibility and modularity of vivafill series allows the customers to cope with a wide range of needs to fill both injectable liquids and powder products into diverse primary packaging forms such as glass vials, infusion bottles, PFS, cartridges, plastic bottles, etc. Either to be processed in bulk or as pre-sterilized (Ready-To-Use), our comprehensive range of machinery can be arranged and configured to meet the user requirements while keeping the most cost-effective and suitable solution.

#### **Product Range**

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The product range includes a series of washers, depyrogenation tunnels, liquid and powder filling equipment, capping machines (Alu/Screw caps) and tray loading systems. Furthermore, it can be easily combined with LYOCORE and LYOSMART series for freeze drying by means of automatic loading and unloading systems to reach a maximum output of 36,000 vials per hour (based on 2R vial).

#### Your Reliable Partner in Aseptic Filling

Whether you are a CXO, a research laboratory, a pharmaceutical or biopharmaceutical company, we at AUSTAR shall support you throughout the entire life cycle of our machines. Rely on our global net of experts to discuss the specifics of your project and together will lead the future of the pharmaceutical industry.



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## vivafill Filling Line Overview



## **Rotary Washing Machine**

## **Depyrogenation Tunnel**





- One needle for one vial
- Inverted vials flushed by WFI and
  Auto pipeline drying system clean compressed air
- Online sampling & rejection

  - Safety cover auto lifting
- Fully servo motor driving system
- Ultrasonic bath

	Specifications							
Model	Max Output		rinner No Formats ' Power WiFi ( onslimption		WFI Consumption	Clean Compressed Air Consumption		
RWU1248	12/48	2ml-20ml	200vpm	17KW	600W	0.2-0.4Mpa; 0.6m³/h	0.35-0.4Mpa; 20m³/h	
RWU2060	20/60	2ml-100ml	300vpm	17KW	600W	0.2-0.4Mpa; 0.7m³/h	0.35-0.4Mpa; 25m³/h	
RWU2080	20/80	2ml-100ml	400vpm	17KW	600W	0.2-0.4Mpa; 0.8m³/h	0.35-0.4Mpa; 30m <sup>3</sup> /h	
RWU30120	30/120	2ml-10ml	550vpm	19KW	1200W	0.2-0.4Mpa; 1.0m³/h	0.35-0.4Mpa; 40m³/h	



- Hot air circulation system realize drying, sterilization depyrogenation of vials
- Auto air pressure balanci
- CIP for belt

	Specifications						
Model	Belt Width	Formats	Max. Output (2ml)	Max. Output (10ml)	Power	Ultrasonic Power	Cooling Water Consumption
HDT300L1	300mm	2ml-30ml	60vpm	30vpm	30KW	600W	$1.0\sim1.5~\mathrm{m^3/h}$
HDT450L1/L2	450mm	2ml-100ml	200vpm	150vpm	45KW	600W	$1.5 \sim 2 \text{ m}^3/\text{h}$
HDT620L1/L2	620mm	2ml-100ml	300/350vpm	200/300vpm	65/72KW	600W	$3\sim4m^3/h$
HDT870L2	870mm	2ml-100ml	500vpm	400vpm	86KW	1200W	$4\sim5\mathrm{m^{3}/h}$
HDT1200L2	1200mm	2ml-100ml	600vpm	500vpm	112KW	1200W	$6 \sim 8  \mathrm{m^3/h}$

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hts		:
n to		Auto/Manual shutter lifting function
on and	•	Auto/Manual vial emptying function
ing system	•	SIP for cooling zone
	•	Inflatable sealing door at outfeed

## Liquid Filling Machine



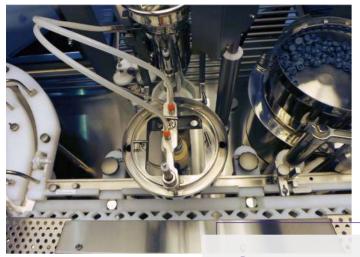
	Specifications							
Model	Filling Needle	Formats	Max. Output (2ml)	Power	Vacuum Consumption	Compressed Air Consumption		
FIL4/8TRC	4 or 8	2ml-100ml	150/250vpm	16KW	Vacuum Level: -8~-100kpa; 90m³/h	0.6Mpa; 30m <sup>3</sup> /h		
FIL10/12TRC	10 or 12	2ml-100ml	350/450vpm	18KW	Vacuum Level: -8~-100kpa; 90m³/h"	0.6Mpa; 30m <sup>3</sup> /h		
FIL14/16TRC	14 or 16	2ml-30ml	500/550vpm	20KW	Vacuum Level: -8~-100kpa; 90m³/h	0.6Mpa; 30m³/h		

Madal	Specifications						
Model	Filling Needle	Formats	Max. Output (2ml)	Power	Vacuum Consumption	Compressed Air Consumption	
FIL2/4-RCP	2 or 4	2ml-100ml	60/120vpm	14KW	Vacuum Level: -8~-100kpa;60m³/h	0.6Mpa; 20m <sup>3</sup> /h	
FIL6/8-RCP	6 or 8	2ml-30ml	150/200vpm	16KW	Vacuum Level: -8~-100kpa;60m³/h	0.6Mpa; 20m <sup>3</sup> /h	

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## **Powder Filling Machine**



#### ( Oscillating Needle Filling

- Fully servo drive
- 100% IPC system
- Nitrogen purge (before & after filling)
- RABS or isolator integration EMS system

• Online sampling & rejection

Media filling station

TypeModelImage: Dosing NeedleFormatsMax. Output (2ml)Oscillating Needle FillingFIP1/2RVCP1 or 22ml-30ml40/80vpmAuger FillingFIP2/4TRC2 or 42ml-100ml150/260vpm



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Specifications						
Power	Fill Weights	Vacuum Consumption	Compressed Air Consumption			
12KW	0.02g-2g	Vacuum Level: -85~-100kpa; 60m³/h	0.6Mpa; 20m <sup>3</sup> /h			
17KW	0.2g-10g	Vacuum Level: -85~-100kpa;90m³/h	0.6Mpa; 30m <sup>3</sup> /h			

## **Capping Machine**

#### ( Disc Blade

• One disc for multiple capping heads

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- Aluminum particles suction
- Stopper sealing inspection
- Online rejection
- EMS sytem
- Isolator integration
- Capping pressure monitor





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Online rejection

RABS or isolator

integration

#### (3) Individual Crimping Disc

- Individual crimping disc for
- containers
- Aluminum particles suction
- Stopper sealing inspection EMS system

<b>T</b>	Madal	Specifications							
Туре	Model	Pump Heads	Formats	Max. Output (10ml)	Power	Vacuum Consumption	Compressed Air Consumption		
	CAP0106	6	2ml-100ml	200vpm	4KW	Vacuum Level: -8~-100kpa; 60m³/h	0.6Mpa; 20m³/h		
Disc Blade	CAP0110	10	2ml-100ml	400vpm	4KW	Vacuum Level: -8~-100kpa; 60m³/h	0.6Mpa; 20m³/h		
	CAP0116	16	2ml-100ml	520vpm	4.5KW	Vacuum Leve: -8~-100kpa; 60m <sup>3</sup> /h	0.6Mpa; 20m³/h		
Individual Crimping Disc	CAP0201/02	1 or 2	2ml-30ml	30/60vpm	2KW	Vacuum Level: -8~-100kpa; 30m³/h	0.6Mpa; 30m³/h		





Tuno	Model	Specifications							
Туре	Model	Leakage Rate V%/H	Application	Cleanliness Level	Material Transfer	Decontamination Time	BIBO		
Isolator for Aseptic Filling	AISF01	<1%	Aseptic filling machine, freeze dryer & ALUS	ISO5	RTP,SART	<4.0 h	-		
Aseptic Isolator for High Potent & Toxic Products	AITF01	<0.5%	Aseptic filling machine, freeze dryer, ALUS, capping machine and external washing machine	ISO5	RTP,SART	<4.5h	H14		

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## **Turn-Key Solutions**

## -• **Freeze Dryer**

- As the leading pharmaceutical engineering solution provider, AUSTAR can offer clients customized cGMP freeze-drying solutions with reduced cost. AUSTAR freeze dryer boasts the technology from Europe and has three sub brands: xLYOLAB、LYOCORE and LYOSMART respectively for lab, API and preparation freeze drying.
- AUSTAR is committed to providing product friendly and intelligent freeze dryer, which is designed and manufactured as per European standard. All systems are fully tested in AUSTAR factory under actual working conditions to ensure excellent performance.
- AUSTAR freeze dryers are applicable to production of biopharmaceuticals, APIs and chemical preparations, which is also in compliance with cGMP and FDA regulatory regulations, satisfying the strictest pharmaceutical and biological industrial standards. The shelf area covers from  $0.5 \sim 40 \text{ m}^2$ .

			Specifica	tions		
Model	Shelves Temp Range	Shelves Heating Rate	Shelves Cooling Rate	Minimum Condenser Temp	Final Vacuum	Leakage Rate
xLYOLAB0.5	-65 ~ 80°C	1°C /min	20 ∼ -40°C ≤ 60min	-85°C	0.005mbar	0.01mbar*L/s
LYOCORE01-40	-55 ~ 80°C	1°C /min	20 ~ -40°C≤ 50min	-75°C	0.005mbar	0.01mbar*L/s
LYOSMART01-40	$-55 \sim 80^\circ \mathrm{C}$	1°C /min	20∼-40°C≤ 50min	-75°C	0.005mbar	0.01mbar*L/s

xLYOLAB







LYOSMART

## Automatic Loading and Unloading System (ALUS)

• The ALUS can act as the aseptic connection from filling and stoppering machine to freeze dryer and further to the

#### The RBR type has two forms-single row and double row and the speed of double row type can reach 600 vpm.

Model	Specifications				
Model	Single Row Loading Speed@2R(ISO)	Single Row Loading Speed@6R(ISO)			
ALU06-R-S	200	150			
ALU09-R-S	300	200			
ALU12-R-S	400	300			
ALU15-R-S	500	400			

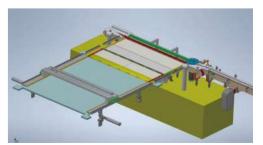


- Simple and novel design with reduced cover space
- Operate within isolator in A level area
- Driven by lithium battery with lower leakage risk
- Easy clean and maintenance with a moveable guarding rail shared for each shelves

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capping machine. By reducing operator intervention, the ALUS can uplift production efficiency and sustain consistent aseptic environment and in the meanwhile integrate with different barrier systems like O-RABS, C-RABS and isolators. There are two ALUS types available from AUSTAR- RBR (Row by row) or GRP (Guideless Robotic Pusher)

#### The GRP type can reach speed of 600 vpm in single row





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