AUSTAR

Brief Introduction of OSD Process System

Your OSD Solution Partner

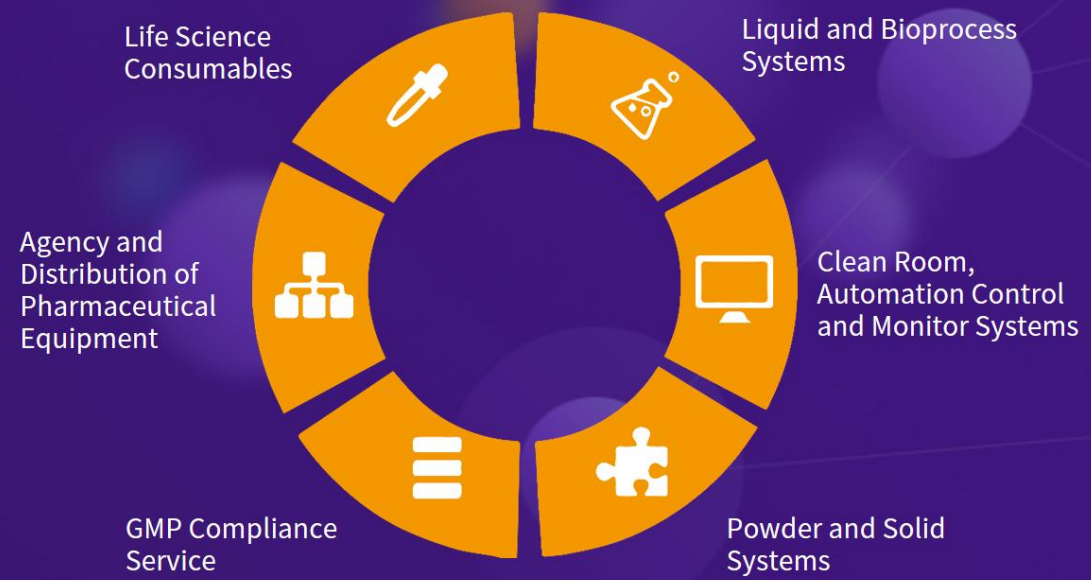
www.austarunion.com

Connecting Extraordinary Ideas

Professional Pharmaceutical Solution Provider

AUSTAR Group is an advanced technology-based pharmaceutical engineering solution provider with comprehensive knowledge and experience in life-science process technology, applications, industry regulatory rules and practices. We take pride in being able to help clients address issues in quality, compliance and operation excellence, and dedicate to providing equipment-engineering-service-consumables turnkey solutions, so as to promote and to promoting industry advancement and create value.

AUSTAR Group was founded in 1991 in Hong Kong, the headquarters is in Beijing, PRC. The Company was listed on the Main Board of the Stock Exchange of Hong Kong Limited on 7 November, 2014 (Stock code: 6118).



Business Milestones

30+ Years' Growth
Dedicating to Providing
Exceptional Values to
Our Clients

Manufacturing Center

AUSTAR has three production sites in Mainland China, which are located in Shanghai, Nanjing and Shijiazhuang.

Two high-tech and quality assembling workshops are located in Dresden, Germany (majority holding) and Huddersfield, UK.

Huddersfield UK

- Containment Isolators
- Aseptic Isolators
- Filling Line Isolators
- DownFlow Booths

Shijiazhuang Manufacturing Center

- Manufacture of Pressure Vessels
- Automatic Control Systems
- Powder and Solid Systems
- Liquid Process Systems
- Clean Room Systems

Dresden Germany

- Water Pretreatment Units
- Purified Water Equipment
- Cold WFI Equipment
- PW & WFI Distribution

Shanghai Manufacturing Center

- Purified Water Generator
- Pure Steam Generator
- Multiple Effect Water Distiller
- Bioreactor and Fermentor
- Various Process Skids Including Medium and Buffer Preparations
- Sanitary Vessels & Heat Exchangers

Nanjing Manufacturing Center

- Freeze-drying System
- Freeze-drying Laboratory
- Filling Line

Introduction/Bio - Ron Ciaglia

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Qualifications – Director of OSD Engineering and Technology with AEG

- Experience – Over 30 years Engineering, Design, Technical Sales and Support, Installation, Start Up Commissioning, Validation, & Processing of OSD equipment for the Pharmaceutical, food, flavor, Industrial and chemical facilities.
- Education
  - Bachelors Science Aerospace Engineering
  - Degree Mathematics
  - Degree Engineering Administration
  - EIT/FE professional engineer, Member of ISPE, SAE, AIAA, continued training/education

- System Engineering, Retrofits/Upgrades Support/Service
  - **High Shear Granulators (Mixer)** …… **Diosna**, Glatt, Niro, Vector, **Fluid Air**
  - **Fluid Bed Dyer/Granulation/Coating** …….. **Glatt**, Niro, Vector, Ohara Aeromatic, **GEA**, **Fluid Air**
  - **Coating Pans** …… Thomas, Vector, Fryma, Glatt, O'Hara, Pelligrini
  - **Bead Making Systems / Pelletizing** …… (Maruemerizers/Extruder) LCI
  - **Spray Drier** …….. Spraying System Fluid Air, Anhydro, SPX
  - **Milling** …… **Fluid Air**, **Fitzmill**, **Co-mill**

- Design, Installed, Commissioned, Validated systems in more than 22 countries on 5 continents, worked in china since 1998
- **Over 30 years of combined solid dosage processing expertise Tested, Developed or Manufactured over 1000 products.**
- **Numerous countries, Class of products, manufacturing levels**

Please feel free to ask questions at anytime throughout the presentation. I am happy to share my experience with you

Introduction of Senior Product Manager – Global OSD Projects

AMSTAR

Mr. Amrit Tiwari has more than 17 years of rich experience in execution of OSD & sterile projects (Greenfield and Brownfield Projects) , Business Development ,Installation & Commissioning, Maintenance ,Validation & Processing of OSD equipment in Pharmaceutical companies in different parts of world .

- Past Companies & key equipment handled :

✓ High Shear Granulators (Mixer) Diosna, Glatt, GEA ,ACG worldwide ,Tapasya

✓ Fluid Bed , Wurster ,Flexstream based Fluid Beds – Glatt, GEA, ACG Worldwide

✓ Coating Pans – Glatt ,ACG worldwide, Sejong

✓ Tablet Press – GEA, Sejong

✓ Continuous Granulation – Glatt , GEA

✓ Sandoz India Ltd (Novartis Group)

Topics

01 What can we provide to the OSD Process System

02 Experience Sharing

03 Advanced Tech/Competitive Advantage of AEC

04 About PSS

Powder & Solid Process Systems

AUSTAR provides turnkey solutions for sophisticated production processes of pharmaceutical intermediates, API, OSD, and pharmaceutical excipients clients and offers a comprehensive service including formulation process technology, containment technology, innovative R&D, process design and project management.

Process Engineering Solution

- Turnkey solution
- Process system
- Core engineering equipment
- Components/Consumables

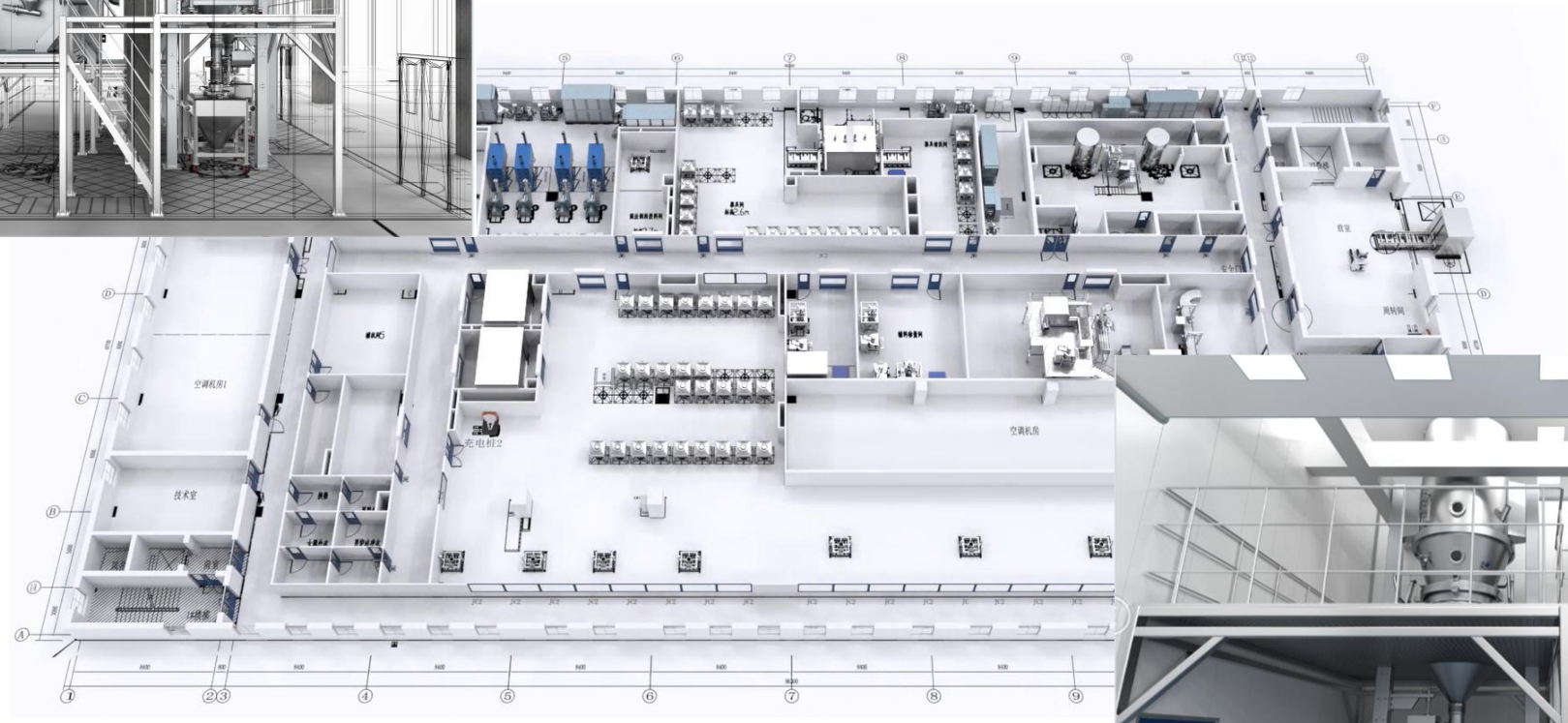
Process Design & Consultation

- Feasibility study
- Conceptual design
- Basic design
- Detailed design

Process Optimization Scale-up Research Services

- Process engineering laboratory
- Joint laboratory with partners
- Formulation technology experts
- Cooperation with universities

OSD Process Systematic Solution



OSD Process Systematic Solution

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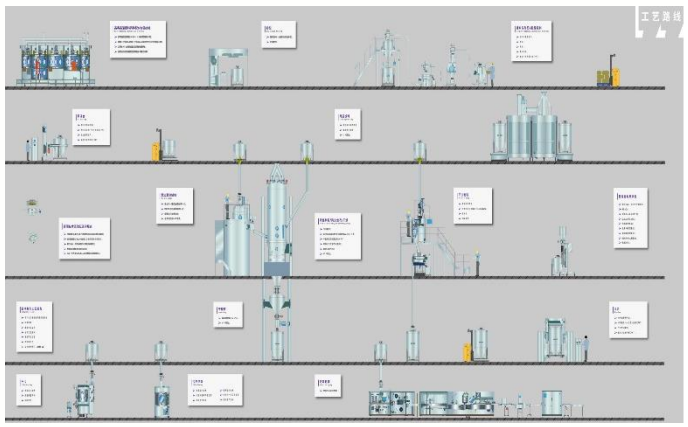
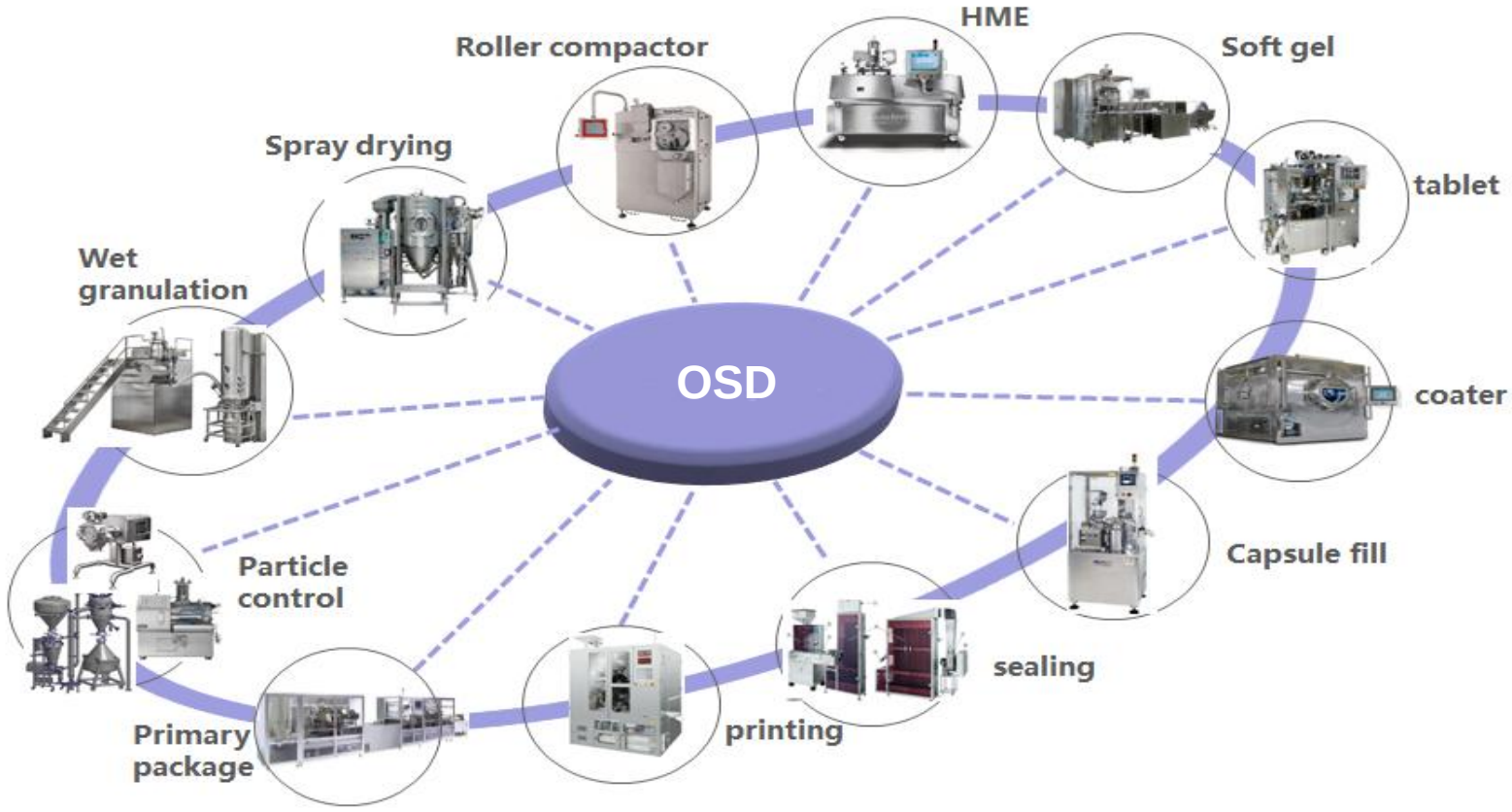
OSD project—High quality resource integration ability

- Mainly focus on Formulation technology
- Lab scale machine from world leading technology providers
- Solid oral dosage engineering team with rich experience
- Various partners provide professional engineering support





Leistritz · Alexanderwerk · NEUHAUS NEOTEC · WAB · 株式會社 菊水製作所 · Thomas

OSD Formulation/Lab Equipment/Process Service

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Hammer Mill

Jet Mill

Impact Mill

Extruder

Roller Compactor

High Shear Mixer

Fluid bed

Tablet Coater

Micro NIR PAT-U

Eyecon$_2$ Real-time particle analyzer

Process Research Center – Scope of Services

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Scope of services

Development and optimization of formulation process

- Process development and optimization
- Determination of CQA,CMA and CPP
- DOE (Design of experiment)
- Development of online PAT
- Determination of design space

Analysis and inspection

- NIR modeling and application
- Eyecon online particle size inspection
- Soft capsules (viscosity, thickness inspection)
- Inspection and analysis of moisture, flowability, density and particle size distribution

Process transfer, scale-up and optimization

- Data analysis
- Determination of process parameters
- Determination of design space
- Control strategy

Scope of process services:

- Particle size control process (wet milling, jet milling and mechanical milling
- Granulating processes (high shear wet granulating, dry granulating, one-step granulating, melt granulating, continuous wet granulating, etc.)
- Fluid bed coating process (pellets coating, granules coating, mini-tablet coating)
- Hot melt extrusion, softgel encapsulating, spray drying, tabletting, capsule filling and tablets coating processes
- Continuous wet granulating, continuous dry granulating, continuous direct compression process route development and optimization, modeling
- PAT application and modeling

Process Research Center – Technical Team

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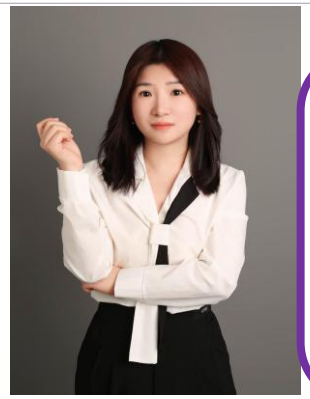

Almost ten years' experience in formulation process development and process scale-up technology transfer;
Familiar with OSD technology and DOE (Design of Experiment);
Rich experience in process development, process and PAT modeling.

13 years' experience in solid preparation production technology management in large scale pharmaceutical enterprise;
7 years' experience in solid preparation project planning and execution in pharmaceutical enterprise;
Research direction: solid preparation process scheme procedural design and layout optimization, schematic design and implementation of digital solid preparation production system, small test, pilot test and commercial batch scale-up study of wet granulating process and fluid bed granulating process (chemical drug and TCM), and unique study of highly viscous and hygroscopic formulations

11 years' experience in R&D and production in large scale pharmaceutical factory;
Familiar with pharmaceutical process, equipment, GMP certification and relevant regulations;
5 years' experience in installation & commissioning of imported equipment and engineering project execution and management;
Rich experience in organic combination of equipment and processes.

Focusing on application technology study for wet granulating;
Familiar with pharmaceutical process, equipment and OSD R&D and technology transfer;
3 years' experience in MNC, and 10 years' experience in drug R&D.

Subject matter expert on solid preparations continuous manufacturing;
Over 10 years' experience in pharmaceutical production and quality management;
Focusing on technical application study for solid preparations continuous process;
Familiar with PAT application in solid preparation field;
Familiar with relevant GMP and FDA regulations.

Focusing on wet milling process and equipment research;
Familiar with pharmaceutical process/equipment, relevant policies and regulations;
Over 10 years' experience in solid preparations production equipment management;
Familiar with solid preparation production process and relevant equipment.

Specializing in solid preparations R&D and industrial transfer;
Rich experience in solid preparations R&D;
Over 3 years' experience in solid preparations R&D and scale-up study.

Focusing on dry granulating process and equipment research;
Familiar with pharmaceutical process/equipment, relevant policies and regulations;
Rich experience in OSD production and equipment management;
Over 5 years' experience in solid preparations production equipment management.

Over 13 years' experience in soft capsules production and maintenance;
Specializing in installation, maintenance and commissioning of softgel encapsulating machine;
Unique understanding of soft capsule production process and process optimization;
Proficient in dry granulator technology.

Process Research Center – Customers

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OSD Process System / Commercial Solution

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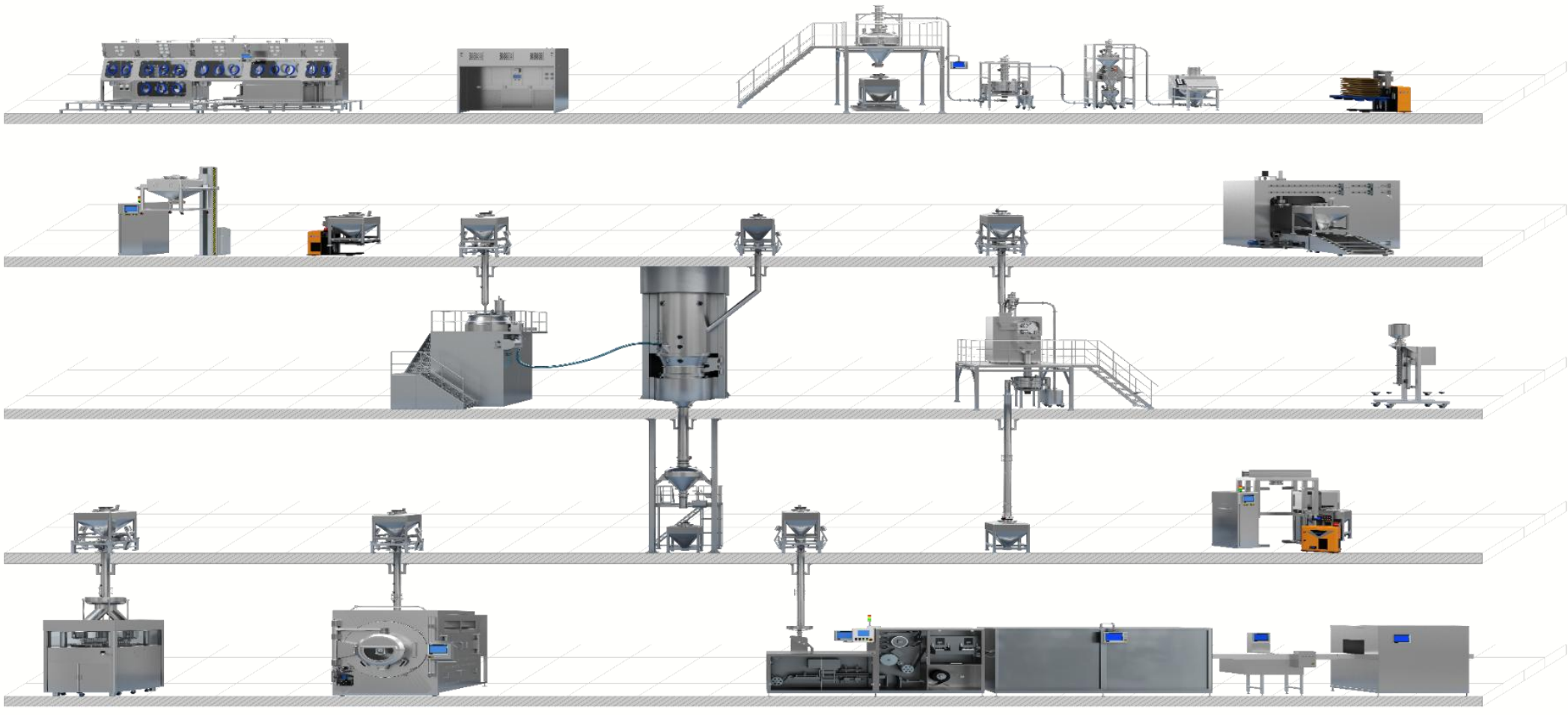

OSD CT Solution

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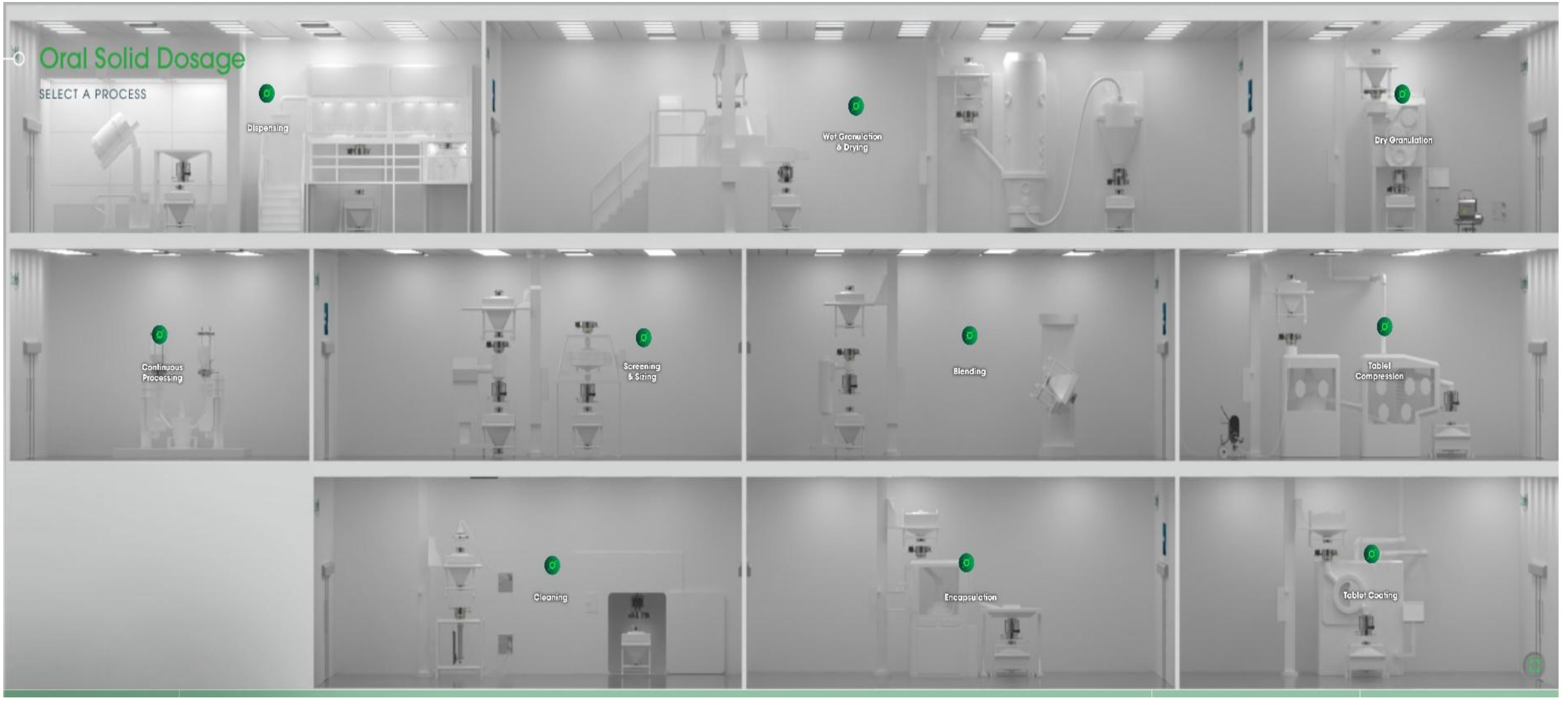
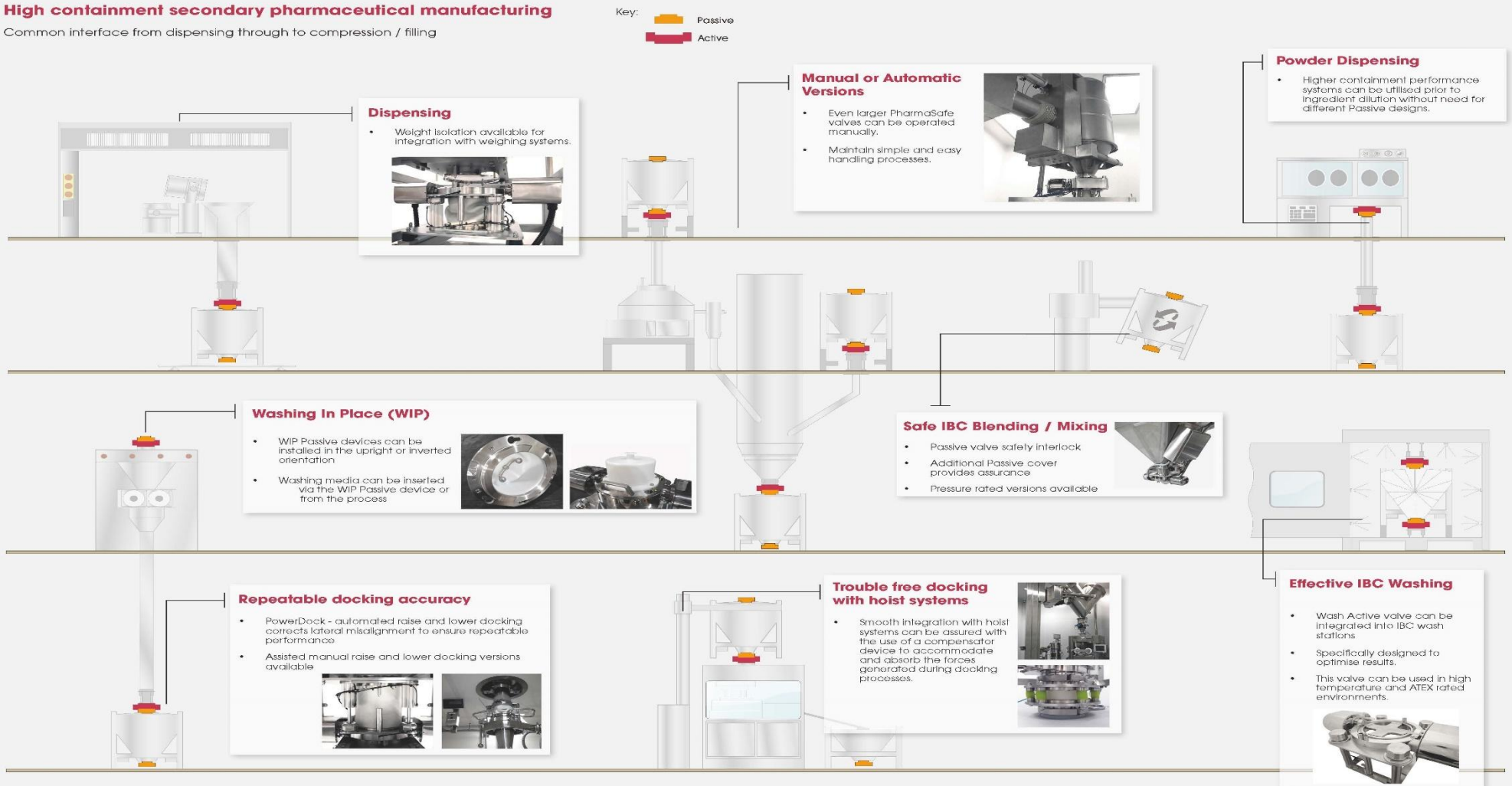


OSD CT Solution



Topics

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03 Advanced Tech/Competitive Advantage of AFC

04 About PSS

Experience on Oral Solid Dosage Forms

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Eisai | Biogen

Experience on Oral Solid Dosage

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Program	Commercial rights	Indication	Zai Lab clinical stage	Partnerships
ZL-2306 (Niraparib)	China, HK and Macau	Ovarian cancer	CTA approved for Phase 3	TESARO
		Breast cancer	CTA approved for Phase 3 (protocol currently under discussion with CFDA)	
		Lung cancer	CTA approved for Phase 2 (protocol currently under discussion with CFDA)	
ZL-2401 (Omadacycline)	China, HK, Macau and Taiwan	ABSSSI	Preparing for CTA Submission for Phase 3	PARATEK
		CABP	Preparing for CTA Submission for Phase 3	
ZL-2301	China, HK and Macau	HCC	Phase 2	Bristol-Myers Squibb
ZL-3101 (Fugan)	Global	Eczema, Psoriasis	Phase 2	gsk
ZL-2302	Global	NSCLC	CTA submitted for Phase 1	SANOFI
ZL-1101	Global	GVHD, SLE	Pre-clinical	ucb

Actavis + Forest Laboratories, Inc.

CNS	GI	Women's Health	URO
Namenda XR	DELZICOL (mesalamine)	Minastrin 24 Fe	RAPAFLO (silodosin)
Viibryd	Asacol HD	Lo Loestrin Fe	Enablex (darifenacin)
Fetzima	Linzess (linaclotide)	Generess Fe	Gelnique (oxybutynin chloride) Gel 10%
Saphris	Carafate	Crinone	ANDRODERM
Lexapro	Canasa	Actonel	AndroGel
	PYLERA	Atelvia	TRELSTAR
	Rectiv	ESTRACE CREAM	

Clear Specialty Focus

Inflammation	Nephrology	Bone	Oncology	Cardiovascular
Enbrel etanercept	EPOGEN (EPOETIN ALFA)	prolia (denosumab) injection	XGEVA (denosumab)	Ivabradine
Brodalumab	Sensipar (cinacalcet) Tablets	Romosozumab	Vectibix (panitumumab)	Evolocumab
AMGEN BIOSIMILARS	Mimpara cinacalcet		Kyprolis (carfilzomib)	Omecamtiv mecarbil
Adalimumab	Aranesp (darbepoetin alfa)		Nplate romiplostim	
Infliximab	AMG 416		Nexavar (sorafenib tosylate) tablets	
			Aranesp (darbepoetin alfa)	
			Neulasta (pegfilgrastim)	
			NEUPOGEN (FILGRASTIM)	
			Talimogene laherparepvec	
			AMGEN BIOSIMILARS	
			Blinatumomab	
			Rituximab	
			Rilotumumab	
			Bevacizumab	
			Trebananib	
			Trastuzumab	
			Cetuximab	

Process Research Center – Process Service

No.	Variety	Product name	Dosage forms	Process
1	Antibiotics	Cephalosporins sustained release tablets	Tablets	wet granulation
2		Azithromycin	Tablets	High shear wet granulation
3		Nimesulide	Tablets	High shear wet granulation
4		Amoxicillin capsules	Hard capsule	NIR modeling for moisture determination
5		Ceftriaxone sodium	Injections	Filtering-washing-drying process
6	Digestive system	Omeprazole magnesium/amoxicillin/Rifambutin compound capsules	Hard capsule	Fluid bed coating (mini-tablet coating)
7		Omeprazole Enteric Capsules	Hard capsule	Fluid bed coating (pellet coating)
8		Changyanning dry ointment	Tablets	Viscous materials transfer and treatment
9		Simethicone Chewable Tablets	Tablets	Hot melt extrusion process(melt granulating)
10		Esomeprazole Magnesium Enteric-coated tablets	Tablets	Fluid bed coating process (pellet coating)
11	Psychotropics	Aripiprazole Tablets	Tablets	Top spray granulating
12		Venlafaxine Hydrochloride Sustained-Release Capsules	Hard capsule	Fluid bed coating process
13		Agomelatine tablets	Tablets	Wet granulating process
14		TL118 (anti-tumor drug)	Tablets	High shear wet granulation process

Process Research Center – Process Service

AVSTAR

No.	Variety	Product name	Dosage forms	Process
21	Anticancer Drugs	Sorafenib tosylate Tablets	Tablets	High shear wet granulation process
22	Antiviral drug	Ritonavir	Tablets	Hot melt extrusion process
23	Antihypertensive drugs	11	Tablets	Hot melt extrusion process
24	Blood system	Heparin	API	Filtering-washing-drying process
25	Blood system	Avatrombopag Maleate Tablets	Tablets	Jet milling process
26	Medications for treating Alzheimer's disease	Memantine Hydrochloride Sustained-release Capsules	Hard capsules	Fluid bed coating process (pellet coating
27	Anti-cold medicine	HuoXiangZhengQiRuanJiaoNang	Soft capsules	Softgel encapsulating process
28	Cardiovascular system	Metoprolol sustained-release tablet	Tablets	Fluid bed coating process (pellet coating)
29	Anti-atherosclerotic drugs	Polyunsaturated fatty acids	N/A	High shear wet granulation process
30	Jianpi Shengxue drugs (Chinese Patent Medicine)	Jianpi Shengxue Pian	Tablets	Top-spray granulating process
31	Vitamins	Vitamin D Soft Capsules	Soft capsules	Softgel encapsulating process
32		Calcium Carbonate and Vitamin D3	Tablets	NIR mix uniformity

Process Research Center – Process Service

No.	Variety	Product name	Dosage forms	Process
41	Others	Cigarette filtering granules	N/A	High shear wet granulation process
42		API granules	N/A	High shear wet granulation process
43		Tamarind cake	N/A	Lab type wet granulating line
44		Hyaluronic acid	N/A	High shear wet granulation process
45		Aluminum powders	N/A	Dry granulating line
46		Saccharose	N/A	High shear wet granulation process
47		ADN-9	N/A	Hot melt extrusion process
48		HP537	N/A	Hot melt extrusion process
49		Hyaluronic acid granular drink	Granules	High shear wet granulation process
50		Hyaluronic acid granular drink	Granules	Top spray granulating process
51		D0077	N/A	Jet milling process
52		WD-1602	Granules	Melt granulating process
53		WD-2010	Granules	Melt granulating process
54		WD-2102	Granules	Melt granulating

Experience on Oral Solid Dosage Forms

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Americas Central, South , North :

- Abbive
- Astra Zeneca – *** (150L, 300L, 500L)

  Bottom discharge
- Actavias
- Frontida
- Genzyme
- Alkermes
- Boehringer Ingelheim
- Teva
- Hoffman La Roche
- Pfizer
- Bristol Myers Squibb
- Forest
- Endo
- Ortho McNeil
- Merck ***

  Bottom discharge
- Reckitt Benckiser
- Mallinckrodt ***

  Bottom discharge
- Covidien
- Avon
- Kimberly-Clark
- Upsher-Smith
- Perrigo
- BiogenIdec
- Watson
- Abbvie
- Amgen
- Glaxo Smith Kline
- Estee Lauder
- Astra Zeneca
- Gillead
- Bayer
- Pharmaceutical Int.
- Alza
- Amgen
- Eisai
- Biogen/IDEC
- TEVA
- Perrigo
- Catalent
- Biogen
- Neogen
- Sanofi
- Pfizer
- Westward
- Wyeth
- Abbott
- Takeda
- SUN
- Chao center – Purdue
- Novell
- Sperics
- Norwich
- Execlixis

Experience on Oral Solid Dosage Forms

Europe:

- Forest Ireland
- Reckitt Benckiser
- Actavias - Ireland
- Abbott UK
- Nestle Switzerland
- Bristol Myers Squibb Ireland

Latin America:

- Merck Brazil ***
  Bottom discharge
- Schering Plough _Brazil ***
  Bottom discharge
- Christalia Brazil
- Pfizer Argentina

Middle East:

- Advanced Pharma Jordan
- Hickma – Isreal

Africa:

- Xechem Nigeria

Canada:

- Lonza
- Apotex ***
  Bottom discharge
- Biovail
- Tetragenics
- Pharmasource

China/Asia:

- Janssen
- Pfizer - *** (2- 800L)
  Bottom discharge
- Avon
- Asymchem
- Apptec
- Hisun
- Pen-Tsao
- ZaiLab – coater ready
- Shenzhen Zhijun
- Pharmaron
- Hengreui
- Zailab

Experience on Oral Solid Dosage Forms

AVSTAR

Customers with common need – An engineered Solution to a Process Services Provided

- Feasibility
- R&D
  - Formulation Development
  - Process Development/Optimization
  - Scale Up
  - Tech Transfer
- Contract Manufacturing
  - Clinical Supplies
  - Commercial Production

Built to Meet Today's Processing Challenges

- Ability to Handle Many Types of Products:
  - Aqueous Based 水溶性
  - OTC Oncology, Controlled substance, etc
  - Solvent Based (No Chlorinated氯 Solvents)
  - Controlled Substances
    - License for Schedule II-V
    - Listed as a manufacturer of Diazepam安定, Codeine 可卡因(II and III), Phenobarbital苯巴比妥 (III and IV), Morphine吗啡, Amphetamine苯丙胺, Hydrocodone氢可酮, and Methyl Phenydate哌醋甲酯.

Experience on Oral Solid Dosage Forms

Our Range of Batch Sizes / Scalability

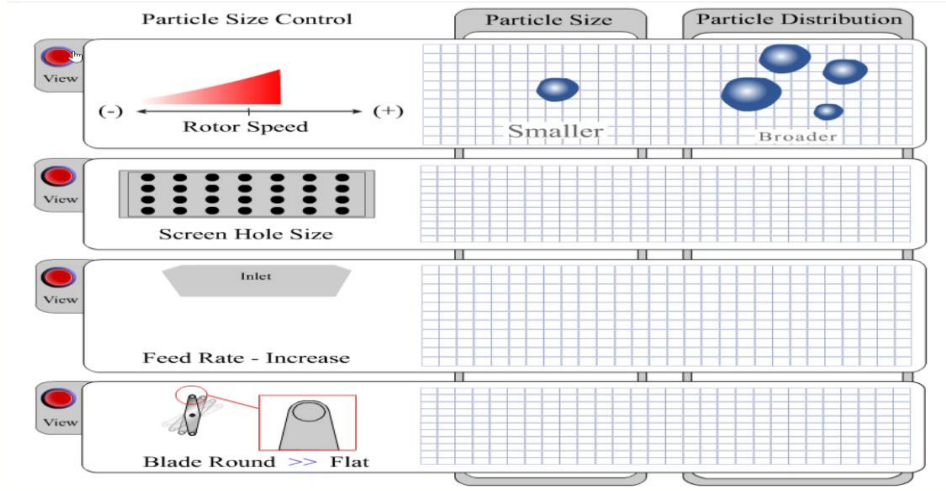
-- Feasibility & Development

➢Bench Top – ½ to 2 Kg Batches

-- Clinical, Stability & Tech Transfer (GMP)

➢Pilot Suite – 25 to 75 Kg Batches

Lab Coating, Granulation & Milling



Experience on Oral Solid Dosage Forms

Pilot Coating, Granulation & Milling

Feasibility & Development

- Bench Top – ½ to 2 Kg Batches

Clinical, Stability & Tech Transfer

- Pilot Suite – 25 to 75 Kg Batches

Production (GMP)

- 300 to 1,500 Kg Batches and larger

Experience on Oral Solid Dosage Forms

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Equipment Features Provide Flexibility to Handle the Most Difficult Products…

- For Drying/Granulating
  - Multiple Air Distribution Plate Types
  - Solvent Handling
  - Spray and Liquid Delivery Systems
  - Desiccant Dehumidification
- For Coating
  - Coating Zone/Holding Zone Air Flow Control
  - Multi-Partition System
  - Solvent Handling
  - Spray and Liquid Delivery Systems

Unique Production Process Control Capabilities

- Process Control Systems incorporate:
  - -- Process Analytical Technologies (PAT)
  - -- Flexible Automated Process Recipes
  - -- Metrology
  - -- Fully Electronic Part 11 Records with Signatures
  - -- Integration of Multiple Equipment Processing Control Centers with BAS
  - -- Wireless Technologies

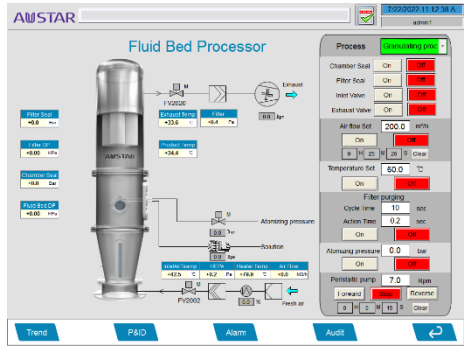
Advantages of AUSTAR AS YOUR PARTNER

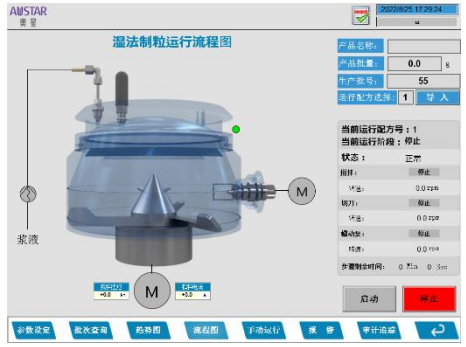
- We are focused on you!
  - -- Your success is our success!
  - -- Our primary focus is the Pharmaceutical Market .
    - We're easily accessible:
      - Factories around the world with global support
- Advanced Processing Features and Techniques *not offered* by Competitors!
- Superior and Immediate Service!

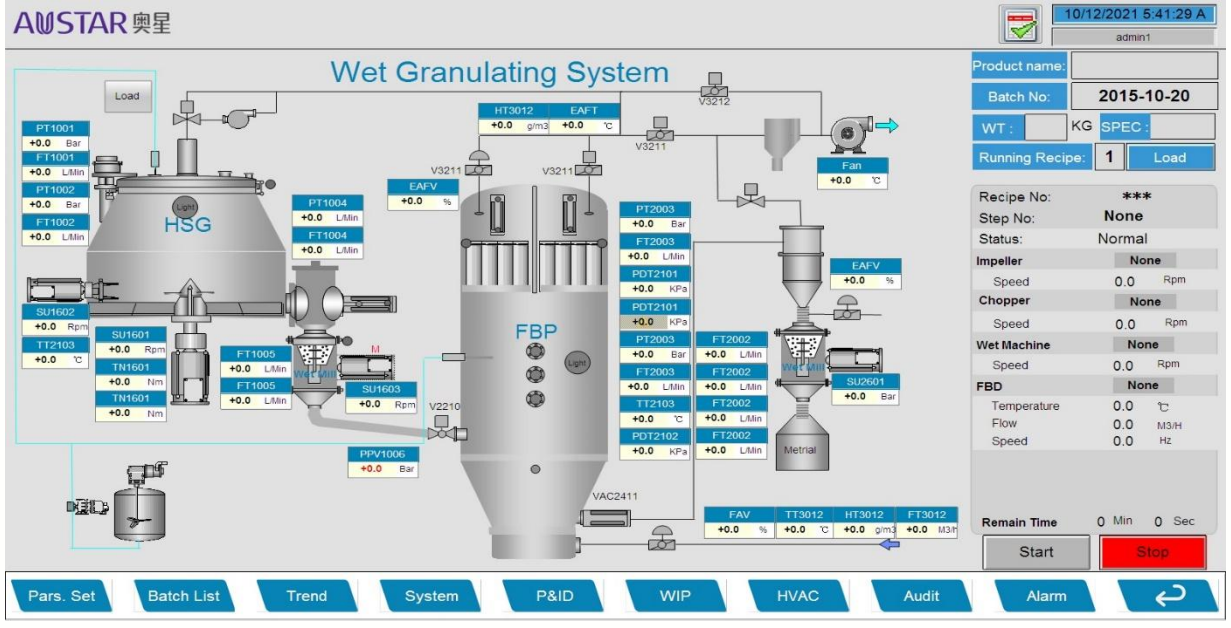
Experience on Oral Solid Dosage Forms

Key Project Review – fully realized systems - Controls

AUSTAR controls system utilizing Siemen PLC, HMI technology with GUI with multi language capability
Recipe driven with manual control and change
Datalogging and CFR 21 Par 11 capability down and upstream utilities.







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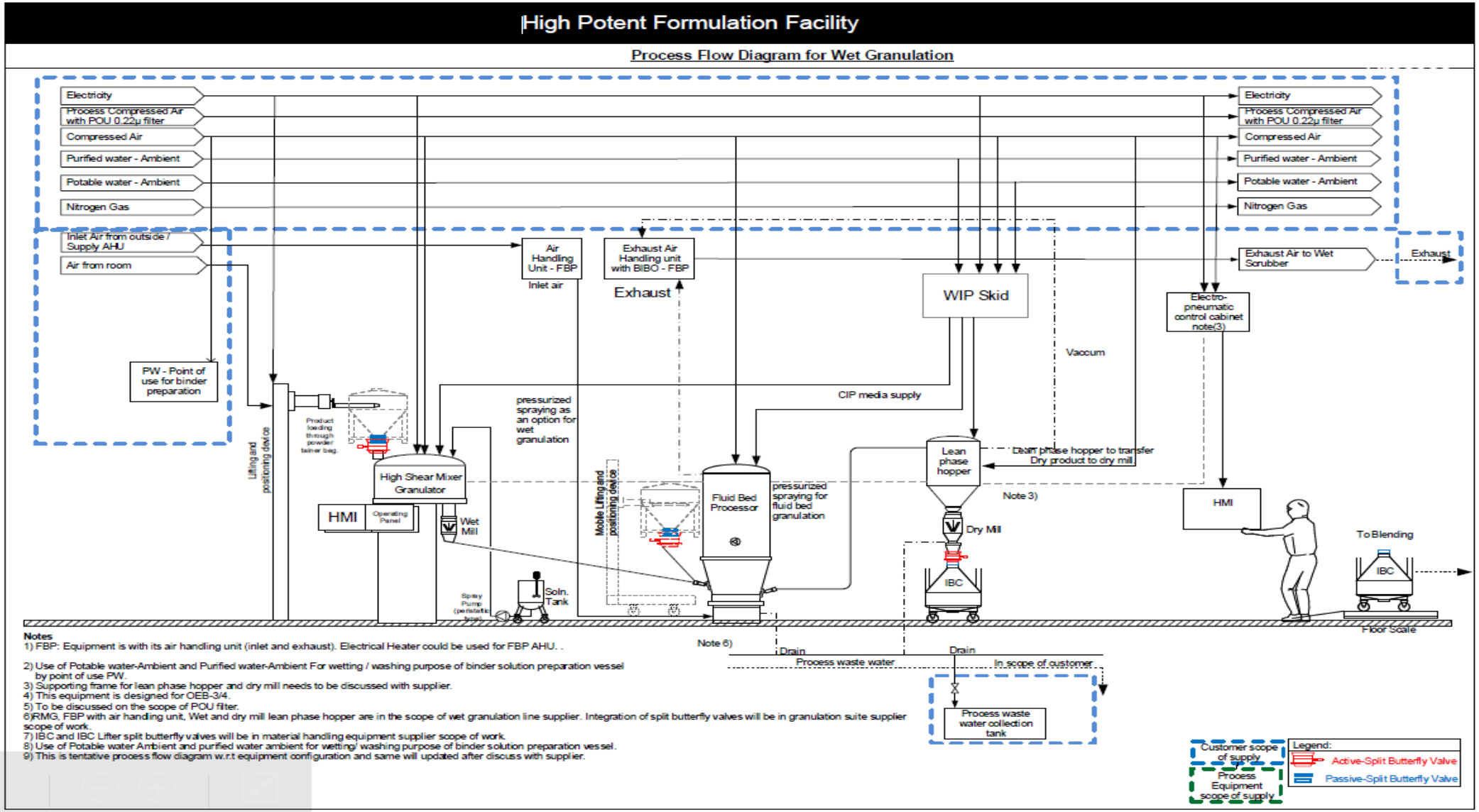
OSD CT Solution



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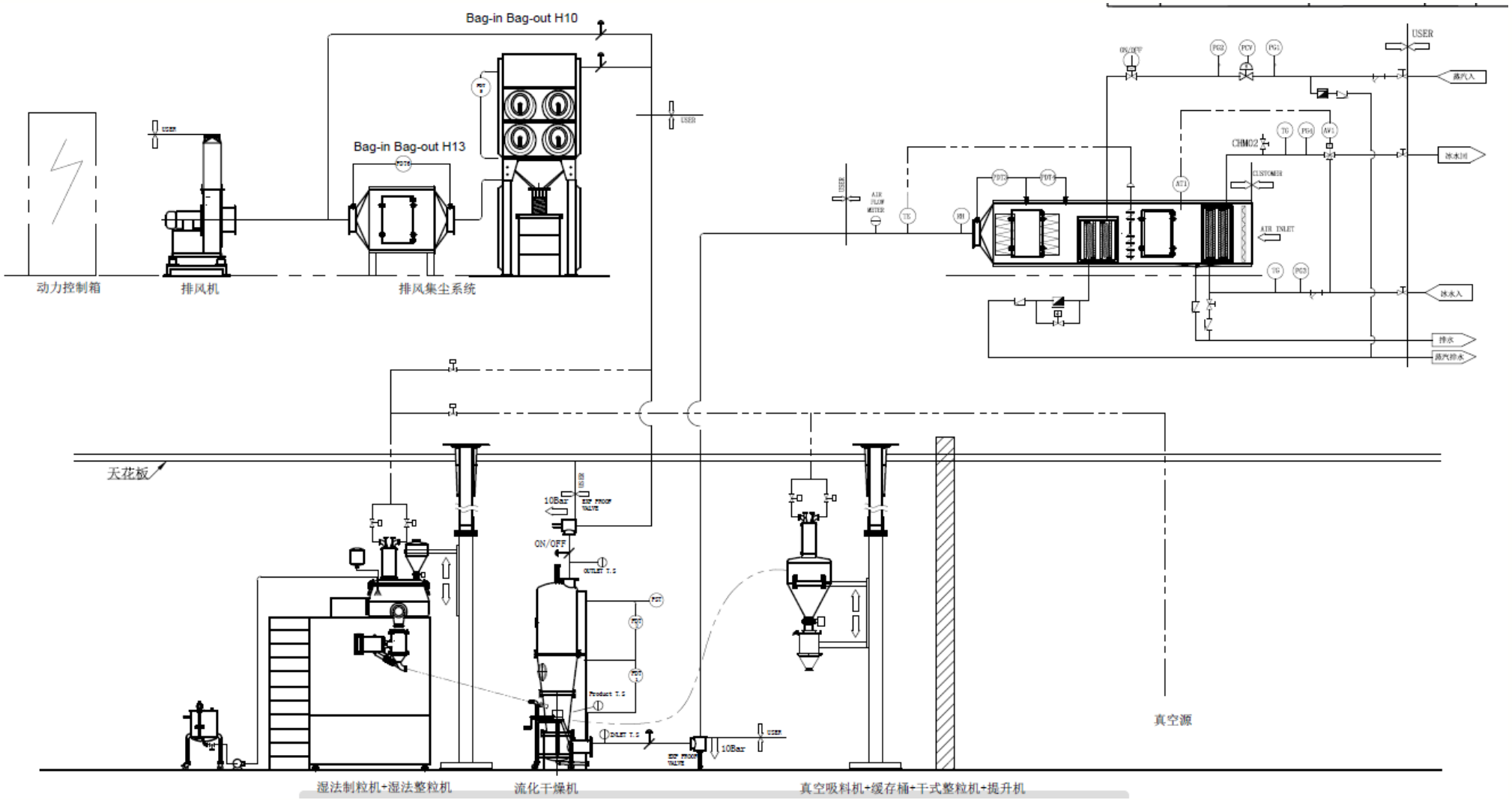
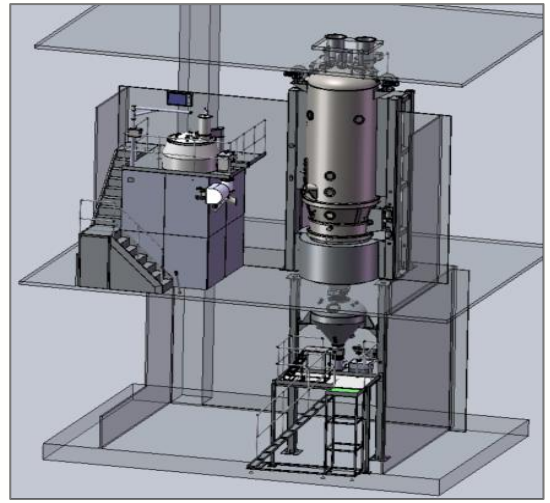


Features & Leading Advantage of PHS

Features & Leading Advantage of PHS



Features & Leading Advantage of HSG

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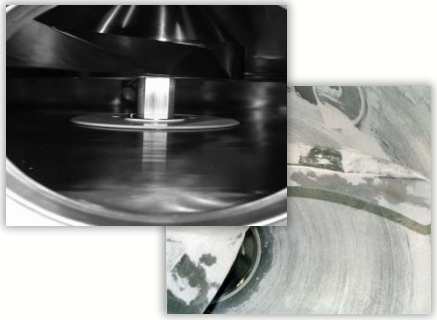
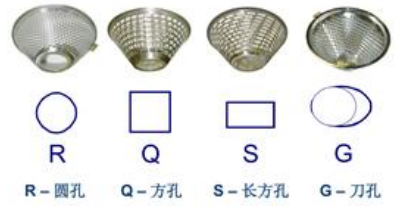
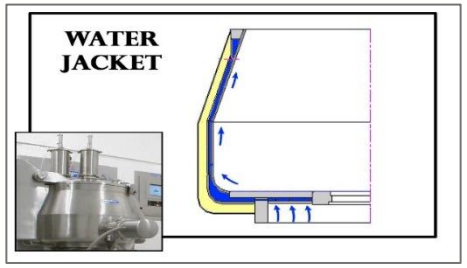
Technical Data Sheet(Standard)			HSG-12 (Container Interchangerable)						HSG-15	HSG-25	HSG-50	HSG-75	HSG-100	HSG-150	HSG-200	HSG-300	HSG-400	HSG-500	HSG-600	HSG-800	HSG-1000	HSG-1250	HSG-1500
Capacity	Full Capacity, L		0.5	1	2	4	8	12	15	25	50	75	100	150	200	300	400	500	600	800	1000	1250	1500
	Working Capacity (30%), L		0.15	0.3	0.6	1.2	2.4	3.6	4.5	7.5	15	22.5	30	45	60	90	120	150	180	240	300	375	450
	Working Capacity (85%), L		0.425	0.85	1.7	3.4	6.8	10.2	12.75	21.25	42.5	63.75	85	127.5	170	255	340	425	510	680	850	1062.5	1275
	Max Batch Size kg (0.5g/cm³)		0.2125	0.425	0.85	1.7	3.4	5.1	6.375	10.625	21.25	31.875	42.5	63.75	85	127.5	170	212.5	255	340	425	531.25	637.5
Drive	Impeller	Drive kw range required	1.0 - 1.1	1.0 - 1.1	1.1-1.3	1.3-1.5	1.5-1.7	1.1 - 1.5	1.1 - 1.5	1.1 - 1.5	1.5 - 2.2	5.3 - 5.6	3.7 - 4.8	7.3 - 7.5	13 - 15	17-20	17 - 20	20 -30*	32 - 38	35 - 55	50 - 72	58 - 80	58 - 80
		Drive, kW	2.2						3	4	4	5.5	7.5	11	15	22	22	37	45	55	75	90	110
		Speed, rpm	10-1340	10-1130	10 - 890	10 - 720	10 - 560	10-460	10-440	10 - 375	10 - 295	10 - 250	10 - 235	10 - 210	10 - 190	10 - 165	10 - 150	10 - 140	10 - 130	10 - 120	10 - 115	10 - 105	10 - 100
	Chopper	Drive, kW	1.1						1.1	3	4	4	4	5.5	7.5	11	11	15	15.0	18.5	22	30	33
		Speed, rpm	1000 - 5000	1000 - 5000	1000 - 5000	1000 - 5000	1000 - 5000	1000 - 5000	1000-4000	1000 - 4000	1000 - 4000	1000 - 4000	1000 - 4000	1000 - 4000	1000 - 3500	1000 - 3500	1000 - 3500	1000 - 3500	1000 - 3500	1000 - 3500	1000 - 3500	1000 - 3500	1000 - 3500
Discharge Port nominal Size (mm)			na	na	35	35	60	60	75	100	100	100	100	100	150	150	200	200	200	200	250	250	250

Features & Leading Advantage of HSG







Features & Leading Advantage of HSG

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End Point Determination – Scale Up

- **TORQUE -** Impeller torque is an excellent measurement of the force on the impeller. Torque rheometeris is the torque required to rotate the impeller used to access rheological properties of the granules and the end point of the granulation process. Sensor must be permanently affixed to the impeller shaft and thus the shaft needs to be removed for calibration thus rendering the mixer out of service for weeks.

- **LOAD –** When using AC motors, impeller load does not vary linearly with the current applied therefore current (AMPS) is completely in-effective as a measurement of impeller load in AC motor. DO NOT USE AMPS FOR ENDPOINT. Not repeatable due to voltage variations. V=IR

- **POWER -** Measurements of Power Consumption of the impeller motor has been widely used for end point determination because it is economical and well co-related with the growth of granules . Power consumption can also be co-related with mean particle size of the granules.

- Drawback of the Load and Power consumption measurement is that it reflects the energy consumed by the motor, gearbox, belts, pulleys etc rather than the energy on the impeller tool where actual action is being performed. But the gearbox etc does not change during the batch, and thus can be negated.

- End Point $\frac{PW - PD}{PL - PD}$ is the same NOT AMPS

PD = Power for Dry Mixing
PL = Power at End of Liquid Addition

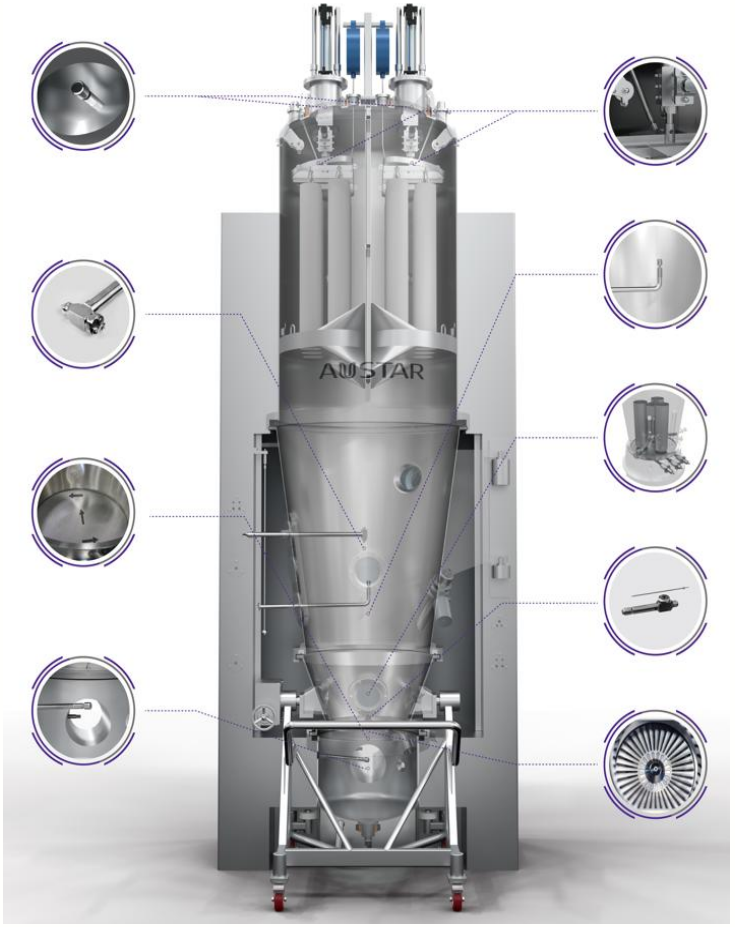
Features & Leading Advantage of Fluid Bed

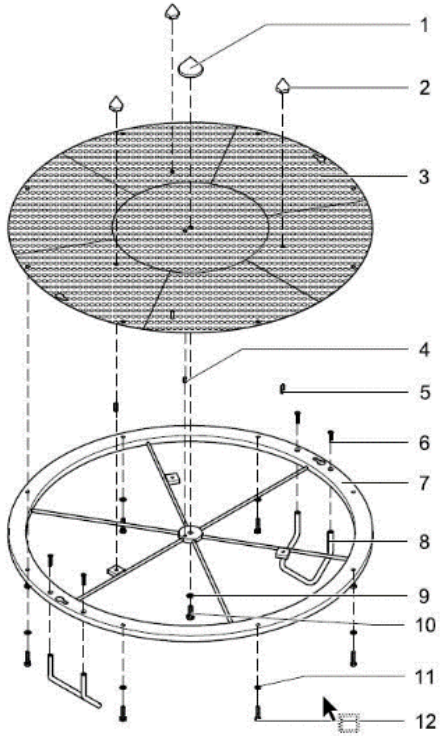
AVSTAR

Drying / Top Spray Granulaing / Coating ··· changeable chamber and conical chamber

	portable		portable			fied or portable										
Model Number	FBDGC-5		FBDGC-20			FBDGC-30		FBDGC-70			FBDGC-170	FBDGC-330	FBDGC-530	FBDGC-850	FBDGC-1400	FBDGC-1900
Design Gross volume Granulation - Dry/TSG Bowl Size (Liters)	2	5	5	10	17	20	30	30	50	70	170	330	525	850	1400	1900
Min Batch - Dry/TSG Bowl Size (Liters) 20%	0.4	1	1	2	3.4	4	6	6	10	14	34	66	105	170	280	380
Max Batch - Dry/TSG Bowl Size (Liters) 80%	1.6	4	4	8	13.6	16	24	24	40	56	136	264	420	680	1120	1520
2 - Min batch - Wurster Coating (liters) NO COLUMN	0.2	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na
2 -Max Batch - Wurster Coating (liters) NO COLUMN	0.5	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na
4 - Min batch - Wurster Coating (liters)	na	0.5	0.5	na	na	na	na	na	na	na	na	na	na	na	na	na
4 -Max Batch - Wurster Coating (liters)	na	1.5	2	na	na	na	na	na	na	na	na	na	na	na	na	na
6 - Min batch - Wurster Coating (liters)	na	na	na	0.6	na	na	na	na	na	na	na	na	na	na	na	na
6 -Max Batch - Wurster Coating (liters)	na	na	na	5	na	na	na	na	na	na	na	na	na	na	na	na
7 - Min batch - Wurster Coating (liters)	na	na	na	na	1.2	1.2	na	na	na	na	na	na	na	na	na	na
7 -Max Batch - Wurster Coating (liters)	na	na	na	na	8.5	8.5	na	na	na	na	na	na	na	na	na	na
9 - Min batch - Wurster Coating (liters)	na	na	na	na	na	na	3	3	na	na	na	na	na	na	na	na
9 -Max Batch - Wurster Coating (liters)	na	na	na	na	na	na	14	14	na	na	na	na	na	na	na	na
12 - Min batch - Wurster Coating (liters)	na	na	na	na	na	na	9	na	9	na	9	na	na	na	na	na
12 - Max Batch - Wurster Coating (liters)	na	na	na	na	na	na	40	na	40	na	40	na	na	na	na	na
18 - Min working batch - Wurster Coating (liters)	na	na	na	na	na	na	na	na	na	15	15	20	20	na	na	na
18 -Max working Batch - Wurster Coating (liters)	na	na	na	na	na	na	na	na	na	75	95	120	120	na	na	na
24 -Min working batch - Wurster Coating (liters)	na	na	na	na	na	na	na	na	na	na	na	35	35	na	na	na
24 -Max working Batch - Wurster Coating (liters)	na	na	na	na	na	na	na	na	na	na	na	162	162	na	na	na
32 -Min working batch - Wurster Coating (liters)	na	na	na	na	na	na	na	na	na	na	na	na	90	90	na	na
32 -Max working Batch - Wurster Coating (liters)	na	na	na	na	na	na	na	na	na	na	na	na	390	390	na	na
46 - Min batch - Wurster Coating (liters)	na	na	na	na	na	na	na	na	na	na	na	na	na	300	300	125
46 - set up -Max Batch - Wurster Coating (liters)	na	na	na	na	na	na	na	na	na	na	na	na	na	790	790	800
55 - Min batch - working Wurster Coating (liters)	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	170
55 - Max Batch - working Wurster Coating (liters)	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	1110

Features & Leading Advantage of Fluid Bed





AUSTAR 奥星

制药工程解决方案专家

Know How Design of PSR ATEX Compliance

International Standards

NFPA 70, National Electrical Code (NEC)

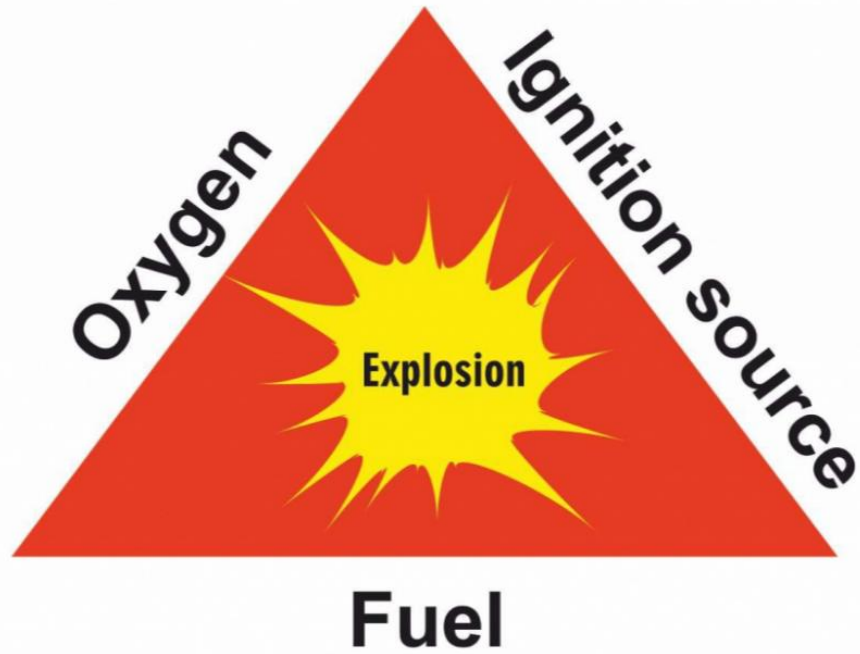
NFPA 79: Electrical Standard for Industrial Machinery

ATEX is the abbreviated name of the European Directive 2014/34/EC

NFPA 68: Standard on Explosion Protection by Deflagration Venting

NFPA 69, Standard on Explosion Prevention Systems

NFPA 652, Standard on the Fundamentals of Combustible Dust



Know How Design of PSR ATEX Compliance

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1.14 General drawing of FEA of fluid bed

流化床应力分析总图

Part II FEA of High Shear Mxier HSG

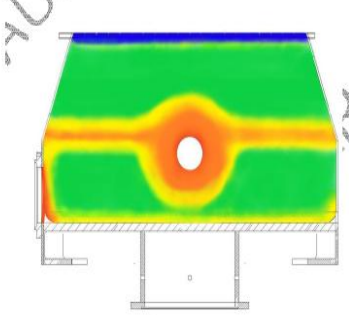
第二部分 高剪切湿法制粒机应力分析

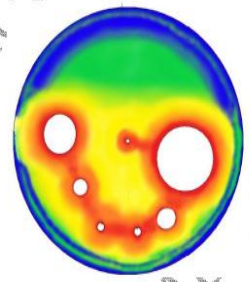
2.1 Viewing windows, sampling port, outlet pipe, and inflatable seals. Inlet flanges etc are engineered to withstand same over pressure.

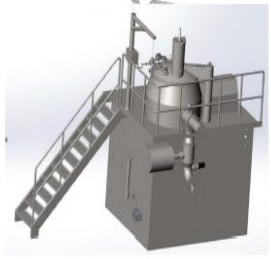
视窗、取样口、卸料口、充气密封、入口法兰等的设计应能够承受相同的过压。

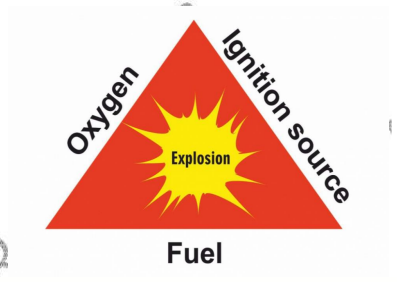
2.2 Once the stress/strain on each node is calculated they are superimposed on the nodal display to show concentrations. In the picture here red is approximately the force equal to 13 BAR thus allowing a safety factor

一旦对每个节点的应力/应变进行了计算，就会与节点显示叠加，显示密集度。在此图中，红色对应大约 18bar 的力，在安全系数允许范围内。









The American Society of Mechanical Engineers

CERTIFICATE OF AUTHORIZATION

U

The named company is authorized by the American Society of Mechanical Engineers (ASME) for the scope of activity shown below in accordance with the applicable rules of the ASME Boiler and Pressure Vessel Code. The use of the ASME Certification Mark and the authority granted by this Certificate of Authorization are subject to the provisions of the agreement set forth in the application. Any construction stamped with the ASME Certification Mark shall have been built strictly in accordance with the provisions of the ASME Boiler and Pressure Vessel Code.

COMPANY:

Austar Pharmaceutical Process Systems (Shijiazhuang) Limited
No.4 Bldg., Industrial Park for GREE,
No. 389, Hengshan Street
Shijiazhuang City, Hebei Province 050035
People's Republic of China

SCOPE:

Manufacture of pressure vessels at the above location and field sites controlled by the above location (This authorization does not cover impregnated graphite)

AUTHORIZED: **January 3, 2020**
EXPIRES: **January 3, 2023**
CERTIFICATE NUMBER: **54316**

Board Chair, Conformity Assessment

Managing Director, Conformity Assessment

Know How Design of PSR ATEX Compliance

AUSTAR

In the event of Deflagration

OSD processing where a solvent will be sprayed into a fluid bed for the purpose of Top Spray Granulation or Wurster Coating is considered a hybrid environment.

Based on NFPA and ATEX codes

Types of Pressure Shock Wave (Deflagration) protection;

- Deflagration Control by Isolation & Venting - The technique for deflagration isolation shall be permitted to be considered for interruption or mitigation of flame, deflagration pressures, pressure piling, and flamejet ignition between equipment that is interconnected by pipes or ducts. Restricted to pressure ~ 2 bar.

- Deflagration Control by Suppression - The technique for deflagration suppression shall be permitted to be considered for most flammable gases, combustible mists, or combustible dusts that are subject to deflagration in a gas phase oxidant. Controlled max pressure through suppression. Cost of suppression hardware.

- Deflagration Control by Pressure Containment - The technique for deflagration pressure containment shall be permitted to be considered for specifying the design pressure of a vessel and its appurtenances so they are capable of withstanding the maximum pressures resulting from an internal deflagration. Heavy and bulky equipment to handle pressure.

Absolute pressure / Shock wave and DP/DT

PAT Integrated Application

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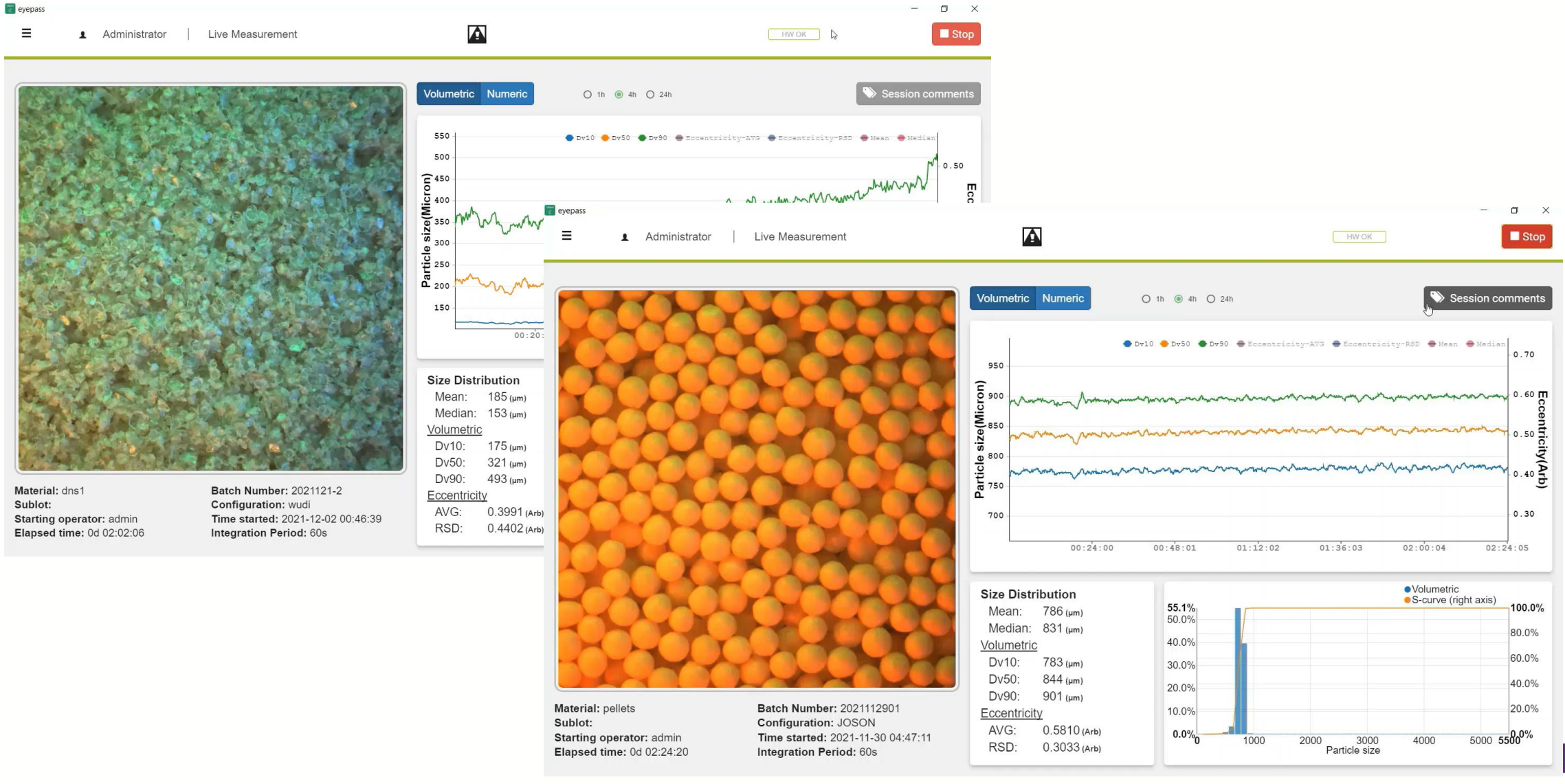
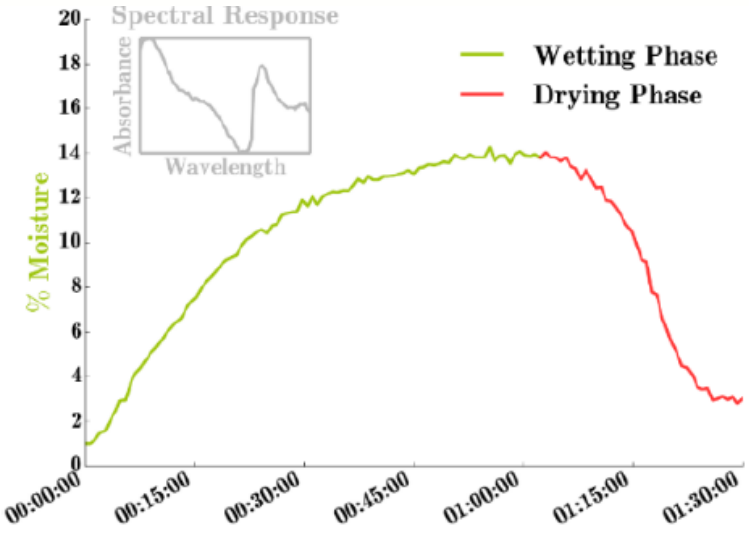
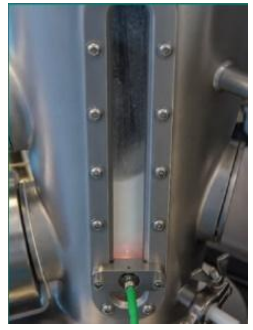


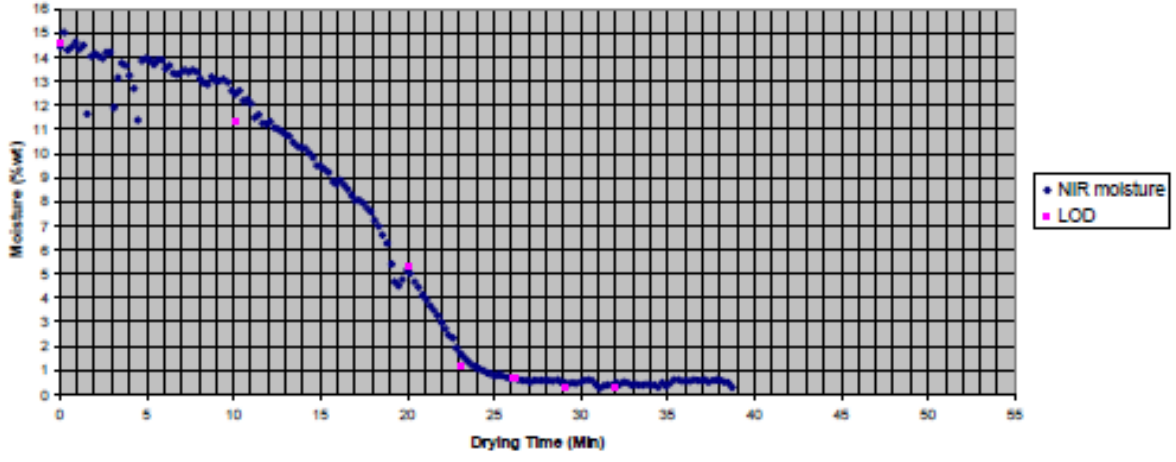
PAT Integrated Application

Blending homogeneity, Water content online monitoring

The application of integrated PAT in wet granulation will facilitate the understanding to the wet granulation process/ product, and shorten the R&D period of new drug and/ or generic drug

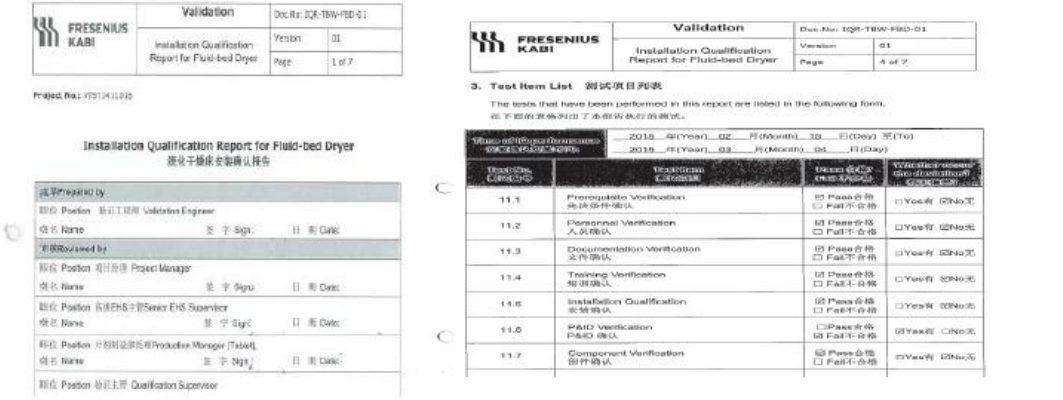






Documentation

Documentation	Specification
GXP	The applicability of equipment/system assessment to potential effect on product quality, GAMP software category, and FDA 21 CFR Part 11.
QPP	Quality and Project Plan
QSD	Providing specific instruction to the scope of commissioning and qualification activities.
FS	Functional Specification
HDS	Hardware Design Specification
SDS	Software Design Specification
SIA	System Impact Assessment
DQ	Design Qualification
FRA/CCA	Functional risk assessment /Component Criticality Assessment
COM	Equipment or system commissioning documents
FAT	Factory Acceptance Test
SAT	Site Acceptance Test
IQ	Installation Qualification
OQ	Operating Qualification
PQ	Performance Qualification (Protocol)
RTM	Requirement Traceability matrix
VSR	Validation Summary Report



IQ/OQ (EU GMP/Germany)

PQ (MHRA GMP)

Topics

01 What can we provide to the OSD Process System

02 Experience Sharing

03 Advanced Tech/Competitive Advantage of AFC

04 About PSS

More Than 1000 Global High-quality Partners

AUSTAR

TAC Advisors

Knowledge Trust Legacy

AUSTAR


Peter Haseley


Ewart Richardson


Austin McDonald


Stephen Robert Ferrell


Rory Budihandojo


Wilfried Kappel


Bill Shifeng Wei


José Castillo


Michael Li


Jack Chu


Jon Nottingham


Frank Eng


Andreas Flückiger


Danny Chou


Nico Oosterhuis


Feng Lei


Rey T Chern


Robert Fretz

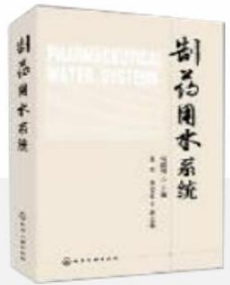

Li Shi


Michael H Prior


Shoubai Chao

Publications

Pharmaceutical Process & Utility System



Pharmaceutical Water Systems (2011)

Pharmaceutical Liquid Process Systems（2013）

Pharmaceutical Water Systems (The Second Edition) （2016）

Implementation Manual of De-rouging for Pharmaceutical Processing System（2015）

Code for Design of Pharmaceutical Water Systems,a National Standard (NO.GB50913-2013)

Drug Life Cycle Compliance

Pharmaceutical Process Validation Manual（2012）

Compilation of EU GMP & GDP Regulations（ Chinese-English Bilingual Version） （2014）

Quality Risk Management in Pharmaceutical Industry: A Practical Guide（2020）

How to Design and Implement Powder-to-Tablet Continuous Manufacturing Systems (2023)

Technical Code for Traditional Chinese Medicine Production Plant Engineering (GB51069—2014)

Production Environment and Process

Pharmaceutical Industry Manufacturing Execution System Manual（2016）

Microbial Control in Pharmaceutical Cleanrooms (2013)

Freeze-Drying （2017）

Guide for Design, Construction and Operation Management of BSL2 (2021)

Why AUSTAR

- **Your partner of OSD TK solution**
- **Safety first**. All core components are validated and tested。
- Balance of process, equipment and automatic monitoring system, and provide a stable process **automatic control system**.
- Based on excellent **know-how** design and quality process control, provide perfect engineering equipment project execution
- Process service and experience shareing, value adding on the OSD process system
- The AUSCON **automatic control system** designed based on the requirements of data integrity meets the requirements of EU, FDA, who, pic/s, TGA and other high-end international regulations
- Perfect verification execution service IQ/OQ/FAT/SAT, execution and report delivery), providing one-stop service

Thank You

www.austarunion.com