

# ID - 800 mm

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## DAC Column



EPCC / PRODUCTS / APPLICATION / SOFTWARE / ACCESSORIES / CONSUMABLES / SERVICES

**Analytical Technologies Limited**

An ISO 9001 Certified Company

[www.analyticalgroup.net](http://www.analyticalgroup.net)

## ►► Information

The purification system will be designed to meet the requirements of the production process for purification of customers' products.

The purification system consists of:

- DAC column unit(ID450\*800mm)
- Mobile phase delivery unit,
- Detection and Fraction unit;
- Control unit(Software, PC, Control cabinet).
- Other accessory system ,etc

The system will be designed according to explosion proof and provide appropriate IQ, OQ validation services, also assist customers to complete PQ validation. Designed explosion-proof level: KCS

The system has the following characteristics and advantages:

1. Multi-solvent inlet, suitable for different systems of cleaning, to avoid cross-contamination;
2. Suitable for the use of flammable and explosive environment, explosion-proof level: KCS; Protection level: IP65
3. Built a variety of operating modes: bypass, reback, etc., select the convenience of a high degree of automation;
4. All wet materials comply with regulatory requirements, and provide third-party authority of the material certificate;
5. The system uses a number of patented technologies, such as: H-TREE distribution mode , to ensure separation and stability;
6. A variety of system protection measures, such as: software alarm and high pressure safety valve, to ensure the safety and reliability of the system;
7. System control and data acquisition software complies with FDA 21 CFR PART11 requirements, such as historical records, audit trails, electronic signatures, etc.

## ►► PURPOSE

The document will become the basis of the integrated design, including selecting material, processing, assemble and manufacture of the system.

## ►► Overview

### Process

After sampling by delivery pump, the rough sample will be separated in the column. The effluent from the column will be detected by the UV detector and distributed to fraction collection tank and waste, so as to get desired target products (such as purity, recovery, capacity and cost control). The system uses a separate explosion-proof cabinet and local computer control.

### Laws and Regulations compliances

Drug administration law

Good Manufacture Practices

Current Good Manufacture Practices

EURO Good Manufacture Practices

FDA examination guide

FDA inspector's guidance manual

Chinese Pharmacopeia (2010)

United States Pharmacopoeia

European Pharmacopoeia

ICH Q 7 (International Conference on Harmonization of Technical Requirements for  
Registration of Pharmaceuticals for Human Use)

International Society for Pharmaceutical Engineering

Good Automated Manufacturing Practice

Environment, Health, Safety (EHS)

Testing and Materials (ASTM) Standard

## Standard compliances

FDA CFR 21 Part 11: electronic records, electronic signature

International engineering consortium

GB/T 5226.1-2008, GB/T 5226.2-2008 Safety of Machinery-Electrical equipment standards

Environmental safety standards

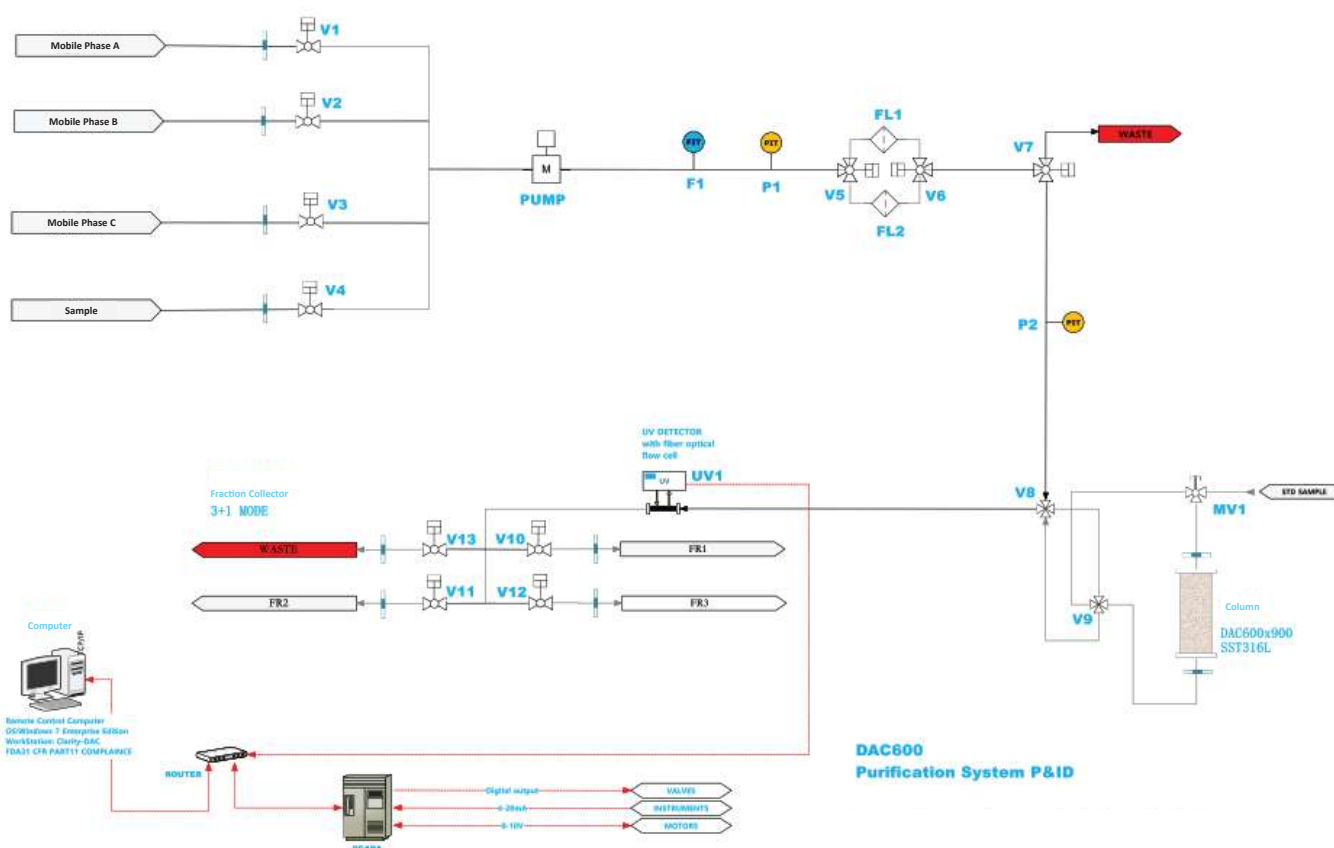
National measurement standards or ISO standards

GB 3836-2010

## ► SYSTEM SPECIFICATION

### P&ID

System liquid road, packed column flow path principle is as follows



## ►► SYSTEM TECHNICAL SPECIFICATION

Item	Description	P&ID Marks
Solvent Option valve	V1 is used for the switch of eluent A; V2 is used for the switch of eluent B; V3 is used for the switch of eluent C; V4 is used for the switch of the sample.	V1、 V2、 V3 、 V4
Delivery Pump	Pump is used for eluent A B C and sample;	Pump
Flow Meter	F1 is used to check system flow rate.	F1
	( Elution+injection ) .	
Pressure transmitter	P1 used to monitor the pressure of the filter; P2 used to monitor the pressure after the column ( Including washing and back washing pressure );	P1、 P2
Filter FL1 and FL2	Filter is used to filter cleaning solvent ,sample and mobile phase. One is normal using and extra one as standby.V5 and V6 are used for switch filter and column.	FL1 、 FL2 V5、 V6
Detector	Detector is used to monitor signal of column outlet	UV1
Valve V7	V7 is used for exhaust and waste discharge.	V7
Manual injector ( MV1 )	MV1 is used for the column efficiency testing or a small amount of injection	MV1
Valve V8	V8 is used for column bypass.	V8
Valve V9	V9 is used to select whether the column in normal mode or back flush mode	V9
Fraction collector	4 channels fraction collector are used to fraction collection tank and waste discharge	V10~V13

## ►► Design Specification

### Design Specification

No	Item	DDS Description
DDS51001	Environmental requirements	No direct sunlight, no strong magnetic field and electric field, no strong vibration, no corrosive gas, no dust
DDS51002	Environmental temperature Requirements	5°C~26°C
DDS51003	Environmental humidity Requirements	≤90%
DDS51004	Power requirements	380V (three phase ) , 50Hz
DDS51005	Air supply	>0.6MPa, >0.6m <sup>3</sup> /min

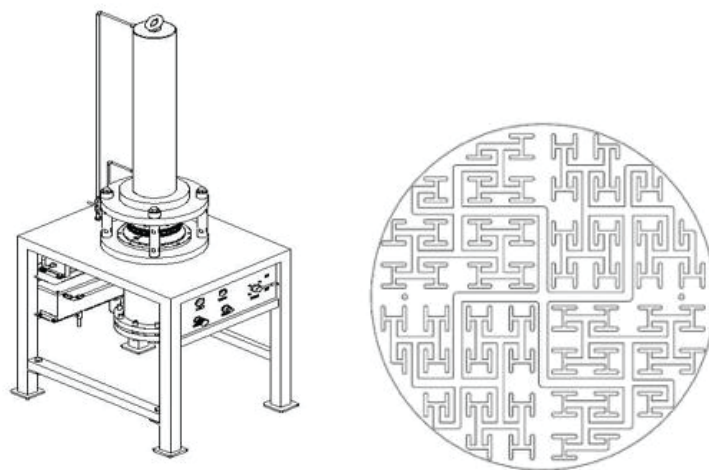
## System Overall Design Instructions

No	Item	DDS Description
DDS52001	System composition	Column Unit;Delivery unit( including delivery pump, valve unit, filter ,piping );Measuring unit(including detector ,mass flow meter, pressure transmitter,etc);and controlling unit( EXP cabinet,PLC,PC and software);Accessory Unit(work-up kit and system frame)
DDS52002	System connection	Pipe Card Sets use to connect with piping, inlet and outlet,screw connection of front of the pump and back of the column
DDS52003	Environmental temperature Requirements	5°C~60°C
DDS52004	Explosion-proof	KCS
	Grade	
DDS52005	Protection level	IP65
DDS52006	FDA compliance	FDA 21 CFR Part 11
DDS52007	Wet material	All materials that are in contact with the liquid medicine must meet the hygiene level requirements. Pumps, pipelines, valves, interfaces, seals and so on should be no leakage, no rust. Materials using 316L, hose and gaskets using food silicone rubber materials, should be in line with the FDA, USP Class VI or European pharmacopoeia requirements, and in the validation documents to provide material documents.
DDS52008	Max Pressure	10MPa

## ►► Hardware Design Specification

### ID450\*800mm DAC Column

Chromatography is a separation and analysis method, separating the core of chromatographic column, so the chromatographic column which bears the separation action is the heart of the chromatographic system. It is an important technical requirement to use the axial compression technology to keep the pressure uniformly constant in each section of chromatographic column. At present, the most advanced way is to adopt dynamic axial compression technology. The dynamic axial compression technique is to complete the loading, maintaining the column pressure and unloading column by the movement of the piston. The perimeter of the piston is equipped with a specially designed seal structure that allows the piston to slide freely along the wall of the cylinder, while maintaining a high sealing ability. Piston movement and pressure maintenance rely on the pressure-retaining system, hydraulic power than the traditional use of spring-driven axial compression column more stable, more uniform, so that the use of separation column is better, can be filled with a large diameter (50mm~1000mm) of the chromatographic column and maintain the separation effect with the analysis column.



The chromatographic column design is based on the dynamic axial compression column, and the column piston has constant pressure on the packing bed, which can effectively avoid the collapse and loosening of the packing bed. The system can realize the positive flush or recoil by the switch of the flow path, which is easy to operate and maintain. The Chromatographic Distributor adopts our H-tree patent distribution technology, which ensures the columnar efficiency and higher separation effect of chromatographic column.



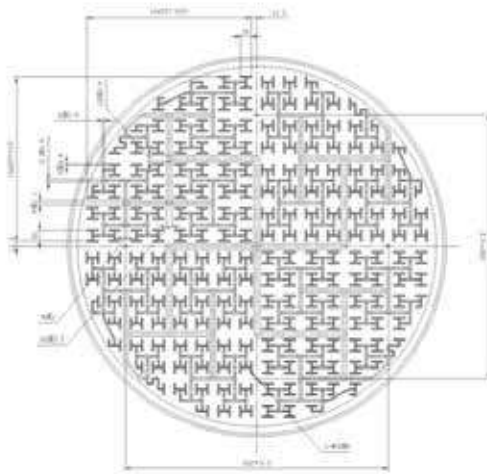
## ID450\*800mm column data:

No	Item	DDS Description
DDS53001	Inner Diameter	450mm
DDS53002	Length of column tube	800mm
DDS53003	Weight	3T(Take the actual design as the subject)
DDS53004	Dimension	1500mm×1500mm×3250mm (Take the actual design as the subject)
DDS53005	Frit	Material: 316L stainless Steel ; Pore size:2μm
DDS53006	Distributor ( Piston and bottom)	Material: 316L stainless Steel
DDS53007	Mode of Distributor	H-TREE
DDS53008	Air Supply	Air pressure≥6bar, air demand 4m <sup>3</sup> /min
DDS53009	Working temperature	5~65°C
DDS53010	Design pressure	10MPa
DDS53011	Material of column support	304
DDS53012	Roughness	Inner surface of column Ra≤0.4μm;Outer surface of column Ra<1.6μm
DDS53013	Manufacturer	Analytical

## Advantages of chromatographic column

### 1) Efficient way to distribute

The exclusive patented technology is used to h-tree the distribution and obtain columnar effect in the purification separation. In the design of the distributor for the large diameter preparative chromatographic column, we have introduced the concept of H-tree creatively, and have used the structure in the high integrated circuit, and designed the forced distributor, as shown in the following figure, the dead volume of the distributor is less than 2% of the dead volume of the prepackage column. The diffusion effect of the sample in the Distributor is unchanged due to the constant number of units per area force allocation. Therefore, the distribution of the sample in the column will not deteriorate with the diameter of the column, thus ensuring that the diffusion effect of the sample on the Distributor and the radial distribution of the column do not change when the column diameter becomes larger.



## 2) Gas Drive liquid pump (for oil circuit)

Gas drive Liquid pump selection of the World brand Haskel, Maximator chemical medium gas Drive fluid pump, the principle of pneumatic liquid pump by the gas-driven part, hydraulic part and reversing control valve three parts. The piston of the gas-driven part is connected with the plunger of the hydraulic part, and the reciprocating motion is automatically controlled by the reversing valve.

The pressure of the driving gas acting on the piston is passed to the plunger through a large area of piston and a small area plunger, thereby increasing the outlet stress of the liquid.



### 3) High Pressure seal

High-pressure seals choose the brand of spring-energy storage seal . The seal is a pressure-assisted sealing device with a polyethylene-PTFE jacket, which is specially equipped with a corrosion-resistant metal storage spring.

The spring is pressed to make the jacket lip close to the sealing groove, thus forming a seal.



### 4) Other

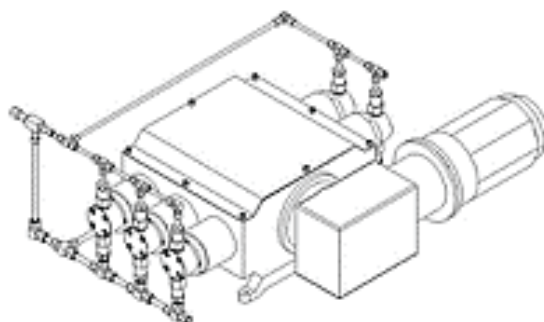
Pneumatic components selected Festo, oil circuit components, especially valves using Germany imported valves, improve the entire system of sealing performance, no leakage, high reliability, while improving the service life of products.

## ►► Delivery Unit

The solvent delivery unit comprises a few parts, such as delivery pump, valve mode system, filter, piping system and so on.

### Delivery pump

Uses Analytical Plunger Type pump head multi pump head, reduce pulsation and improve pump precision, used to complete the system flow phase and sample conveying function.



No	Item	DDS Description
DDS54001	Work mode	Plunger pump with multi pump head
DDS54002	Max flow rate	15L/min
DDS54003	Max. pressure	10MPA, with overpressure protection
DDS54004	Flow accuracy	±1.5%
DDS54005	Reproducibility of flow	≤1%
DDS54006	Motor and controller	EX motor and frequency converter
DDS54007	Communication Mode	LAN port communication protocol, control by the PC
DDS54008	Wet material	316L,PTFE
DDS54009	Manufacturer	Bran+Luebbe

## Online filter



No.	Item	DDS Description
DDS55001	Inner Diameter	300mm
DDS55002	Design pressure	10MPa
DDS55003	Frit	Material: 316L pore size:5μm
DDS55004	Frit material	316L
DDS55005	Support material	304
DDS55006	Fastening mode	Chain Type Clamp Connection
DDS55007	Manufacturer	Analytical

## Valves

Manual three-way ball valve



No.	Item	DDS Description
DDS56001	Controlling Mode	Manual
DDS56002	brand	MILLER
DDS56003	Max pressure	10MPa
DDS56004	Wet material	316L

### Pneumatic Two-way ball valve



No.	Item	DDS Description
DDS57001	Controlling Mode	Pneumatic, controlledby PC
DDS57002	brand	MILLER
DDS57003	Max pressure	2MPa
DDS57004	Wet material	316L

### Pneumatic Three-way ball valve



No.	Item	DDS Description
DDS58001	Controlling Mode	Pneumatic, controlledby PC
DDS58002	brand	MILLER
DDS58003	Max pressure	10MPa
DDS58004	Wet material	316L

## Pneumatic Four-way ball valve



No.	Item	DDS Description
DDS59001	Controlling Mode	Pneumatic, controlled by PC
DDS59002	brand	Swagelock
DDS59003	Max pressure	10MPa
DDS59004	Wet material	316L

## FRACTION COLLECTION



No.	Item	DDS Description
DDS51001	Collection method	Semi-Auto, Automatic
DDS51002	Channel	4 outlet ports
DDS51003	Valve	Pneumatic ball valve
DDS51004	Max. Pressure	10Mpa
DDS51005	Wet material	316L, PTFE
DDS51006	Manufacturer	MILLER/FITOK

## Piping

### Piping System Design Instructions

The whole system includes the hydraulic pipeline, the gas pipeline and the oil pipeline. The whole set of equipment of the hydraulic pipeline using no dead angle design, piping system design should meet the requirements of ASME BPE standards.

No.	Item	DDS Description
DDS51101	Material	Liquid piping:SUS316L, the pipeline as far as possible hardening (except must use soft connection parts, such as chromatographic column inlet for PTFE high-pressure hose)
DDS51102	Connection mode	Liquid piping: Thread or Chuck connection; Air piping:Quick-mount Connector mode connection
DDS51103	Manufacturer	FITOK

## ►► Detection and monitoring unit

Detection and monitoring, including detectors, fiber circulating tanks, testing instruments (pressure transmitter, flowmeter) and other parts of the composition

### Detector and Fiber optic

UVD3000 is a new-generation detector based on ARM core control, which has the advantages of high sensitivity, wide detection range and fast maintenance. UV3000UD uses LAN communication mode, through a network cable very convenient connection data processing device, optical fiber version with high signal strength, signal transmission distance, stable and reliable characteristics, widely used in industrial preparation of chromatographic system.





No.	Item	DDS Description
DDS51201	Type	UVD2.1L
DDS51202	Wavelength range	190-400nm (standard)
DDS51203	Connection mode	Fiber 30M×2
DDS51204	Max flow rate	15L/min
DDS51205	Max pressure	2MPa
DDS51206	Wet material	316L、PTFE、Quartz Glass
DDS51207	Communication mode	LAN, controlled by PC
DDS51208	Baseline noise	±2×10 <sup>-5</sup> AU at 254 nm
DDS51209	Baseline drift	400μAU/h at 254 nm
DDS51210	Wavelength accuracy	±2 nm
DDS51211	Manufacturer	KNUER

## Mass Flow meter



No.	Item	DDS Description
DDS51301	Model	Mass flow meter
DDS51302	Manufacturer	Endress+Hauser
DDS51303	Measuring flow rate	0~15L/min
DDS51304	Max pressure	10MPa
DDS51305	Wet material	316L
DDS51306	Measuring accuracy	±0.2%
DDS51307	Power system	4-Wire power supply system
DDS51308	Display and button	Double-line LCD display, single button
DDS51309	Communication mode	4-20mA
DDS51310	Piping and connection	Flange connection (if necessary to design according to the actual size of the shrinkage diameter)

## Pressure transmitter

The pressure transmitter in the system can monitor the pressure change in the system flow in real time, and the pressure alarm can be set in the software, when the system pressure is higher or lower than the setting value, the system will automatically send out a warning or alarm prompt, which provides a reliable guarantee for the safe operation of



No.	Item	DDS Description
DDS51401	Model	PMP 51
DDS51402	Manufacturer	Endress+Hauser
DDS51403	Measuring range	0~10MPa
DDS51404	Max pressure	10MPa
DDS51405	Wet material	316L
DDS51406	Measuring accuracy	±0.15%
DDS51407	Piping connection	Threaded connection
DDS51408	Transmitter connection	Transmitter frame+bottom support ( Analytical )

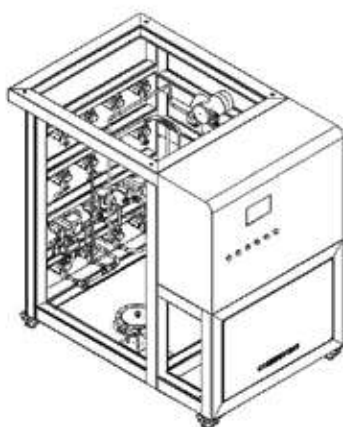
## System control unit

System control unit includes electronic cabinets, PLC, computer, chromatography station.

The chromatographic workstation is used for the control, data acquisition and implementation of FDA related requirements, and the whole process of purification is instructed, when the system is abnormal, the parameter and the setting value are deviated, the system will alarm and related action.

PLC is the control center of the whole system, the communication between the host computer software (chromatographic workstation) and the hardware of the equipment is established through PLC, which ensures the program operation of the delivery pump, the execution of data collection and the data communication of other testing units of the system.

The core components of the system control unit are placed inside the electrical cabinet, such as PLC, solenoid valve, ultraviolet detector, etc. The system has no explosion-proof cabinet. Pump, valve control cabinet, circulating pool and so on in the explosion-proof area. Other such as, electrical cabinets (PLC, solenoid valve, detector, etc.), computer and so on in the non-explosion-proof area.



## Electronic cabinet

Electric cabinet contains PLC, solenoid valve unit and other electrical devices, not explosion-proof. Valve control in the valve and solenoid valve separate, the valve in the explosion-proof zone, solenoid valve in the explosion-proof area of electrical cabinets, through the gas source hose connection.



No.	Item	DDS Description
DDS51501	Rated voltage	220VAC
DDS51502	Dimension	600*600*1800mm
DDS51503	Material	304

## PC



No.	Item	DDS Description
DDS51601	Power Supply	AC: 220V
DDS51602	Software	Windows7 32bit flag version
DDS51603	Hardware	computer, remote control

## PLC Control System

Siemens PLC controller has: maintenance of small workload, easy maintenance, low failure rate, and a sound self-diagnosis and display. PLC or external input device and actuator failure, according to the PLC on the light-emitting diode or programmer to provide information to quickly identify the cause of the failure, with the replacement module method can quickly remove the fault.



## Software

### Compliance Requirements

It is full compliance with cGMP and FDA CRF 21 PART11

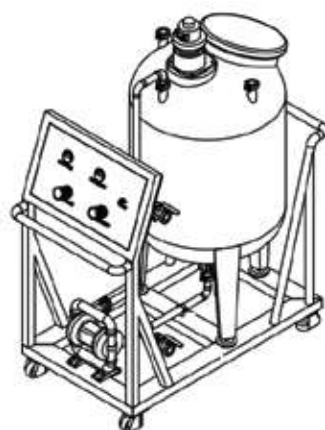
System integrates the fool operating mode and manual mode with advanced personality.

No.	Item	DDS Description
DDS51701	Basic parameter Settings and Acquisition function	<p>The system has online monitoring various parameters of the entire purification systems in running. It can display setting and actual parameter value at the same time, such as time, flow, column pressure, loading column pressure, sample the peak. And it can be used for important parameters setting, Some parameters such as beyond the set range, this system can make relevant response ( Alarm or automatic stop running )</p>
DDS51702	PID function	<p>Includes a good interface (P&amp;ID), and the related parts from P&amp;ID button control in purification of a complete set of the operation of the system. It can finish including but not limited to the follow operation :</p> <p>Can set up related parameters to ensure the normal operation of the system, Such as system pressure limit, maximum flow, etc.</p> <p>Choose a different line for distillate collect (1-4).</p> <p>Normal operation system to carry out system balancing, sampling, sample elution, collect fraction, etc.</p> <p>Select manual sample or automatic sample. The solvent conveying unit purge operation.</p> <p>To chromatographic column system recoil operation. Set detector related parameters, such as detection wavelength.</p>

DDS51704	Calculation function	Chromatographic column performance calculation, such as the peak of the theoretical plate number, resolution, symmetry factor etc.
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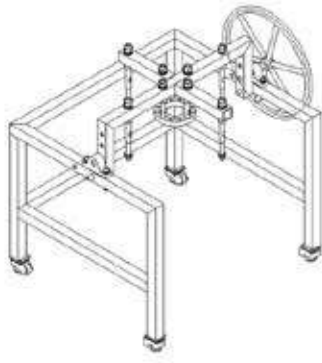
## ►► Accessories unit

### Slurry Tank



No.	Item	DDS Description
DDS51801	Volumn	200L
DDS51802	Dimension	1250*700*1650
DDS51803	Wet material	316L
DDS51804	Mixing method	Pneumatic motor with agitator
DDS51805	Mixing speed	0-120rpm/min
DDS51806	Delivery flow	150L/min
DDS51807	Consist unit	Tank, motor, delivery pump, pipe
DDS51808	Air requirement	≥6bar;≥3m3/min
DDS51809	Working pressure	Normal pressure
DDS518010	Brand	Analytical

## ►► Flip Bracket



No.	Item	DDS Description
DDS51901	Material	304
DDS51902	Running mode	Manual
DDS51903	Brand	Analytical



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**HPLC Servicing** :HPLC Servicing : We have team of service engineers who can attend to any make of HPLC promptly @the most affordable cost.

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Laser Particle  
Size Analyzer



Ion Chromatograph



Water purification  
system



## Regulatory compliances



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Analytical Foundation is a nonprofit organization (NGO) found for the purpose of:



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