



WE PURE  
微纯生物科技



## PREPULITE® PREPARATIVE CHROMATOGRAPHY PACKING MEDIA, AND CASE STUDIES ON PURIFICATION PROCESSES FOR GLP-1RA AND OTHER PEPTIDES



WePure Biotech (Guangzhou) Co., Ltd.



## About WePure Biotech

WePure Biotech a National High-Tech Enterprise and a Guangzhou Specialized, Refined, Distinctive, and Innovative Enterprise, dedicated to "Becoming an excellent supplier of Global Analysis, Testing, Separation & Purification Solution".

As one of the few global manufacturers with comprehensive expertise in both silica-based and resin-based chromatographic filler production technologies, our team brings over 20 years of industry experience and extensive application development knowledge. We maintain a complete industrial chain, from raw material synthesis (silica/resin microspheres) to internationally advanced surface bonding/modification processes, and production of analytical/semi-prep columns and preparative Packing Media. We provide high-quality, cost-effective, stable-supply, and fast-delivery products and services to industries such as pharmaceutical manufacturing, biotechnology, food safety, chemical production, and environmental testing.



**INTEGRITY INNOVATION,  
OPENNESS GROW TOGETHER**





**THE GLOBAL SEPARATION & PURIFICATION SOLUTION PROVIDER**



- ◆ **MicroPulite® Analytical Columns**
- ◆ **BioPulite® Bioanalytical column**
- ◆ **PrePulite® Semi-Prep Columns/Semi-prep and Industrial Preparative Media**
- ◆ **UPulite® Sample Pre-Prep Packing Media /SPE**
- ◆ **WeChromlite® Guard Column**



## WePure Biotech's three technology platforms



### Stable porous microsphere syntheses technology

WePure can produce microsphere in a stable and large scale, includes 1.7 $\mu$ m-100 $\mu$ m high-purity silica, organic-inorganic structure hybrid silica (XP) and high-strength silica (HSS), inorganic-inorganic structure hybridized SiZ microspheres and soon.



### Advanced surface modification technology

WePure provides triple bond C18/C8, double bond C18/C8, single bond C18/C8, NH<sub>2</sub>, Amide, Hexyl-Phenyl, Fluoro-Phenyl (PFP), Diol, RP18/18 Plus, PHS charged modification technology, unique T3 bond technology, mix mode bond technology, meet the needs of analysis, separation and purification.



### High efficient and stable columns packing platform

WePure products cover UPLC, UHPLC, HPLC and semi-preparative columns, with stable production technology and strict testing, ensure excellent stability and reproducibility of column to column, batch to batch.



“WePure” Headquarter located in Guangdong



### Our facilities include:

- A 1,950 m<sup>2</sup> R&D, production, and application development base in the Guangdong Medical Valley National Incubation Park (Nansha, Guangzhou).
- A subsidiary with a 5,000 m<sup>2</sup> plant for large-scale production of preparative chromatographic packing media.
- A 26,000 m<sup>2</sup> self-built production base in the Wengyuan Innovation API Industrial Park (Guangdong), launched in December 2023, expected to commence operations in Q1 2026. This facility will produce 25,000 kg of silica-based fillers, 10,000 kg of resin-based packing media, and 50 tons of functional microsphere materials annually.

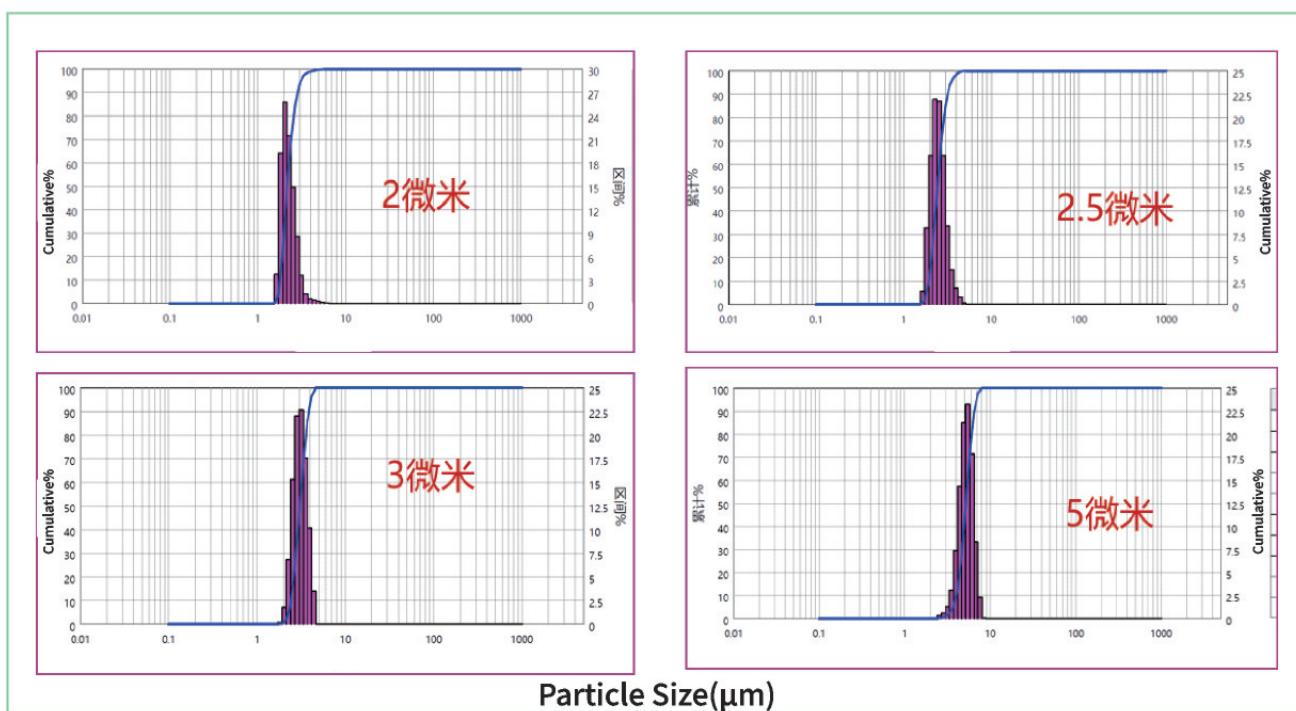
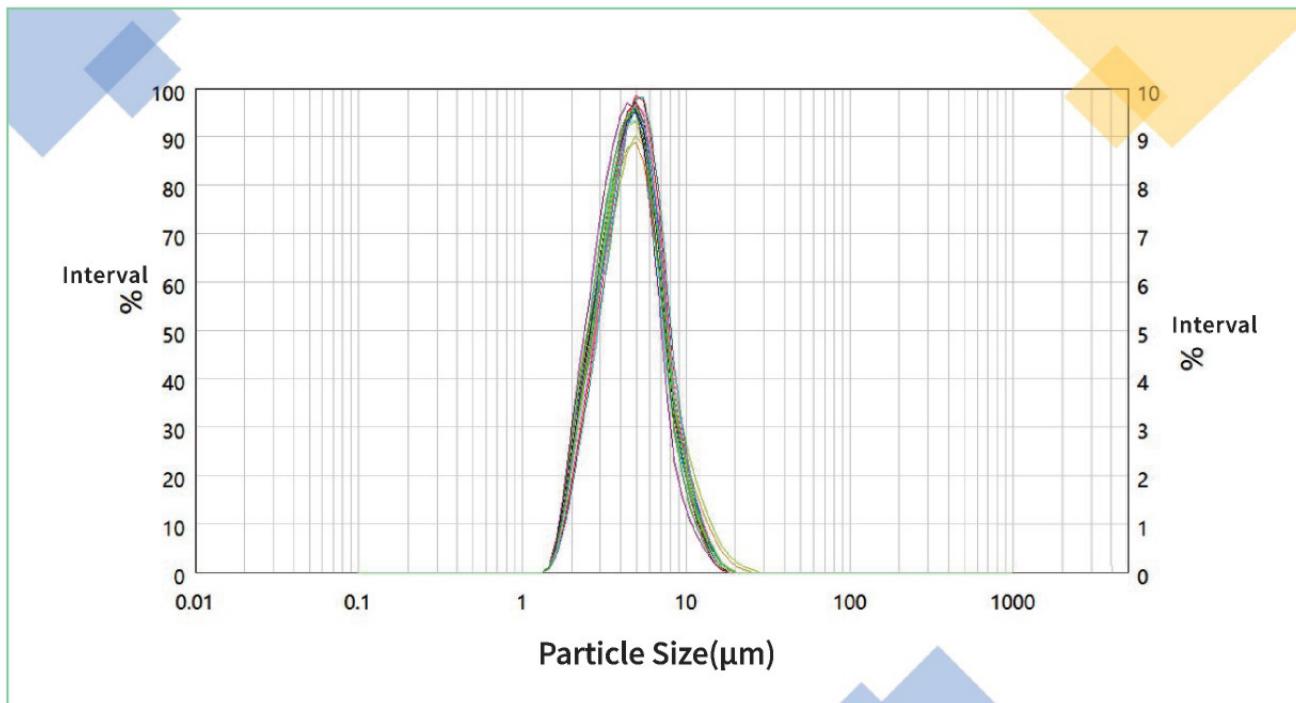


“WePure” production base in Foshan

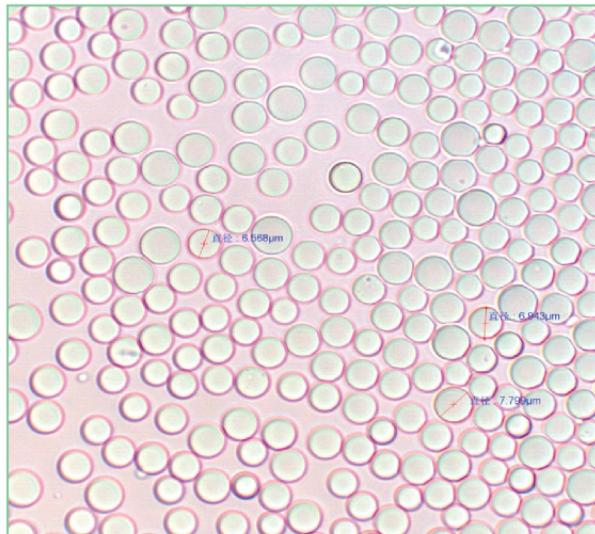
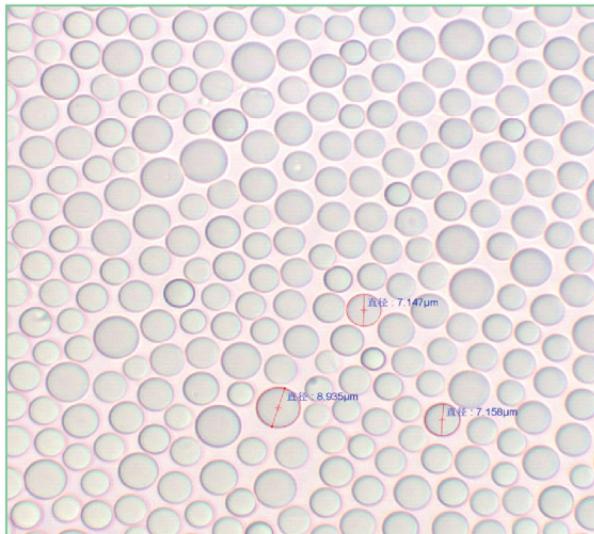


“WePure” production base in Shaoguan Guangdong

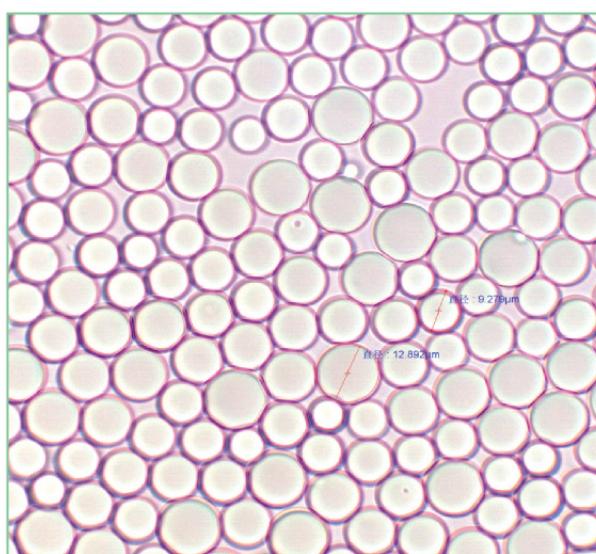
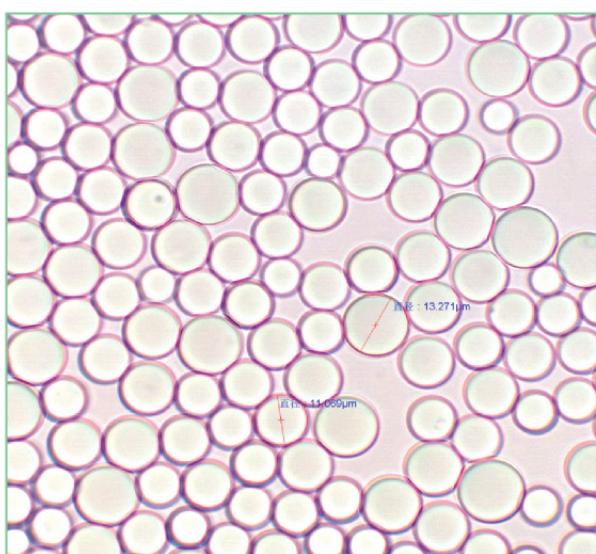
»» The particle size of silica gel is stable from batch to batch, ensure products consistency



## »» WePure 7μm、10μm Packing Media

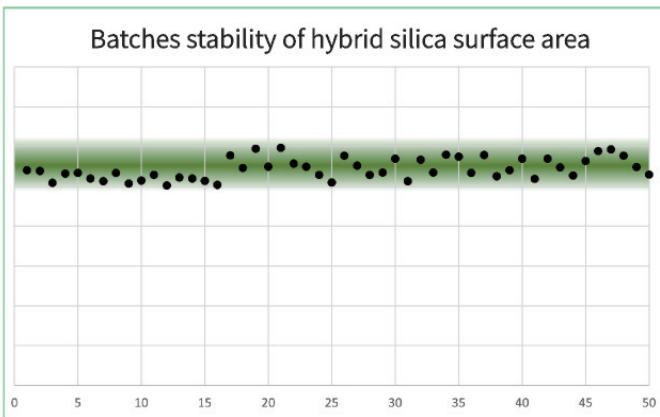
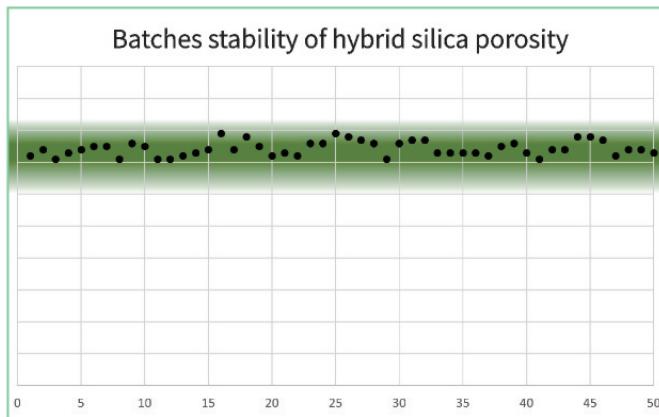


7μm Packing Media

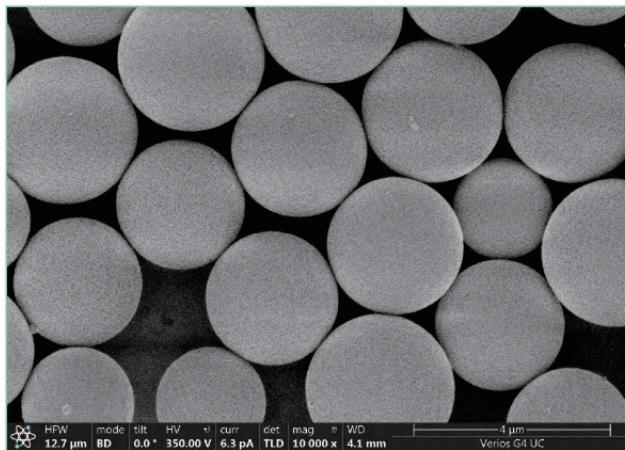


10μm Packing Media

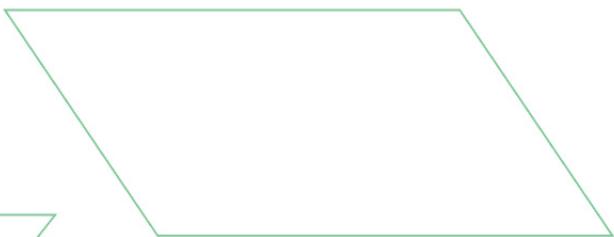
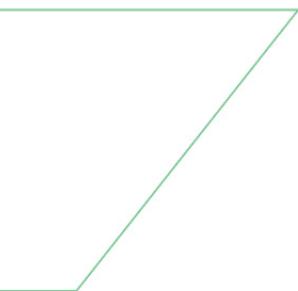
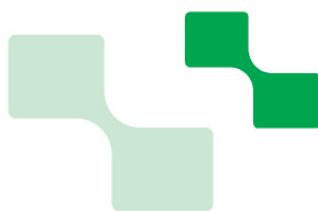
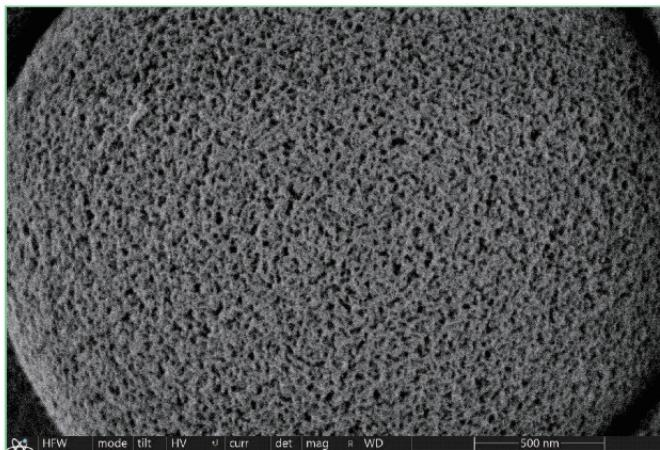
## »» Batches Stability of Porosity and Surface Area



»» The control of particle size uniformity is a good guarantee of column efficiency



»» Homogeneous, penetrating pore structure is a good guarantee of chromatographic performance



## ● PrePulite Series Packing Media

Packing media	Bonded Phase	Particle Size (µm)	Pore Size (Å)	Pore Volume (mL/g)	Surface Area (m <sup>2</sup> /g)	End-capped	Carbon Load (wt%)	Packing specification (g/bottle)	Part No
Gold	Silica	7	120	0.9	300	NO	-	50	GDH-07-50G
								100	GDH-07-100G
		10	120	0.9	300	NO	-	500	GDH-07-500G
								1000	GDH-07-1000G
	C18	7	120	0.9	300	YES	19%	50	GDC18-07-50G
								100	GDC18-07-100G
		10	120	0.9	300	YES	19%	500	GDC18-07-500G
								1000	GDC18-07-1000G
Gold	C8	7	120	0.9	300	YES	12%	50	GDC08-07-50G
								100	GDC08-07-100G
		10	120	0.9	300	YES	12%	500	GDC08-07-500G
								1000	GDC08-07-1000G
	C4	7	120	0.9	300	YES	3.9%	50	GDC04-07-50G
								100	GDC04-07-100G
		10	120	0.9	300	YES	3.9%	500	GDC04-07-500G
								1000	GDC04-07-1000G
Gold	Phenyl-Hexyl	7	120	0.9	300	YES	13%	50	GDPH-07-50G
								100	GDPH-07-100G
	Phenyl-Hexyl	10	120	0.9	300	YES	13%	500	GDPH-07-500G
								1000	GDPH-07-1000G
Gold	Phenyl-Hexyl	7	120	0.9	300	YES	13%	50	GDPH-10-50G
								100	GDPH-10-100G
	Phenyl-Hexyl	10	120	0.9	300	YES	13%	500	GDPH-10-500G
								1000	GDPH-10-1000G

Packing media	Bonded Phase	Particle Size (μm)	Pore Size (Å)	Pore Volume (mL/g)	Surface Area (m <sup>2</sup> /g)	End-capped	Carbon Load (wt%)	Packing specification (g/bottle)	Part No
Platinum	AQ-C18	7	120	0.9	300	YES	-	50 100 500 1000	GDAQ-07-50G GDAQ-07-100G GDAQ-07-500G GDAQ-07-1000G
		10	120	0.9	300	YES	-	50 100 500 1000	GDAQ-10-50G GDAQ-10-100G GDAQ-10-500G GDAQ-10-1000G
	C18	7	100	0.9	320	YES	16%	50 100 500 1000	PTC18-07-50G PTC18-07-100G PTC18-07-500G PTC18-07-1000G
		10	100	0.9	320	YES	16%	50 100 500 1000	PTC18-10-50G PTC18-10-100G PTC18-10-500G PTC18-10-1000G
XP	Silica	7	130	0.7	185	NO	-	50 100 500 1000	XPH-07-50G XPH-07-100G XPH-07-500G XPH-07-1000G
		10	130	0.7	185	NO	-	50 100 500 1000	XPH-10-50G XPH-10-100G XPH-10-500G XPH-10-1000G
	C18	7	130	0.7	185	YES	19%	50 100 500 1000	XPC18-07-50G XPC18-07-100G XPC18-07-500G XPC18-07-1000G
		10	130	0.7	185	YES	19%	50 100 500 1000	XPC18-10-50G XPC18-10-100G XPC18-10-500G XPC18-10-1000G
	tC18	7	130	0.7	185	YES	18%	50 100 500 1000	XPtC18-07-50G XPtC18-07-100G XPtC18-07-500G XPtC18-07-1000G
		10	130	0.7	185	YES	18%	50 100 500 1000	XPtC18-10-50G XPtC18-10-100G XPtC18-10-500G XPtC18-10-1000G

Packing media	Bonded Phase	Particle Size (µm)	Pore Size (Å)	Pore Volume (mL/g)	Surface Area (m²/g)	End-capped	Carbon Load (wt%)	Packing specification (g/bottle)	Part No
XP	C8	7	130	0.7	185	YES	14%	50 100 500 1000	XPC8-07-50G XPC8-07-100G XPC8-07-500G XPC8-07-1000G
		10	130	0.7	185	YES	14%	50 100 500 1000	XPC8-10-50G XPC8-10-100G XPC8-10-500G XPC8-10-1000G
	tC8	7	130	0.7	185	YES	13%	50 100 500 1000	XPtC8-07-50G XPtC8-07-100G XPtC8-07-500G XPtC8-07-1000G
		10	130	0.7	185	YES	13%	50 100 500 1000	XPtC8-10-50G XPtC8-10-100G XPtC8-10-500G XPtC8-10-1000G
	tC4	7	130	0.7	185	YES	8%	50 100 500 1000	XPtC4-07-50G XPtC4-07-100G XPtC4-07-500G XPtC4-07-1000G
		10	130	0.7	185	YES	8%	50 100 500 1000	XPtC4-10-50G XPtC4-10-100G XPtC4-10-500G XPtC4-10-1000G
	C4	7	130	0.7	185	YES	9.5%	50 100 500 1000	XPC4-07-50G XPC4-07-100G XPC4-07-500G XPC4-07-1000G
		10	130	0.7	185	YES	9.5%	50 100 500 1000	XPC4-10-50G XPC4-10-100G XPC4-10-500G XPC4-10-1000G
T3	T3	7	130	0.7	185	YES	14%	50 100 500 1000	XPT3-07-50G XPT3-07-100G XPT3-07-500G XPT3-07-1000G
		10	130	0.7	185	YES	14%	50 100 500 1000	XPT3-10-50G XPT3-10-100G XPT3-10-500G XPT3-10-1000G

Packing media	Bonded Phase	Particle Size (μm)	Pore Size (Å)	Pore Volume (mL/g)	Surface Area (m <sup>2</sup> /g)	End-capped	Carbon Load (wt%)	Packing specification (g/bottle)	Part No
XP	Phenyl -Hexyl	7	130	0.7	185	YES	15%	50 100 500 1000	XPPH-07-50G XPPH-07-100G XPPH-07-500G XPPH-07-1000G
		10	130	0.7	185	YES	15%	50 100 500 1000	XPPH-10-50G XPPH-10-100G XPPH-10-500G XPPH-10-1000G
		7	130	0.7	185	YES	18%	50 100 500 1000	XPotC18-07-50G XPotC18-07-100G XPotC18-07-500G XPotC18-07-1000G
		10	130	0.7	185	YES	18%	50 100 500 1000	XPotC18-10-50G XPotC18-10-100G XPotC18-10-500G XPotC18-10-1000G
	tPFP	7	130	0.7	185	NO	7%	50 100 500 1000	XPtPFP-07-50G XPtPFP-07-100G XPtPFP-07-500G XPtPFP-07-1000G
		10	130	0.7	185	NO	7%	50 100 500 1000	XPtPFP-10-50G XPtPFP-10-100G XPtPFP-10-500G XPtPFP-10-1000G
	C18+PFP	7	130	0.7	185	NO	14.5%	50 100 500 1000	XPtFP18-07-50G XPtFP18-07-100G XPtFP18-07-500G XPtFP18-07-1000G
		10	130	0.7	185	NO	14.5%	50 100 500 1000	XPtFP18-10-50G XPtFP18-10-100G XPtFP18-10-500G XPtFP18-10-1000G
C18+AX	C18+AX	7	130	0.7	185	YES	17%	50 100 500 1000	XPtC18AX-07-50G XPtC18AX-07-100G XPtC18AX-07-500G XPtC18AX-07-1000G
		10	130	0.7	185	YES	17%	50 100 500 1000	XPtC18AX-10-50G XPtC18AX-10-100G XPtC18AX-10-500G XPtC18AX-10-1000G

Packing media	Bonded Phase	Particle Size (µm)	Pore Size (Å)	Pore Volume (mL/g)	Surface Area (m <sup>2</sup> /g)	End-capped	Carbon Load (wt%)	Packing specification (g/bottle)	Part No
PHS XP	tC18	7	130	0.7	185	YES	17%	50 100 500 1000	XPtC18P-07-50G XPtC18P-07-100G XPtC18P-07-500G XPtC18P-07-1000G
		10	130	0.7	185	YES	17%	50 100 500 1000	XPtC18P-10-50G XPtC18P-10-100G XPtC18P-10-500G XPtC18P-10-1000G
	Phenyl -Hexyl	7	130	0.7	185	YES	15%	50 100 500 1000	PHSPH-07-50G PHSPH-07-100G PHSPH-07-500G PHSPH-07-1000G
		10	130	0.7	185	YES	15%	50 100 500 1000	PHSPH-10-50G PHSPH-10-100G PHSPH-10-500G PHSPH-10-1000G
	tPFP	7	130	0.7	185	NO	10%	50 100 500 1000	PHStF5-07-50G PHStF5-07-100G PHStF5-07-500G PHStF5-07-1000G
		10	130	0.7	185	NO	10%	50 100 500 1000	PHStF5-10-50G PHStF5-10-100G PHStF5-10-500G PHStF5-10-1000G
Perfect	T3	10	120	1.0	300	YES	14%	50 100 500 1000	PFTT3-10-50G PFTT3-10-100G PFTT3-10-500G PFTT3-10-1000G
	Diol	10	120	1.0	300	YES	15%	50 100 500 1000	PFTD-10-50G PFTD-10-100G PFTD-10-500G PFTD-10-1000G
	HILIC	10	120	1.0	300	NO	-	50 100 500 1000	PFTH-10-50G PFTH-10-100G PFTH-10-500G PFTH-10-1000G

## ●Packing Media for Upulite and Polypulite Pre-treatment/SPE Packing

Packing media	Bonded Phase	Describe	Packing specification	Part Number
PolyPulite	HLB	PolyPulite HLB 30μm	1000G	HLB -30-1000G
	HLB	PolyPulite HLB 60μm	1000G	HLB -60-1000G
	HLB Pro	PolyPulite HLB Pro 30μm	1000G	HLBP-30-1000G
	HLB Pro	PolyPulite HLB Pro 60μm	1000G	HLBP-60-1000G
	MCX	PolyPulite MCX 30μm	1000G	MCX-30-1000G
	MCX	PolyPulite MCX 60μm	1000G	MCX-60-1000G
	MAX	PolyPulite MAX 30μm	1000G	MAX-30-1000G
	MAX	PolyPulite MAX 60μm	1000G	MAX-60-1000G
	WCX	PolyPulite WCX 30μm	1000G	WCX-30-1000G
	WCX	PolyPulite WCX 60μm	1000G	WCX-60-1000G
	WAX	PolyPulite WAX 30μm	1000G	WAX-30-1000G
	WAX	PolyPulite WAX 60μm	1000G	WAX-60-1000G
Upulite	C18	Upulite C18 60μm	1000G	C18-60-1000G
	PSA	Upulite PSA 60μm	1000G	PSA-60-1000G

## ◆ PrePulite® XP Hybrid Silica packing media Overview

The XP series of hybrid silica gel Packing Media adopt a special hybrid technology, which combines the characteristics of organic and inorganic Packing Media. It not only retains the properties of pure silica but also has the characteristics of polymer materials, such as stability in wide pH range and low activity of silanol groups. This ensures both the separation performance and service life. There are various specifications of the Packing Media available for selection, which can be linearly scaled up from analytical columns to preparative columns, ensuring the continuation and transfer of the method, improving work efficiency.

### 1. Advantages of PrePulite® XP Hybrid Silica Packing Media

Ordinary silica gel is composed of a Si-O-Si structure. In an acidic system, the bonded phase of this structure is prone to detachment, and in an alkaline system, the silica - oxygen bonds are liable to dissolve. XP hybrid silica introduces organic groups into the silica skeleton, significantly delaying the dissolution of silica and hydrolysis of the bond phase, so the pH tolerance range expand to 2-12.

#### 1.1 excellent Chemical Stability and pH Tolerance

Wide pH Range: Ordinary pure silica is prone to bonded phase detachment under strong acid ( $\text{pH} < 2$ ) or strong alkali ( $\text{pH} > 8$ ) conditions, while XP hybrid silica significantly delays the dissolution of silica and hydrolysis of bonded phases by introducing organic groups into the silica skeleton, extending the pH tolerance range to 2-12.

Hydrolysis Resistance: Organic groups enhance the chemical inertness of the skeleton structure, especially show more stability in alkaline mobile phases, and extend the service life of columns.

#### 1.2 Separation Performance

Reduced Silanol Effect: XP hybrid silica gel effectively reduces the ion - exchange interaction between basic compounds and silanol groups by decreasing the density of silanol groups. XP series can improve peak tailing and enhances the separation resolution.

#### 1.3 Mechanical Strength and Structural Stability

High Rigid Skeleton: The XP packing media possesses the high strength of silica and the ability to withstand high pressure. Meanwhile, it also has the flexibility of polymers, which can reduce the risk of the packing media breaking.

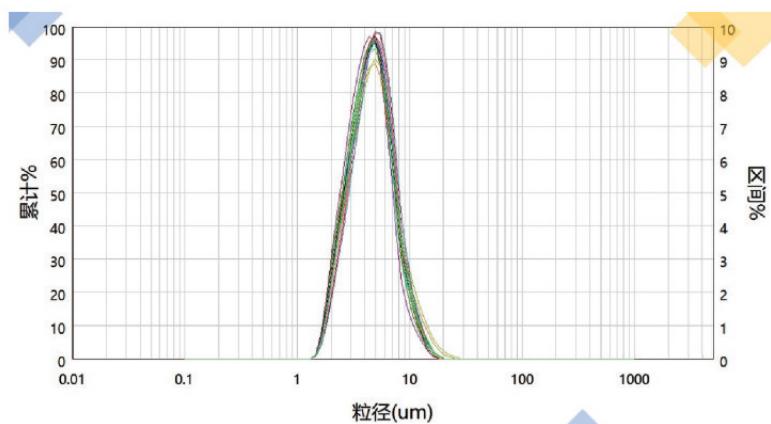
## 1.4 Expanded Application Range

Industrial Preparation Scaling-up: The stable structure and consistency between batches support seamless scaling-up from laboratory-scale to industrial production, it is beneficial to improving work efficiency.

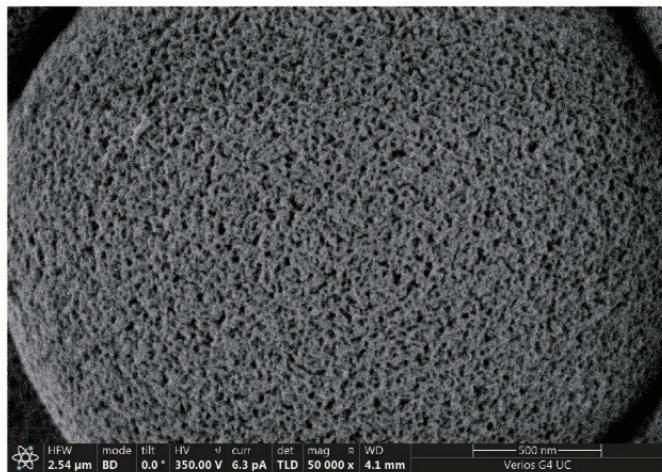
## 2. Product Performance

### 2.1 Excellent Particle Size ,Pore Size Distribution and Batch Stability

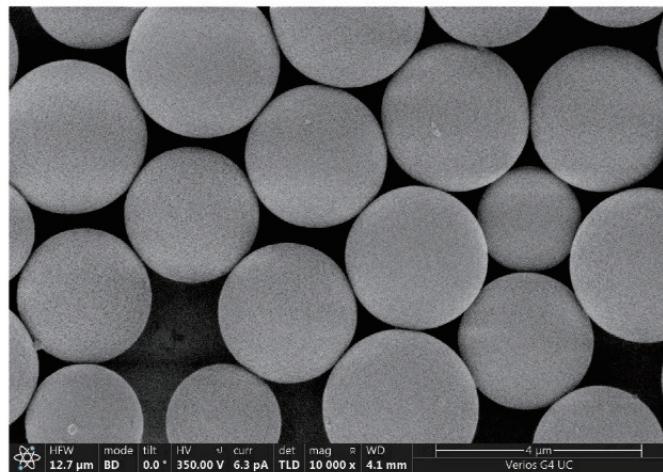
»» The batch-to-batch stability of silica synthesis particle , ensures the consistency of subsequent products.



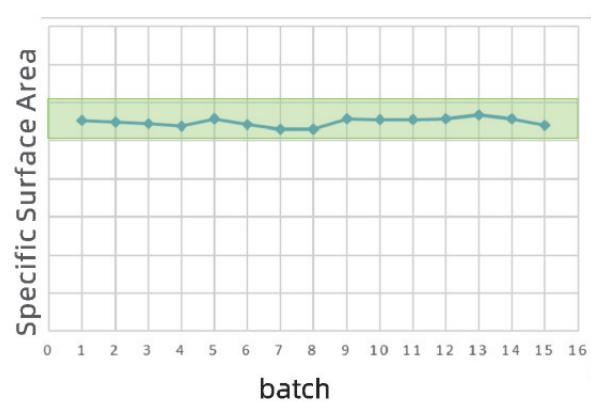
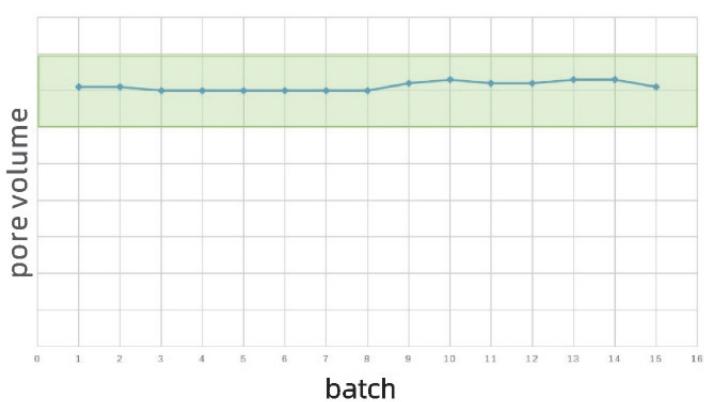
»» Homogeneous, penetrating pore structure is a good guarantee of chromatographic performance



»» The control of particle size uniformity is a good guarantee of column efficiency



## »» The silica gel is stable from batch to batch, ensure products consistency



## 2.2 Alkaline resistance performance

In the pharmaceutical field, strong alkaline conditions (such as NaOH solution) are commonly used for in-situ cleaning (CIP) to remove protein adsorption impurities on the surface of packing media, especially widely used in the purification process of biopharmaceuticals, such as insulin, GLP-1 and so on. Traditional packing media is prone to chemical degradation (such as hydrolysis or bonded phase detachment) under strong alkaline condition, resulting in a shortened service life of packing media. The XP series of hybrid packing media, through innovative organic-inorganic hybrid technology, constructs an alkali-resistant three-dimensional skeleton structure, which can withstand extreme pH conditions of 2-12. Experimental data shows that the packing media still maintains stable performance (column efficiency  $\geq 95\%$ , back pressure  $\leq 110\%$  initial pressure) after 40 hours of CIP cleaning in 0.1M NaOH solution, significantly superior to traditional silica. This outstanding alkaline resistance makes it an ideal choice for processes requiring frequent alkaline cleaning, effectively reducing the cost of consumables and downtime of production process.

### Alkaline Wash Test Conditions :

Packing Media : PrePulite® XP C8 10 $\mu$ m

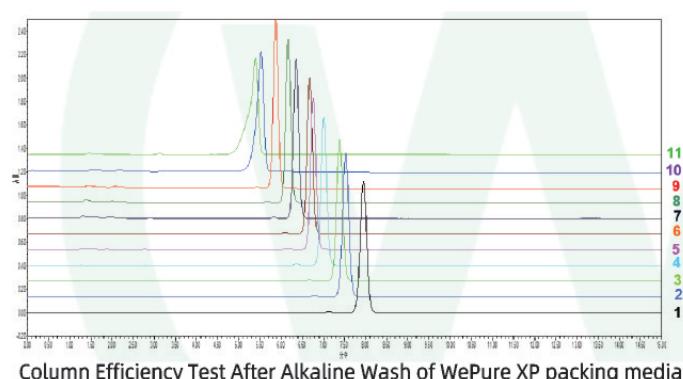
Column : 4.6\*250mm

Mobile Phase: ACN: 0.1mol NaOH Solution = 7:3

Flow Rate : 1mL/min

Column Temperature : 30°C

Alkaline Wash Time: 300 min/ time



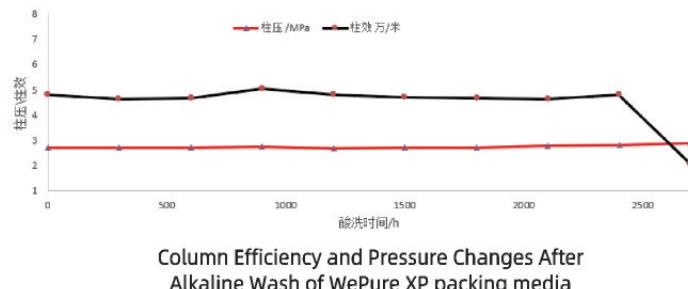
### Column Efficiency Test Conditions :

Mobile Phase : ACN:Water=7:3

Flow Rate : 1mL/min

Column Temperature : 30°C

Standard Sample : 1ml/mL Naphthalene 5μL



**Conclusion:** Under the condition of pH=13, the continuous alkaline washing of XP C8 packing media results in a lifespan of 2400 minutes.

### 2.3 Acid resistance performance

In reverse-phase purification processes, 0.1% TFA acidic mobile phase is commonly used elution system. However, traditional silica matrix packing media is prone to bonded phase breakage under long-term acidic environment. XP hybrid packing media show outstanding acid resistance in 0.1% TFA mobile phase.

### Acid Wash Test Conditions :

Packing Media : PrePulite® XP C8 10μm

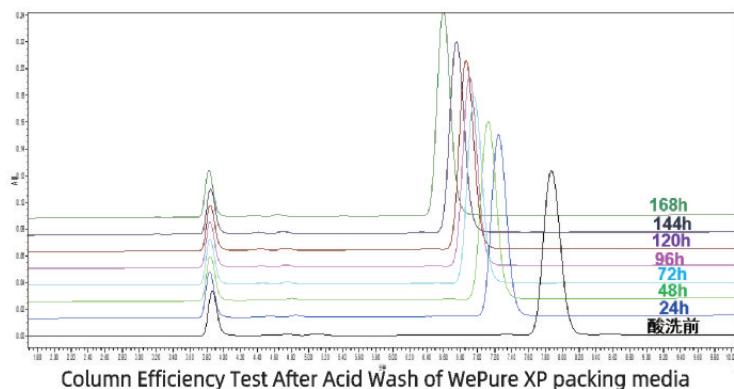
Column : 4.6\*250mm

Mobile Phase : ACN:0.1TFA Solution =7:3

Flow Rate : 1mL/min

Column Temperature : 60°C

Acid Wash Time : 24h/time



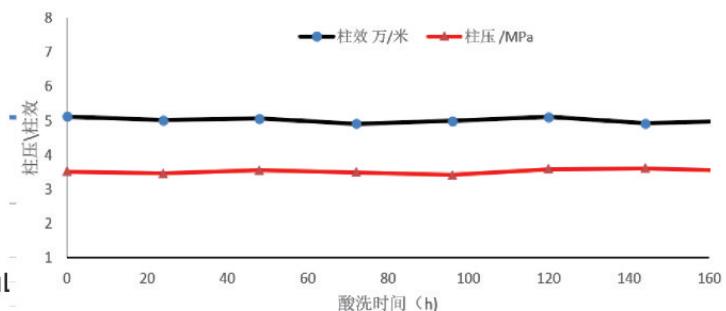
### Column Efficiency Test Conditions :

Mobile Phase : ACN: Water =7:3

Flow Rate : 1mL/min

Column Temperature : 30°C

Standard Sample : 1ml/mL Naphthalene 5μL



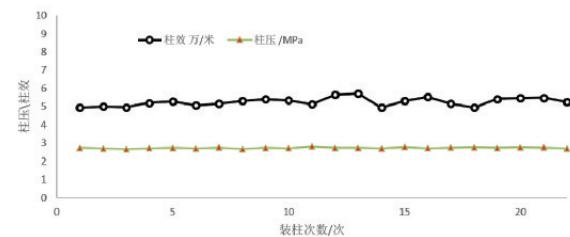
**Conclusion:** The XP packing is continuously flush at condition of 60°C and pH 1, the packing life is more than 160 hours.

## 2.4 Mechanical Strength

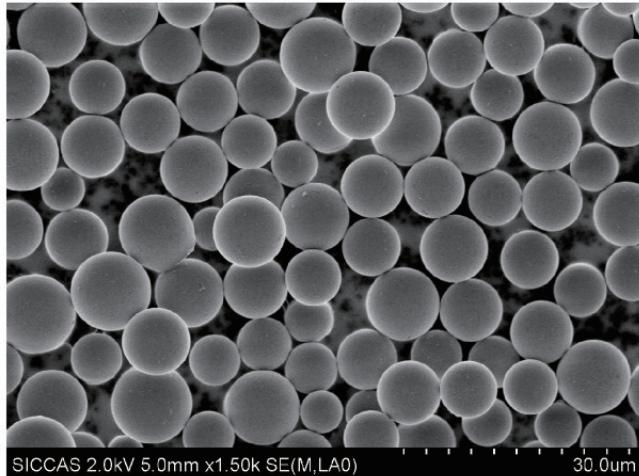
In industrial chromatography purification, the high-frequency loading and unloading operations of the dynamic axial compression (DAC) system put forward strict requirements for the mechanical properties of the packing media. The rigid skeleton design of the XP hybrid packing media (organic-inorganic hybrid) can effectively resist mechanical stress, avoid the production of fragments due to particle breakage, thereby maintaining the stability of the column bed porosity and preventing a sudden rise of column pressure. PrePulite® XP C8 10μm packing media is still intact after being loaded and unloaded 22 times in the DAC.



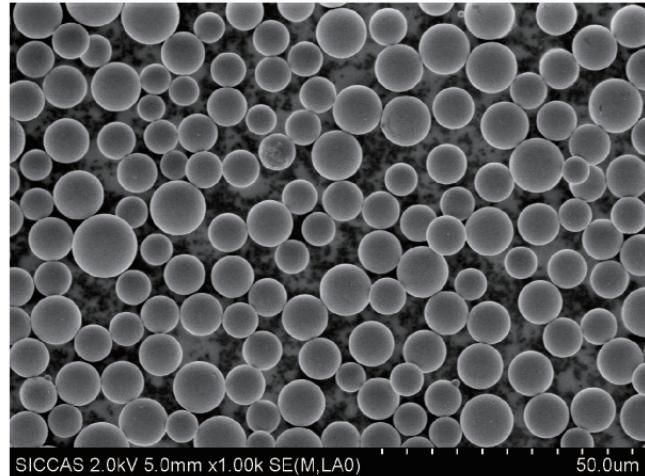
Column Efficiency after Repeated Packing Test of WePure XP Hybrid packing media



Column Efficiency and Pressure Changes After Repeated Packing of WePure XP Hybrid packing media



Before Packing the material



After Packing the material 20 Times

## ◆ Preparative Column and DAC Packing Method

1. To meet the needs for pilot-scale and semi-industrial scale production, in addition to the conventional columns(4.6\*250mm ), we also provide the following 15 specifications of pre-packed columns:

Column Length (mm)		Diameter (mm)			
150					
250	10	20	21.2	30	50
300					

## 2. DAC Column Packing Method

### 2.1 Main Equipment and Reagents

Table 1: List of Main Equipments and Reagents

Item	Specification	Quantity	Main Purpose	Remarks
Preparation System	As required	1 set	Column packing and column efficiency testing	
Ultrasonic Device	As required by the preparation system	1 unit	Cleaning sieves, homogenizing packing media	Consult the equipment supplier for the ultrasonic device size required for ultrasonic sieves
Air Compressor /Air Source	As required by the preparation system	1 set	DAC loading and operation	Pressure and airflow need to be communicated with the equipment supplier in advance
Homogenization Tank/Bottle	Refer to Table 2	1 set	Used for packing media homogenization	It is recommended to configure a homogenization tank for DAC with a size of 300mm or above
Balance	Accuracy 0.1 gram	1 unit	Weight packing media	
Measuring Cylinder	1L	1 piece	Measuring solvent	
Ruler	Over 30cm	1 piece	Measuring column height	
Packing Media	As required by the process	Refer to Table 2	DAC packing media	
Isopropanol	Chromatographic grade /preparative grade	As needed	Homogenization solution and cleaning reagent	
Acetonitrile	Chromatographic grade /preparative grade	As needed	Mobile phase for column efficiency testing	
Water	Purified water recommended	As needed	Column efficiency testing	
Sodium Hydroxide		As needed	Cleaning	
Acetic Acid	Analytical grade	As needed	Cleaning	
Acenaphthene	Analytical grade	As needed	Column efficiency test sample	

## 2.2 Weight of the packing media

The required weight of packing media is calculated according to the following formula:

Weight of packing media (g) = DAC cross-sectional area (cm<sup>2</sup>) × Packing height (cm) × Packing density (g/cm<sup>3</sup>)

For example, packing a 150mm DAC with XP C8 10-micron packing media to a height of 25 cm, the packing media to be prepared is:

Weight of packing media=0.6 × 3.14 × 7.5 × 7.5 × 25 =2649g

**Table 2. Packing Data for Different Specifications of DAC**

Column Inner Diameter (mm)	Packing Media Usage (kg)	Homogenization Solution Volume (L)	Solvent Volume (L)
50	0.3	0.9	0.7
100	1.2	3.6	2.8
150	2.7	7.8	6
300	10.6	30	24
450	23.8	67	54
600	42.0	120	95

Note: The packing media density is assumed to be 0.6g/mL; the column length is calculated as 25cm.

Remarks:

- The density is different because packing media type is different. When calculating, the actual density of packing media should be used instead of 0.6 g/cm<sup>3</sup> in this case.
- There will be losses of material during the processes of cyclic packing and disassembly. It is recommended to purchase 10% to 20% more than the theoretical quantity.

## 2.3 Homogenization Solvent

Choose an appropriate homogenization solvent according to the type of packing media. Isopropanol is recommended for reverse-phase materials, and the homogenization concentration is about 35%. The classic operation is as follows: the volume of the homogenization solvent : the weight of packing media = 2 mL : 1 g.

Taking the 150mm DAC as an example, considering the losses, approximately 2.7 kg of material is actually packed each time, and the volume of the solvent required is approximately 6 L.

## 2.4 Column Packing

### 2.4.1 Cleaning

According to the requirements of the DAC manufacturer, clean the frit and other components successively with alkaline solution, hydrophilic solvent, and organic solvent. Clean the inside of the column tube, and finally flush it with the column packing reagent.

#### 2.4.2 Leak Test

It is recommended to use pure water to test whether the system will leak. The column pressure of test should be slightly higher than the actual packing pressure.

#### 2.4.3 Homogenization

Pour the material into the homogenized solution while stirring. In order to remove the bubbles and disperse the material better, it is advisable to ultrasonicate for about 10 minutes. And keep stirring until it is transferred into the column tube.

#### 2.4.4 Packing

Pour quickly the homogenized solution into the DAC column tube, clean the residual packing media on the column head, quickly pack the column, and let it stand for more than 30 minutes after packing, then measure the height of column bed.

#### 2.5. Column Efficiency Test

First, flush the column with the homogenizing solution at a low flow rate for 1 - 2 column volumes, and then replace the homogenizing solution with the mobile phase for column efficiency testing. The flow rate should be increase gradually from low to high. To prevent the baseline from becoming unstable due to heat absorption during solvent mixing, pre - mix the organic phase and water in proportion in advance, stir the mixture, and wait until the temperature returns to room temperature before column efficiency testing.

After packing, the column bed is not yet very stable. If the column efficiency is not satisfactory, you can repeat the column efficiency test several times. If it still fails after 3-5 times testing, it is recommended to test overnight or repack the column.

##### Column Efficiency Test :

Mobile Phase: Acetonitrile/Water (70/30, v/v)

Flow Rate: 60%-80% of the normal preparation flow rate

Detection Wavelength : 254 nm

Sample: Naphthalene (1mg/mL)

#### ◆ Ordering Information

Packing Media Type	Bonded Phase	Particle Size (μm)	Pore Size (Å)	Pore Volume (mL/g)	Specific Surface Area (m <sup>2</sup> /g)	End-capping	Carbon Loading	Packaging Specification	Part Number
XP	C8	10	130	0.7	185	Yes	14%	50 100 500 1000	XPC18-10-50G XPC18-10-100G XPC18-10-500G XPC18-10-1000G
XP	C18	10	130	0.7	185	Yes	19%	50 100 500 1000	XPC18-10-50G XPC18-10-100G XPC18-10-500G XPC18-10-1000G

## Case: Insulin Purification

Packing Material: PrePulite® XP C18 10μm

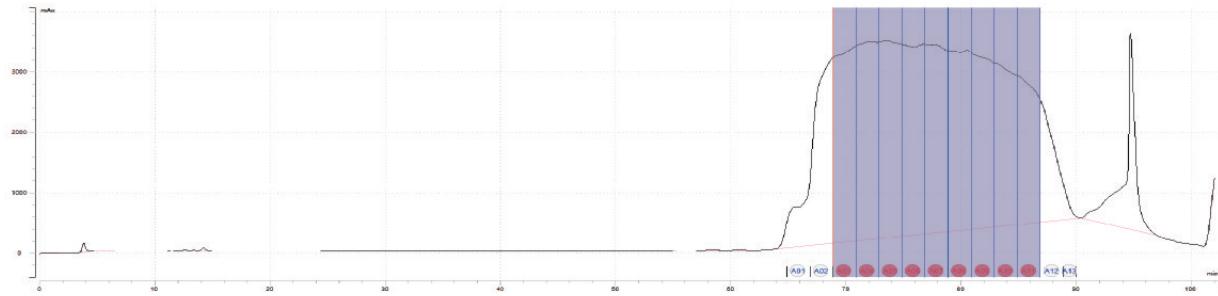
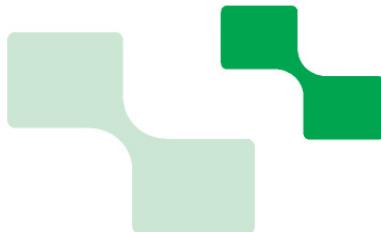
Loading Capacity: 8g/L

Purity of crude product: 97.31%

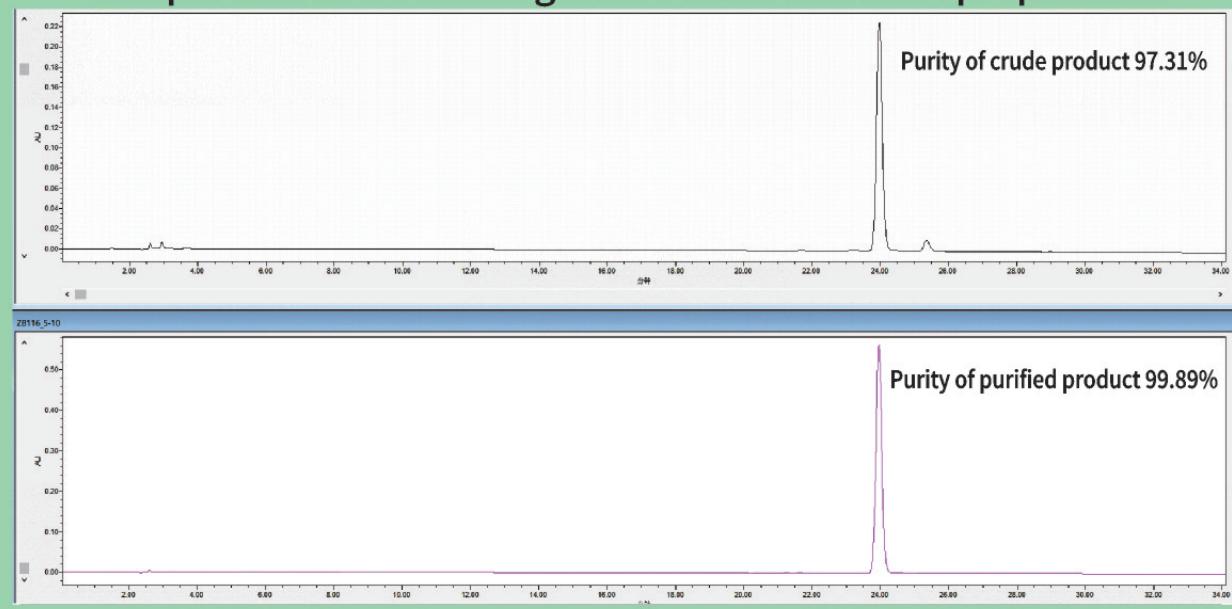
Purity of purified product: 99.89%

Largest single impurity: 0.09%

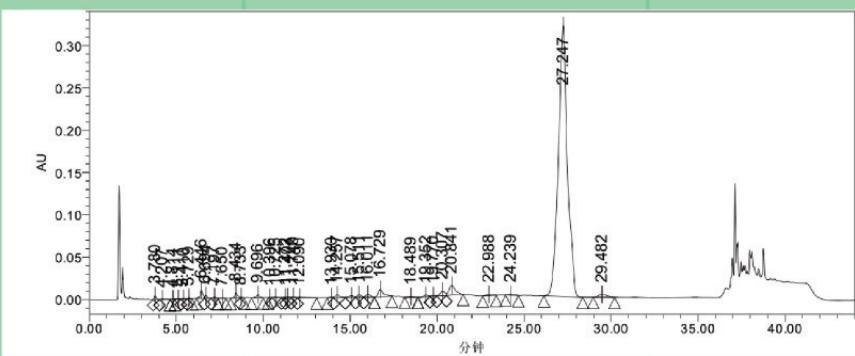
Total Recovery Rate: 87.83%



### Comparison of chromatograms before and after preparation



## Case: GLP-1 drug purification



## Crude product inspection chart

## Oral Simeglutide API

Packing Material: XP C8 10µm

Loading Capacity: 10g/L

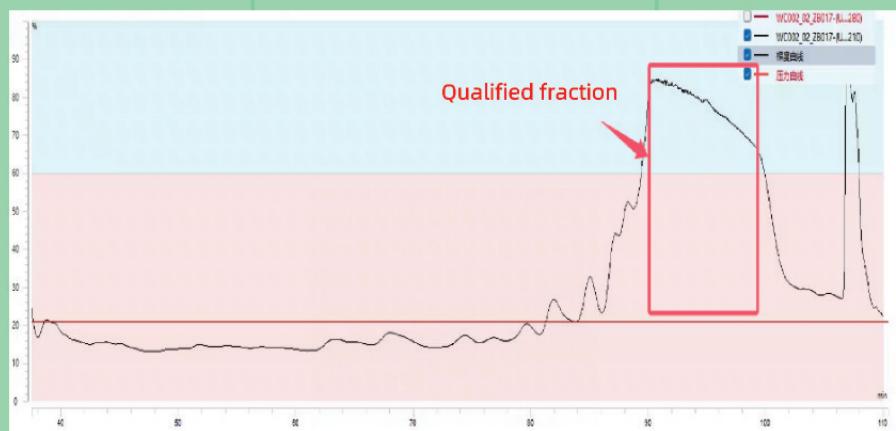
Purity of crude product: 88.55%

Purity of purified product: 98.89%

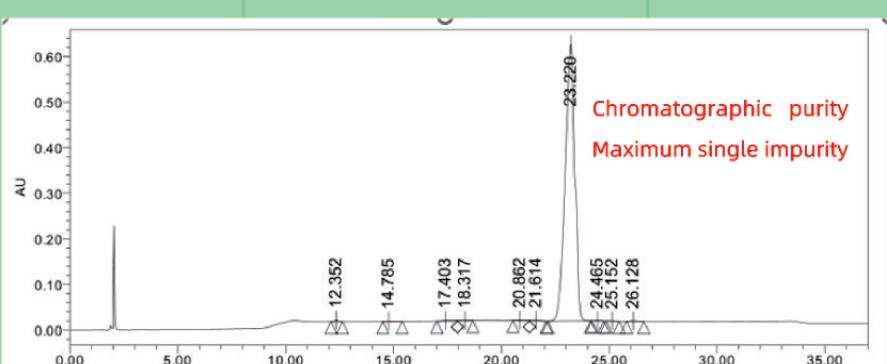
Largest single impurity: 0.23%

Total classification yield: 90%

Total purification yield: 90%



### Preparation of chromatogram



## Qualified fraction detection diagram

## Injection of Simeglutide API

Packing Material: XP C8 10μm

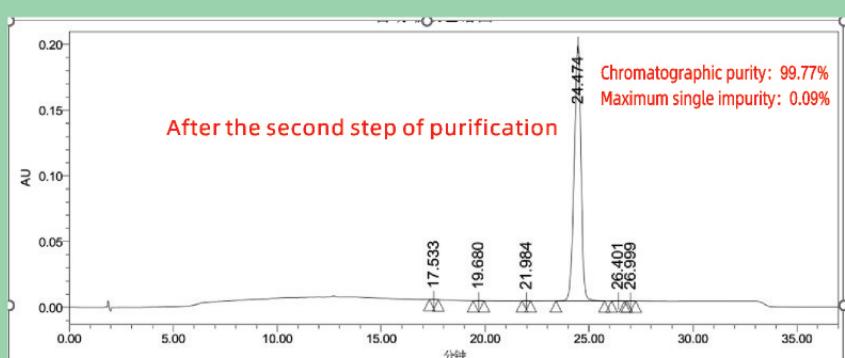
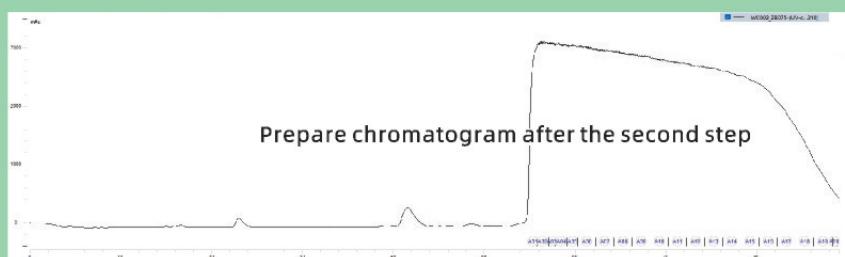
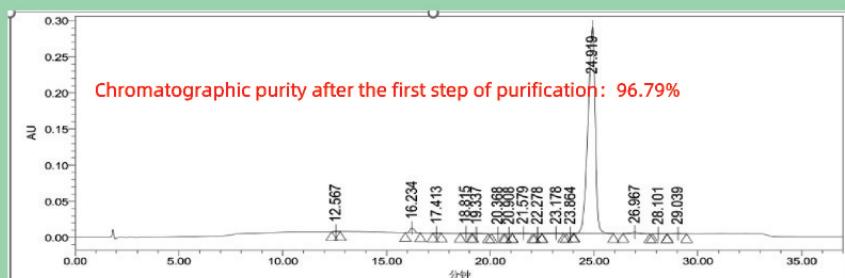
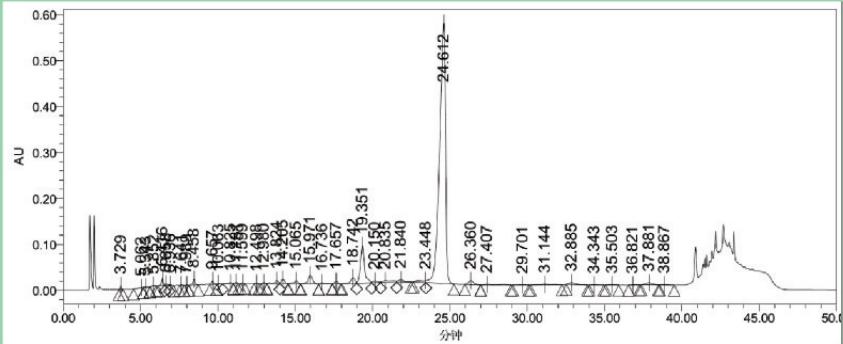
Loading Capacity: 10g/L

Purity of crude product: 77.09%

Purity of purified product: 99.77%

Largest single impurity: 0.09%

Total purification yield: 65%





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