SPG

山东药玻

NOVOLyo™

Type I Moulded Glass, Alkali-Resistant Glass, Coated Rubber Stopper,Tubular Products

Shandong Pharmaceutical Glass Co., Ltd.

Introduction of NOVOLyo™

Because of its advantages such as the high stability and convenient storage, the proportion of the lyophilized drug is rising rapidly. Shandong Pharmaceutical Glass Co., Ltd., has developed a kind of high quality light weight borosilicate moulded glass vial- NOVOlyo™vial to answer to the fast growing demand of freeze-drying in the pharmaceutical and biotech industries.

Our NOVOlyo™ vial is the most cost-effective choice for your freeze-drying process, it can not only meet the requirements of drugs packaging, but also meet your demand in market competition. From the above 7ml, our NOVOlyo™- light weight borosilicate moulded glass vial can completely replace the type I tubular glass vials.

What's your benefit from NOVOLyo™

@ Minimize the risk of breakage;
@ Most cost-effective;
@ Much stronger;
@ Much higher hydrolytic resistance;
@ Lighter in weight up to 30%;
@ Dimensional stability.

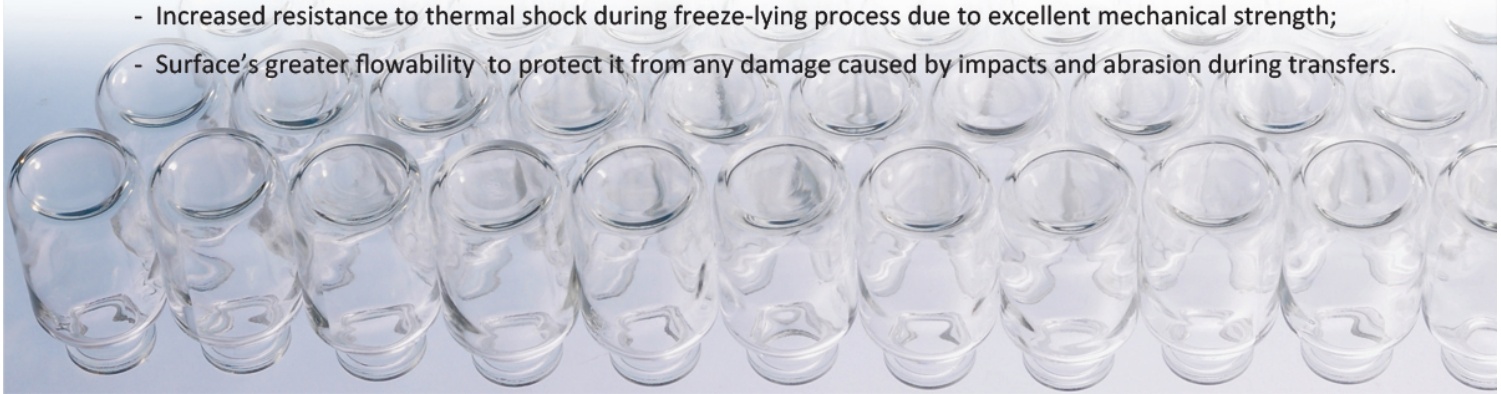
Tubular

or

Moulded?

Features of NOVOLyo™

- Wide range of sizes, from 7ml to 100ml, to match all outer diameter of tubular vials;
- Made of 5.0 expansion borosilicate glass,type I, more excellent in hydrolyitic resistance of the inner surface;
- Accurate, mellow and rounded mouth of vial; Variable more flat and round bottom of vial as you request;
- Lighter up to 20-30% than normal ISO standard moulded glass vial, with thin body thickness similar to tubular;
- Increased resistance to thermal shock during freeze-lying process due to excellent mechanical strength;
- Surface's greater flowability to protect it from any damage caused by impacts and abrasion during transfers.



The advantages of NOVOLyo™

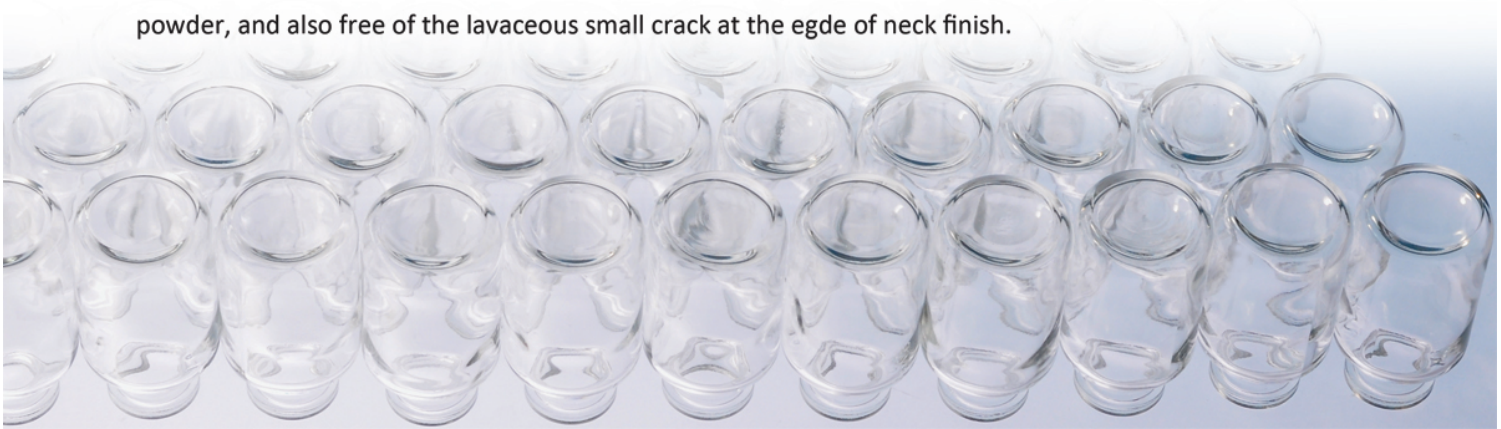
because of high performances

NOVOLyo™ vial can improve your lyophilization process to be more safe and effective

The following characteristics have already been studied and verified by SPG

- Inner surface hydrolytic resistance: much better than tubular vial made of 5.0 and 7.0 expansion tubing;
- Vertical pressure resistance: 1 to 2 times more to withstand the verticle pressure than tubular glass vial;
- Transverse mechanical impact strength: 20-50% higher than tubular vial by point impact;
- The ability of anti-friction: basically it can achieve zero scratch defects during loading/unloading & transfer;
- The coin bottom breakage and broken: almostly reaches zero under very fast freezing condition.

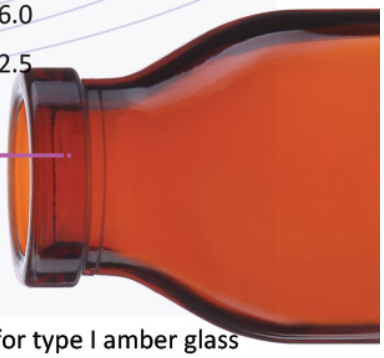
ADDED VALUE FOR THE CUSTOMER: When using *NOVOLyo™* vial, you feel it like the tubular vial, no need to m-odify or change the freeze-drying cycle. However,compared with tubular vial, the *NOVOLyo™* vial is free of glass powder, and also free of the lavaceous small crack at the egde of neck finish.



Available production range

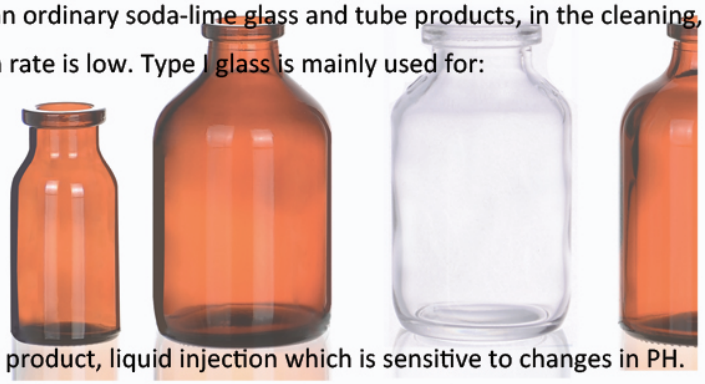
The existing *NOVOLyo*™ vials listed. ***Waiting for you to creat new sizes!***

Reference	Nominal	Brimful	Weight	Neck Finish	Height	Body Dia.
130101	10	12.5	14.0	ISO20	45.0	24.0
130151	15	18.0	17.0	ISO20	52.0	26.5
130201	20	24.0	22.5	ISO20	53.5	30.0
130301	30	35.0	27.0	ISO20	55.8	36.0
130501	50	58.0	49.0	ISO20	68.5	42.5
.....						



Type I Amber Moulded Glass Vials/Bottles

In order to meet the demand of pharma industry, we began commercial production for type I amber glass in 2016. As we know that Type I glass is more stable in surface structure because of their high hydrolytic r-esistance and less alkaline ion precipitation, so type I molded bottles are widely used in biological products, blood products and pH-sensitive drugs.Type I molded bottle is borosilicate glass, its low thermal expansion coefficient of product has a high resistance to quench and heat; in addition, its physical strength Degree a-nd mechanical properties are much higher than ordinary soda-lime glass and tube products, in the cleaning, drying, freeze-drying, sterilization links broken rate is low. Type I glass is mainly used for:



Human albumin,
Hepatitis B immunoglobulin,
Intravenous gamma globulin,
Clotting factor, Rabies vaccine,
Fructose diphosphate,
Lyophilized preparation and fat emulsion product, liquid injection which is sensitive to changes in PH.

Molded diagnostic reagent bottles USP type I is used for clinical and biochemical reagent filling, including determination for enzyme, carbohydrate, lipid, protein and non-protein nitrogen, also control of inorganic elements, liver function and serum clinical chemical. In order to provide customers with one-stop service, and meet diverse needs of the North American market and competition, following the flint USP type I molded bottle, our company has developed amber USP type I molded bottle, according to market demand and inventory, the production of amber type I molded bottle usually to be in the second half of the furnace cycle of the flint type I.

Type I Alkali Resistance Glass Botte

because of high performances

Sodium bicarbonate injection is a direct intravenous infusion for the treatment of metabolic acidosis and alkalized urine, it's mainly packaged in the glass bottles and non - PVC coextruded film at present. For the high alkali sodium bicarbonate injection, there is a high risk of glass flakes if packaged in the Type II soda-lime infusion bottles during it's period of validity,eventhough the Type I borosilicate glass is superior than the soda-lime glass, but it's also cannot solve the glass flakes completely as the alkali resistance of borosilicate glass and soda-lime glass only up to the level II.However,the uses of multilayer coextruded film has many inconveniences in the production and quality control process,such as,the filling medicine easily appeared quality problems during the storage and sterile process.So it's really need to develop an alkali resistance glass bottle to pack the sodium bicarbonate injection. With nearly three years trial- produce and verification,our company have developed the alkali resistance borosilicate infusion bottle successfully for packaging the sodium bicarbonate injection,after the accelerated tests and medicine stability tests during it's period of validity,all the test results meet the related standards and requirements.

Clear high durability of Glass Container can improve your production process to be more safe and effective

Through product testing and stability test, Type I alkali - resistant borosilicate glass infusion bottle have the following characteristics:

It meets the quality requirements under the current version of USP <660>, EP Ph.Eur 3.2.1 and CFDA YBB standards, including hydrolytic resistance, heavy metal irons releasing etc. The hydrolytic resistance meets Class I requirement under ISO4802-2 & ISO4802-1. The alkali resistance meets Class I requirement under ISO695: 1991 and CFDA YBB00352004-2015.

Through relevant inspection and testing to show that its alkali resistance is higher than borosilicate glass infusion bottle. In the compatibility test, the relevant irons releasing complies with the related requirement,the exfoliation was not found during the accelerated test of filling sodium bicarbonate injection solution, pharmaceutical company did the accelerated stability test of filling sodium bicarbonate injection solution, and its test results complies with the requirement,applicable to pack the alkaline preparations such as sodium bicarbonate injection solution,our company just in process registering the product on the primary and secondary packaging information platform at the national pharmaceutical examination center, and actively cooperating with customers to carry out the compatibility and association review.

Available Format for Type I Moulded Glass Vials/Bottles

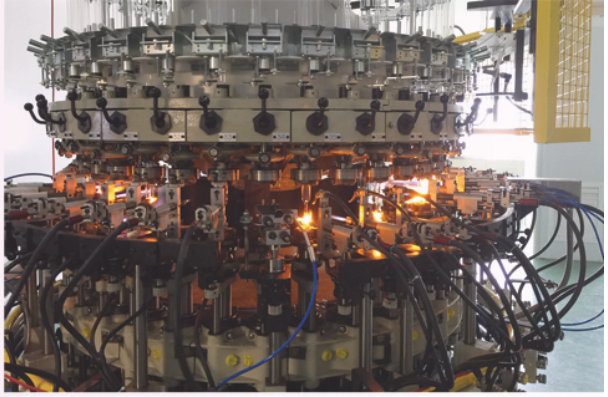
Product Name	Ref. No.	Drawing No.	Filling Capa.	Brimful Capa.	Weight(g)	Neck Finish(mm)	Total H(mm)	Dia. of Body(mm)
Moulded Vial, type I	110071	7A	7ml	9ml	13	20+0.1/-0.2	40.8	22.1
Moulded Vial, type I	110101	10A	10ml	14ml	21	20+0.1/-0.2	53.5	25.4
Moulded Vial, type I	110151	15A	15ml	15ml	24	20+0.1/-0.2	58.8	26.5
Moulded Vial, type I	110201	20A	20ml	24.9ml	28	20+0.1/-0.2	58	32
Moulded Vial, type I	110301	30A	30ml	36ml	34	20+0.1/-0.2	62.8	36
Moulded Vial, type I	110501	50A	50ml	58.2ml	52	20+0.1/-0.2	73	42.5
Moulded Vial, type I	111001	100A	100ml	116.2ml	91	20+0.1/-0.2	94.5	51.6
Moulded Vial, type I	110072	7v	5ml	6ml	24	19.8+021/-0.2	40	25
Moulded Vial, type I	120075	7.5B	7.5ml	8.5ml	14	19.9+0.1/-0.2	36.2	24.6
Moulded Vial, type I	120109	10YS	10ml	13ml	20	19.9+0.1/-0.2	51.1	24.6
Moulded Vial, type I	120159	15YS	15ml	17ml	23.5	19.9+0.1/-0.2	58.8	26.5
Moulded Vial, type I	110202	20K	20ml	23ml	30	19.7+0.1/-0.2	62.5	31
Moulded Vial, type I	110221	22ASH	22ml	30ml	31.5	20+0.1/-0.3	65	32
Moulded Vial, type I	110302	30TL	30ml	36.5	40.5	20+0.1/-0.2	64	36
Infusion bottle, type I	210501	50A	50ml	68ml	57	32+0.2/-0.2	68	46
Infusion bottle, type I	210701	70ASY	60ml	69ml	71	32+0.3/-0.3	75	46
Infusion bottle, type I	211001	100mlA	100ml	128ml	97	32+0.2/-0.2	104	49
Infusion bottle, type I	211501	150YB14383	150ml	207ml	136	32+0.3/-0.3	102.5	66
Infusion bottle, type I	212501	250SH	250ml	308ml	175	32+0.2/-0.3	136	66
Infusion bottle, type I	215001	500mlA	500ml	588ml	250	32+0.3/-0.3	177	78

Type I Tubular Glass Vials for Inj.

Nominal Size	Dia.of Finish	Inner Dia	Thickness of Finish	Thickness of body	Total H(mm)	Body Dia.(mm)
1ml	13±0.2	7±0.2	3.8±0.2	1.0	32±0.4	14.5±0.2
2ml	13±0.2	7±0.2	4.1±0.2	1.0	35±0.4	16±0.2
2ml	13±0.2	7±0.2	4.09±0.2	1.0	35±0.4	15.85±0.2
2ml	13±0.2	7±0.2	4.1±0.2	1.0	34±0.4	16±0.2
3ml	13±0.2	7±0.2	4.4±0.2	1.0	35±0.3	16±0.2
4ml	13±0.2	7±0.2	3.9±0.2	1.0	45±0.3	16±0.2
5ml	20±0.2	12.6±0.2	4.2±0.2	1.0	34±0.3	22±0.2
5ml	20±0.2	12.6±0.2	4.1±0.2	1.0	40.7±0.4	20.75±0.2
6ml	20±0.2	12.6±0.2	3.98±0.2	1.0	40±0.3	22±0.2
6ml	20±0.2	12.5±0.2	4.2±0.2	1.0	40±0.3	22±0.2
7ml	19.7±0.2	12.5±0.2	4.6±0.2	1.0	40±0.4	22±0.2
7ml	19.6±0.2	12.6±0.2	3.9±0.2	1.0	39.7±0.3	22±0.2
8ml	20±0.2	12.5±0.2	4.2±0.2	1.0	45.5±0.3	22±0.2
10ml	20±0.2	12.6±0.2	3.93±0.2	1.0	45±0.3	24±0.2
10ml	19.6±0.2	12.6±0.2	4.2±0.2	1.0	49.7±0.4	22±0.2
15ml	20±0.2	12.6±0.2	3.6±0.2	1.0	60±0.5	24±0.2
15ml	19.6±0.2	12.6±0.2	3.9±0.2	1.0	59.4±0.4	22±0.2
20ml	20±0.2	12.6±0.2	3.9±0.2	1.0	65±0.3	24±0.2
20ml	20±0.2	12.4±0.2	3.8±0.2	1.2	54±0.4	27.4±0.2

Available format

Type I Ampoules and Tubular Vials



With the in-depth development of the quality and efficacy consistency evaluation of generic drugs in China, and the promotion and implementation of the related reviews and approvals between drug and packaging materials, so the demand for high-quality packaging materials in the pharma industry has increased, in order to meet the demands of the diversification of the pharma packaging market, we have introduced a number of Italian and German vertical forming machines for ISO form B & C ampoules and vials, and established GMP standard plant and facilities. Due to the optimization of glass sources and the upgrading of production, the product quality stability and compliance has been aqualitative leaped, continue to meet the differential high-end needs of customers.

Technical information:

ISO 15378:2011 & ISO 9001:2008

Registration Numbers

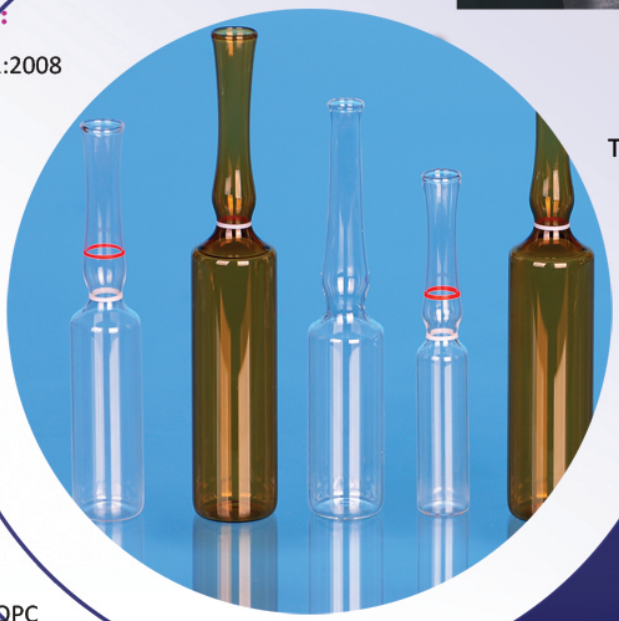
Ampoules: 国药包字20170851

Tubular vials: 国药包字20150160

Form B

&

Form C



Break form: color ring and OPC

Quality control: automatic photographic examination and manual auxiliary inspection.

Products Range *and What we can do?*

Available size range: ISO form B & C of 1ml,2ml,3ml,5ml,10ml,20ml

Glass tube sources： glass tube with COE between 5-5.7 according to customer's request.

The automatic detection system: ensures high precision product size control and good consistency of product.

Color ring and printing:

Method： screen printing

Color ring: rolling ring printing

Dot mark printing: dot printer

Pigment ink: colorful ceramic materials

SPG keeps the leading position in the industry

Mainly due to the following competitive advantages:

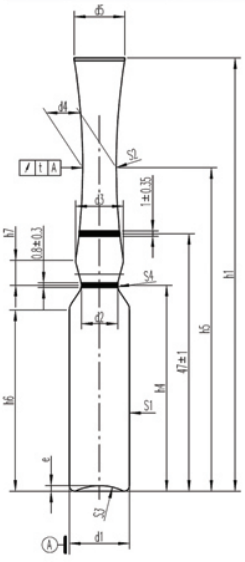
One is brand service and market competition advantage. We have been practiced to build the world first-class enterprise and to create century-old pharmglass enterprise. Uphold the concept of customer satisfaction is the quality standards, SPG has been in the world's leading position in pharmaceutical glass packaging industry and is a national key high-tech enterprise and a national torch plan enterprise. and is also a national standards drafting member for pharma-packaging products,and is the national advanced packaging enterprises. The market of the company covers 32 provinces, municipalities and autonomous regions in China, and exports to more than 90 countries and regions in five continents, serving more than 2,000 direct users worldwide and more than 200 overseas agents and exclusive agents.

Second, the advantages of production equipment and technology research and development. Main production workshop is equipped with advanced automatic production, inspection lines and packing line. The company has a postdoctoral research station, existing scientific and technological achievements 172, the patent technology 146. Currently, the products of borosilicate ampoules and tubular vials are produced in the PFS workshop . More than ten production lines are made by the vertical ampoules forming production line of Italian OCMI company and the vertical production line of German Ambeg company. Each production line has realized automation in the production process such as upper tube, tempering, inspection and packing, which improves the production efficiency and reduces the labor intensity at the same time.

Third, the advantages of perfect quality management system. The company has obtained certificate of ISO9--01,ISO15378(GMP), ISO14001, OSAS18001.

Fourth, strong quality inspection advantages. In December 2009, the quality inspection center of the company was approved by the laboratory of China national accreditation service for conformity assessment and obtained the laboratory accreditation certificate (registration number CNASL4302), which met the general requirements of testing and calibration laboratory capacity of ISO/ iec17025-2005.

High borosilicate glass containers can improve your production process to be more safe and effective

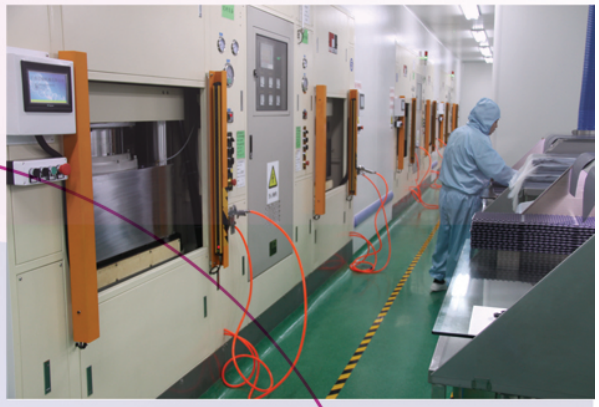


Available format for ISO Form B & C

ml	Form(类型)	d1	d2	d3	d4	d5	h1	h4	h5	h6(最小)	s1
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*
1	B	10.75±0.15	6.5±0.5	8.5±0.5	6.0±0.35	8.0±0.8	60±1	25.5±0.5	47±2	21 Min	0.5±0.03
	C					9.0±1.0	67±1				
2	B	10.75±0.15	6.5±0.5	8.5±0.5	6.0±0.35	8.0±0.8	72±1	37.5±0.5	57±2	33 Min	0.5±0.03
	C					9.0±1.0	79±1				
3	B	12.75±0.15	6.5±0.5	9.0±0.5	6.0±0.35	8.0±0.8	75±1	39.5±0.5	62±2	35 Min	0.5±0.03
	C					10.7±1.0	82±1				
5	B	14.75±0.15	7.0±0.5	9±0.5	7.0±0.35	9.0±1.0	83±1	46.5±0.5	68±2	41 Min	0.55±0.03
	C					12.2±1.0	90±1				
10	B	17.75±0.20	7.5±0.5	9.5±0.5	7.1±0.35	9.5± 1	102± 1	62.0±1.0	87±2	55 Min	0.60±0.04
	C					13.0±1.0	109±1				
20	B	22.5±0.20	8.5±0.5	12.0±0.5	7.8±0.5	11.0±1.0	113±1.5	76.0±1.0	100±2	65 Min	0.70±0.04
	C					14.0±1.0	120±1.5				

Note: we can fully meet the requirements of CFDA YBB standard and customization.

Coated Rubber Stopper



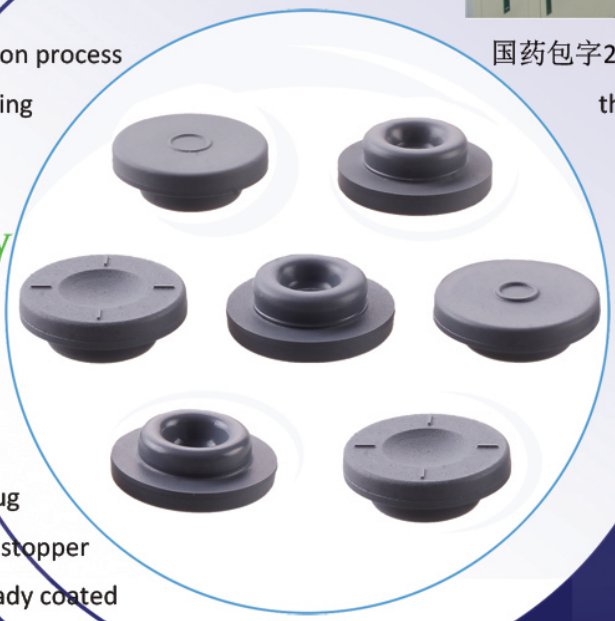
The "Coated Rubber Stopper" refers to a naked rubber stopper with a "coating film" between the drug and the naked rubber stopper contact surface, such as fluorine-coated rubber stopper. For normal rubber stopper usage, the compatibility problems may occur because of the direct contact between the rubber stopper and the sensitive drugs. However, by adding the obstructive plastic film on the surface of the rubber stopper, it can shield the contact between the rubber stopper and the sensitive drugs. It can effectively reduce the absorption, leaching and penetration between the rubber stopper and the sensitive drugs, in order to effectively reduce or delay the occurrence and development of compatibility problems and improve the long-term stability of the drug.

国药包字20150162/国药包字20110714

The technology and production process we are using now are by adding the coating film on the surface of the rubber stopper in first time forming process and

Coating only **at the plunger**

finally obtain the neck area coated rubber stopper only without crown area coated after the second time forming. The coated rubber stopper produced using such kind of production technology will not cause drug contamination in direct contact with the rubber stopper because the neck area of the rubber stopper is already coated and the crown area of the rubber stopper can be pressed closely with the vial mouth surface because the crown area is uncoated which can assure a favourable leakproofness.



Technical information:

Our product design and manufacturing conform to the requirements of ISO15378:2011 (GMP) , and the quality conforms to the relevant national standards and the requirments specified in the current EP & USP. We has obtained the production registration certificate in China.

The scope and characteristics of our products:

We produce a complete range of coated rubber stoppers, including the most common materials like ETFE, FEP and PET, the crown (flange) of rubber stopper does not cover the film so that it can ensure sealing,because of the smoothness of coating can reduce the product silicification silicone oil addition, and reduce the hanging phenomenon of liquid injectables; Because of high barrier performance, it can prevent water from penetrating into drug, thus ensures the safety of antibiotics and freeze-dried products.

Coated Rubber Closure/*Product features*

because of high performances

ETFE is the abbreviation of "Ethylene-Tetra-Fluoro-Ethylene". It is a inert material which has excellent chemical stability & non-stick; high antifoulant surface & rinses easily; high tensile strength, not easily torn & ductility is more than 400%; low density, radiation resistance, easy processing, high toughness, and weather-proof. It can be used for a long time within 150 degrees.

FEP is the abbreviation of "Fluorinated Ethylene Propylene". It is a inert material which has excellent chemical stability & weather-proof; high impact strength, creep resistance, non-toxic, non-stick, electric insulativity, and abrasive resistance. It can be used for a long time from -85 to +205 degrees, and for a short time from -200 to +300 degrees.

PET is the abbreviation of "polyethyleneterephthalat". It has resistance to oil, fat, dilute acid, dilute alkali, most solvent and high & low temperature, it can be used for a long time within 120 degrees, and for a short time from -70 to +150 degrees. It also has excellent resistance to gas, water, oil & odor; non-toxic, tasteless & good safety.

As far as the price is concerned, ETFE is slightly higher than FEP and much higher than PET, but because ETFE has better tensile properties, the thickness of the film can be thinner in production, so the price of the actual product FEP is higher than ETFE. Production and processing performance: ETFE is better than FEP, FEP is better than PET.

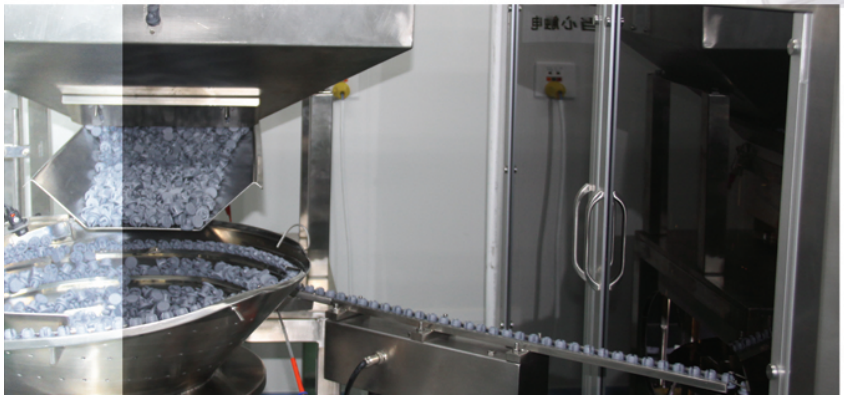
Scope of application: Because of good perfomance of the three membranes, so the three membranes can meet the use requirements, but for high acid, alkaline drugs, not suitable for the use of PET coated.

Coated rubber stopper can improve your production process

to be more safe and effective

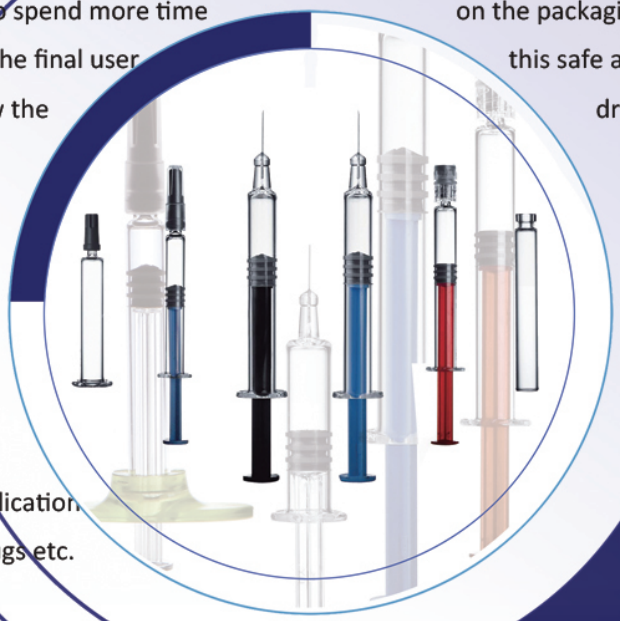
Available format

Size	Dia. of flange	Flange thickness	Dia. of plunger	Total height
20C-1	19.5±0.20	3.0±0.25	13.0±0.10	8.4±0.30
20C1-1	19.5+0.25/-0.20	3.0±0.25	12.9±0.10	7.7±0.30
20C2-1	19.5±0.20	2.8±0.20	13.2±0.10	7.0±0.30
20E6-1	19.5±0.20	3.0±0.25	13.2±0.10	6.7±0.30
20P8-1	19.5±0.20	3.0±0.25	13.15±0.10	6.7±0.30
20P9-2	19.5±0.20	3.0±0.25	13.2±0.10	6.5±0.40



Prefilled Syringe & Cartridge

The prefilled syringe(PFS) is an injection device and exempts the procedure that get the medicine from ampoule and moulded injection bottle, PFS has a history of more than 30 years. PFS is the packaging material that has been sterilized and doesn't have pyrogen and particulate, it could be filling directly in the clean room of the pharmaceutical enterprise. Its advantage is exempting the pharmaceutical company's complex program of cleaning the packaging containers and reducing the investment of the cleaning equipment. In addition, the accessories of PFS have good compatibility with drug. Meanwhile, PFS has good sealing performance, the drug could be stored for long time and it replaced a part of market of tubular vial and ampoule. In the current European and American market, the use of PFS is very common. In China, the medical industry is accepting this product and the PFS is preferred for more new product, especially the vaccines and bioengineered drugs. In the rapidly developing biological and immunotherapy industry, the advantage of avoiding the waste of high value drug has been fully develop.The reason why the PFS is popular is that the companies don't need to spend more time on the packaging, but can improve the level of products effectively. For the final user this safe and simple packaging exempts the inconvenience that draw the drug liquid into the syringe and reduces the occurrence of many accidents.



The application range of the cartridge is also very wide, but the main application field is insulin and anesthetic and sedation drugs etc.

Registration No. in CFDA:

PFS：国药包字20160277,20140640　　Cartridge：国药包字20130833

What we can do?

Regarding of the continuous growth in the market share of drug delivery systems and pharmaceutical packaging, prefilled syringe has a considerable commercial value. In order to adapt to the changes in the market demand for pharmaceutical packaging materials and further optimize the structure of products, our company introduced German pre-potting in 2008. The production line will carry out project construction in accordance with the quality management regulations for pharmaceutical production and achieve commercial production in 2011.

PFS products range：1-3ml

Glass Cartridge range：1-5ml

Production Process

Neutral glass tube→forming→annealing→needle staked (or without staking)→barrel washing&siliconization → tip capping→ Nest loading→placing breathable paper→sealing→bagging→packing tray→EO sterilization → EO release → finished product.

All procedures that may affect the cleanliness of PFS are performed in the clean rooms, including the acceptance and needle staked process in D zones, and the process of wishing&siliconization in C+A clean environment. All raw materials and packaging materials are preferably used by the mainstream suppliers, the product design and production management are in accordance with the requirements of ISO15378 (GMP) that ensures the safety and reliability of the products.

Key Process Control and Quality Assurance

Forming process:our company adopts several vertical forming machines made by Ambeg from Germany.Compared with horizontal forming machine, it has advantages of compact structure, high degree of automation, good moulding of needle parts and high production capacity. The glass barrel is with flat shoulder to increase the contact area between the surface of rubber plunger and the syringe shoulder, reduce the residual of injection and ensure the filled medicine can be used effectively to the maximum extent. The automatic detection system can ensure each glass barrel to meet the requirements in physical dimension and apprearance.

Needle staked process: use automatic needle staked machine maded by Sortimat and R+E from Germany.The lines are equipped with on-line detecting functions for needle's perpendicularity, patency, needle tip and firmness so as to remove unqualified products in time. The needle is fixed by UV glue, with available size of 1" 23G, 5/8" 25G and 1/2" 27G.

Washing & siliconization process: designed according to the new version of GMP requirements, including class C area used for washing. After the washing and drying, the products is transferred to class C area under the protection of class A environment, the subsequent.processes such as nest and tub loading, sealing, bagging all are done under the protection of class A environment. The washing of the product is rinsed with 0.1μm filtraded WFI, and dried by 0.2μm filtraded compressed air, and siliconized by DC360 silicone oil. The packaging production line is from B+S with 4sets of equipment system, including automatic release, washing & siliconizing, nesting & tubing. all lines are equipped with the automatic detection system. In addition, the siliconization of the inner wall of syringe is supplied with silicone oil by a micrometer pump. The product is cleaned by 4times of washing and 5times of blowing. We use above 85°C WFI to clean the product, and dry it with three class filter system of compressed air filter to make sure the cleanliness of inner & outer wall of syringe barrel and stainless steel needle.

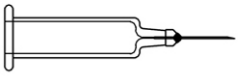
The workshop is equipped with the equipment for dust particle detection, insoluble particles test.QC should have a test on the environment, pressure air, the quality of WFI before each production. The trial production can be made after examination is qualified.The batch production should be done after being qualified, each hour to check the sliding performance and insoluble particles,and dynamic environmental monitoring.

AVAILABLE FORMATS for PFS & GLASS CARTRIDGE 预灌封和卡式瓶规格表

PFS Specification

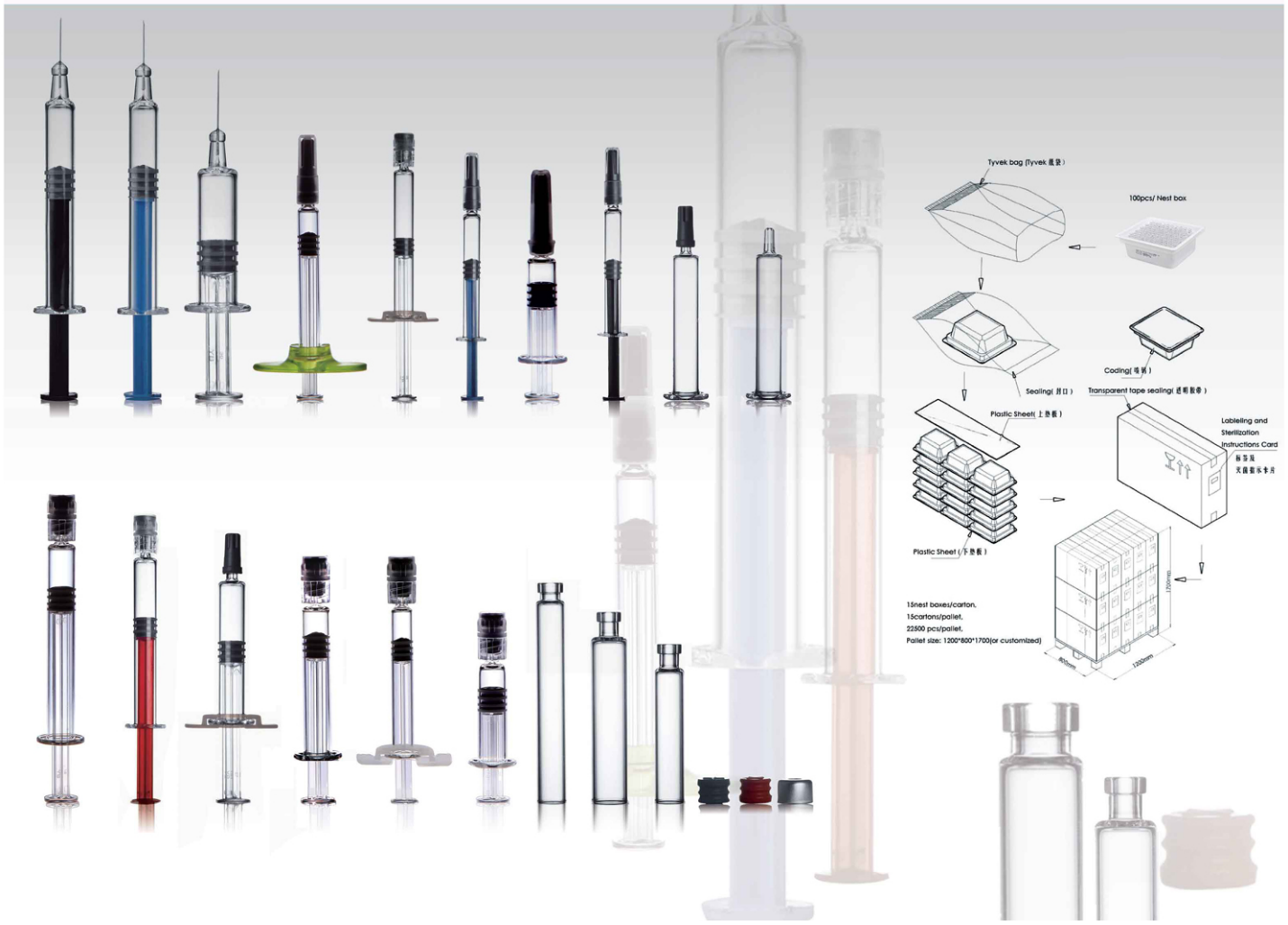
- Sizes: from 1ml to 3ml
- Nest: 10x10pcs
- EO sterilization
- Customized ceramic printing(optional)
- "☆" means available

Tubing Glass from Schott, Needle from Nipro

	Supplier	RNS/硬护帽 Rigid Needle Shield SPG WEST	NS/软护帽 Needle Shield WEST	TC/Ribbed Tip Cap SPG	鲁尔锁套 Luer Lock SPG	LLA Luer lock Adapter WEST	柱塞 Rubber Plunger WEST	推杆 Plunger Rod QIAOPAI
	1ml long Φ8.15 Needle,1/2" 27G, 5/8" 25G, 1" 23G	☆					☆	☆
	1ml STD Φ10.85mm Needle,1/2" 27G, 5/8" 25G, 1" 23G	☆					☆	☆
	2.25ml, 3ml Φ10.85mm Needle, customized						☆	☆
	1ml STD,2.25ml, 3ml Φ10.85mm Luer cone			☆	☆		☆	☆
	1ml Long Φ8.15mm Luer cone			☆	☆		☆	☆
	1.5ml Φ8.65mm x H57mm		Finish Dimension OD:7.15mm ID:3.15mm			Al-seal Dim. ID7.45*H4.9		Piston 7.3
	1.8ml Φ8.65mm x H63mm							Piston 7.3
	3.0ml Φ11.6mm x H62.3							Piston 9.95
	1.8ml Φ8.56mm x H63mm	Finish	OD:7.42mm ID:3.71mm		**SPG Made**	ID7.82*H4.96	**SPG Made**	Piston 7.24

预灌封和卡式瓶产品及包装图解

Products Pictures for PFS and Glass Cartridge



实验室认可证书和生产质量体系证书　Laboratory Accreditation Certificate and Production Quality System Certificate

CNAS证书

中国合格评定国家认可委员会

实验室认可证书

（注册号：CNAS L4302）

兹证明：

山东省药用玻璃股份有限公司质检中心

山东省淄博市沂源县药玻路 1 号，256100

符合 ISO/IEC 17025：2005《检测和校准实验室能力的通用要求》（CNAS-CL01《检测和校准实验室能力认可准则》）的要求，具备承担本证书附件所列服务能力，予以认可。

获认可的能力范围见标有相同认可注册号的证书附件，证书附件是本证书组成部分。

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CISO15378：2011(GMP)

SGS

此为证书 CN15/10580 译本

山东省药用玻璃股份有限公司

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ISO 15378
直接接触药品包装材料 — 参照药品生产质量管理规范（GMP）的 ISO 9001:2008 的特殊要求
（2011 年 11 月 1 日第 2 版）

药用卤化丁基橡胶塞的设计和制造
低硼硅玻璃/中性硼硅玻璃管制药用玻璃瓶的制造
中性硼硅玻璃/钠钙玻璃模制药用玻璃瓶的设计和制造
预灌封注射器组合件(带注射针和不带注射针)的制造

该证书的有效期自 2016-09-05 至 2018-10-14
并须经过符合要求的监督审核保持有效
持续认证需在 2018-08-27 之前执行
版次 3 初始注册日期 2015-10-15

第 1 页 共 1 页

ISO9001:2008

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

IQNet and CQM
hereby certify that the organization
Shandong Pharmaceutical Glass Co.,Ltd.

Organization Code:16861186-8
Domicile: Yiyuan County, Zibo City, Shandong, P.R.China
Certification Add. No.1,Taocto Road, Yiyuan County, Zibo City, Shandong, P.R.China

Post code: 256100
is in conformity with
ISO 9001:2008 Standard

This certificate is valid to the following product(s)/service:

Design and manufacture of the injection vials made of moulded soda lime glass, infusion bottles made of soda lime glass, medicinal bottles made of soda lime glass, pharmaceutical tube made of low borosilicate glass, injection vials made of low borosilicate glass tubing, oral liquid bottles made of low borosilicate glass tubing, ampoules made of low borosilicate glass, injection vials made of moulded neutral borosilicate glass, injection vials made of neutral borosilicate glass tubing, infusion bottles made of neutral borosilicate glass, glass containers cosmetic bottle, glass bottle for food package, borosilicate glass barrels for pen-injectors, assemblages for prefilled syringes
For the subsidiary site and certification scope to the attachment

Issued on: 2015-08-25
Effective date: 2015-08-25
Validity date: 2018-08-24
Registration Number: CN-00215Q14937R2L

Michael Drechsel
President of IQNet

JI XiaoDong
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