

Product Descriptions Three way stopcock with extension tube & without extension tube			Prepared by	Chen Jufang
			Checked by	Miao Jinfeng
Doc. No.	MDK/CE03-06		Approved by	Gao Qing
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Product Descriptions

1. Description of the product

Product name: Three way stopcock with extension tube & without extension tube

Brief introduction: The device is mainly used to change the media flow, used for injection for reagents that cannot be mixed directly, an emergency medicine from the same vein. The product is comprised with valve body, valve core, screw cap, and locking cap, in which valve body and screw cap are manufactured with PVC by injection molding; valve core and locking cap are manufactured with PE by injection molding. The product is for single use, biocompatibility test proved there is no hemolysis reaction, no cytotoxicity, no pyrogen, physical, chemical and biological performance are complying with requirements.

Intended use: Used in human body vein injection, transfusion and blood-transfusion together with other medical device for single use. It is composed with screw cap, valve body and knob, for single use. It's for short-term use.

Contraindication:

Drug efficacy will vary after mixing, it need clinicians guide.

Sterilization method: EO sterilization.

Validity: 5 years.

2. Product Structure and parameters

2.1 Structure



2.2 Technical Parameters

Item	Requirements
Physical Performance	Appearance :1.The device should be sterile. 2. The device ethylene oxide residues should not exceed 10µg/g. 3. tube length according to the order, a tolerance of $\pm 10\%$.

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	4. Protecting cover should be closed, but easy to remove. 5. Three-way Stopcock bore and the spool with the parts should be close, and turn the adjustment. 6. Spool should spin freely, and spool surface liquid flow direction should be clearly marked. 7. Three-way Stopcock external surfaces should be smooth and round, no flash, burrs, dirt, impurities, cracks or other obvious defects. Should be flexible rotating spool, spool arrows indicate the surface should be obvious that the channel should be smooth.
	1. taper joints and locking cone and size of 6% of Three-way Stopcock cone should be consistent with GB/T1962.1-2001 and / or GB/T1962.2-2001 requirements. 2. Under 0.3mpa water pressure for 30s, Three-way Stopcock should be no leakage. 3. Three-way Stopcock spool rotate freely about 5 times, the seal test, the spool should be no leakage. 4. All components should be connected firmly and reliably. When it being pulled at least 15N for 15s, there should be no part to fall off. 5. By GB/T14233.1-2008 test method specified in 5.4.1, Three-way Stopcock for the test solution and control solution with batch control, pH, the difference shall not be greater than 1.5.
Chemical Performance	1. By GB/T14233.1-2008 test, the use of potassium permanganate solution [c (KMnO₄) = 0.002mol / L] of the total should not exceed 2.0mL. 2. Dissolution liquid lead, zinc, tin, chromium, barium and other metal ions should not exceed the total content 5µg/mL, cadmium should be less than 0.1µg/mL.

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2. Materials and its suppliers

S/N	Components	Raw material	Supplier
1	valve body	PC	Changzhou Kai You Medical Equipment Co., Ltd.
2	valve core, screw cap, and locking cap	PP, PVC	Jiangsu Ya Bang Tian Long medical new material Co., Ltd.
3	Internal packing	Paper plastic bag	Jiaxing Tian Ye Packing Material Co., Ltd.
4	Outer packing	Carton	HuaiAn Yongchang Paper Co., Ltd.

3. Manufacturing process

The products manufacture flow chart

