

常州市回春医疗器材有限公司

CHANGZHOU HUICHUN MEDICAL EQUIPMENT CO.,LTD.

Analysis certificate of Blood Collection Needle

According to: ISO13485:2003

Test NO.	LOT: 20130305	Report NO.	20130305-6
Production LOT	2013/03	Spec.	22G×1 1/2"
Sterilizing LOT	Exp: 2018/03	Test Dates	2013\03\10
Quantity	40000pcs	Report Dates	2013\03\25

Inspection items	Guideline	Result
Chemical requirements	EO residua of each set of Infusion set≤0.1mg	0.030mg per set
	Deoxidization substrates≤2.0ml	0.3ml
	UV absorbency≤0.1	0.007
	Difference of PH should not be more than 1.5	0.1ml
Biological requirements	There should be sterile	Measure up
	There should be no pyrogen	Measure up
Physical requirements	Particles contamination index	0.02-0.18/ml
	15μm-25μm Particles:≤1/ml	0.02-0.17/ml
	≥25μm Particles: ≤0.5/ml	
	The linkage can endure≥20N steady pull force for 10s	Measure up
	Needle should be no burr	Measure up
	Needle size should be conform with prescription of ISO13485:2003	Size:0.7mm Length: 38mm
	The rate of medicine solution filter is not less than 80%	98%-99%
	Needle Holder Color should be conform with prescription of YY/T0296	Measure up

Conclusion: Products measure up according to: ISO13485:2003.

