

Add: No.39, Anye Road, Gaoqiao Street, Huangyan, Taizhou, Zhejiang, China, 318020 Tel: 0086-576-84031666 Fax: 0086-576-84036668 Http://www.skgmed.com

### **Centrifuge Tube Data Sheet**

Section 1 - Specifications / Details				
Description	3050205 Centrifuge Tube 50ml, conical sterile			
Volume	50mL			
Material	Polypropylene (PP)			
Colour	Transparent tube with blue cap, white graduation			
Basic feature	Sterile			
Sterilization	Sterilize by Radiation			
Quality Check	Dual quality system of 13485 quality management			
Other information	Single Use only			
Centrifugation	Up to 6000RCF			
Feature	Non-cytotoxic, DNA / RNA Free			

Section 2 – Storage Condition		
Temperature Range	0 degC to +40degC	
Shelf life	3 years from manufacturing date	
Storage	Atmospheric temperature, dry and clean	

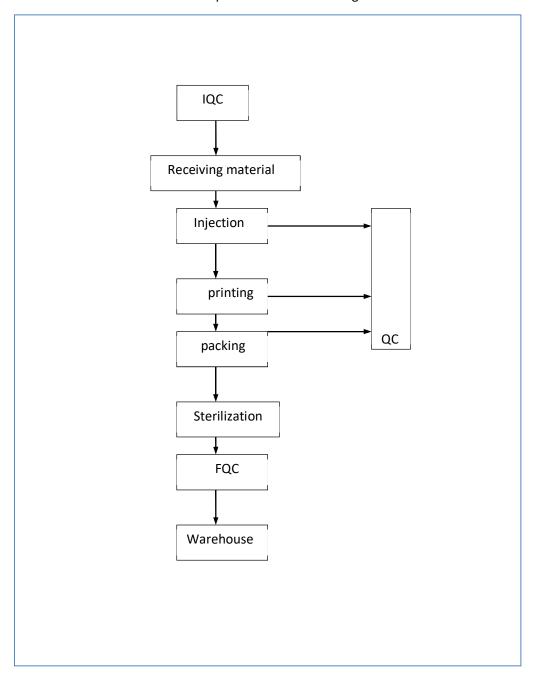
Section 3 – Packaging		
Inner Pack	50pcs/bag	
Outer Pack	500pcs/carton	
Lot No.	YYMMDD	
Other information	Certificate of Quality	

Section 4 - Other Information		
Certification	Conforms to EN550 & Corporation Standards Q/HGS005-2000	



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### Flowchart for Disposable Plastic Centrifuge Tube





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### **Quality Control**

- 1)Inspection of the purchased products
  - 1) Object

Material of tube(PP): The physical character etc.

2 The frequencies of execute.

When the material manufacturer change the specification of the material or important workmanship, make inspection on the material. (Request for the products test report) .

- 2)Procedure test & Examination
  - 1) Examination project name & item
- ·Injection procedure Examination: Clean of the inner and outer test tube, no distort, scraper, air bubble, impurity, blot etc. The lubricity of side of the test tube, thick etc.
  - ·Packing procedure Examination: Clean of the inner and outer test tube, no distort, scraper, air bubble, impurity, blot etc. No other sort products.

Frequency of executive

Injection procedure test: once a week;

- 2 Package procedure test according to packing.
- 3) Final test & Examination
  - ①Checking item
  - $\cdot \text{Appearance checking: Appearance} \ \ \text{condition} \ \ \text{clean of inner \& outer of package} \ \ \text{notify} \ \ \text{package status.}$
  - ·Physical character test: tolerance of the tube、airproof of the bag.
    - 2 Executive Frequency

 $\cdot Appearance\ checking\colon\ once/style \cdot lot$ 

·Physical character test: once/style·lot

4) Permission to be dispatched from the factory

After the final inspection and a confirmed completion of incoming inspection and in-process inspection, the product is allowed to be dispatched from the factory.  $\circ$ 



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#### **Environmental control**

1) Control of the manufacturing environment

The procedure for cleaning and disinfecting the working areas and for monitoring environment conditions in the areas is detailed in the standard for Process Hygiene Control (BQ 110).

The Manager of Quality Assurance Section is responsible for the documenting and the correlated department should carry out reporting the monitoring results when any unacceptable data is obtained through the monitoring manufacturing environment, and the appropriate corrective actions.

2) Frequency of monitoring executive

Once a month

3) Manufacturing environment standard

Inspection item	Standard	Monitor frequency	Specification
Temperature and humidity	18 ~ 28°C, 50 ~ 65%RH	Each shift	
Particles	$\geqslant$ 0.5 $\mu$ m : $\leqslant$ 1×10 <sup>5</sup> /ft3	Each month	Internal standard
Airborne microorganisms	≤30/160L	Each month	
Differential Pressure	≥5Pa	Each month	
Wind velocity	≥0.25m/s	Each month	
Initial contamination	Not exceeding 100	Each month	

Note: Control standard of clearing area.

### Packaging and labeling and traceable control

Packaging specification

1 Inner package

Material of film: polyethylene(PE) bag (about 100um thick)

2 Shipping carton

·50pcs/bag\*10bags=500pcs/carton

Shipping carton: 5ply corrugated cardboard

Zhejiang Skg Medical Technolog

QC Dept.