

Product Testing Report

Report No. C1611008

Report	Date:	Nov.	22,	201	6
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Product Description	Leucocyte reduction filter with transfusion set	Sterile Batch No.	161108-1	
Type/Code/Ref.	LRF-BB/ BBF2	Mfg. Date	2016.11	
Batch No.	161107	Defe	"Guide to the Preparation, Use and	
Batch Qty.	1300 pcs	Reference	Quality Assurance of Blood Components", ISO1135-4:2010	

Testing Item	Criteria	Result			
	Part I Physical test				
Appearance	Filter chamber shall own smooth surface, keep clean inside and outside, without obvious impurity, weld smooth.	Pass ⊠			
Particles contamination	The number of particles shall be not exceed the contamination index.(≤90)				
Sealing function	It shall no signs of air leakage.				
Linkage strength	The linkage of parts/fittings shall not break under 15N steady axial tension for 15s				
Close-piercing device	It shall be capable of piercing and penetrating the closuer of a fluid container without chip.				
Air-inlet device	The air-inlet device shall be provided with a protective cap over the Close-piercing device or needle	Pass 🛚			
	The Air-inlet device shall be provided with an air filter	Pass 🛛			
	When the Air-inlet device is inserted into a rigid infusion container, the air admitted into the container shall not become entrained in the liquid out flow.	Pass ⊠			
	It should be Transparent or sufficiently Transparent	Pass 🛚			
Tubing	Inner diameter 3.5+/-0.1mm	Pass 🛚			
	Outer diameter 5.2+/-0.1mm	Pass 🛚			
Flow regulator	The flow regulator shall adjust the flow of the blood components between zero and maximum	Pass ⊠			
Label	Meet the requirement	Pass ⊠			
Package	Meet the requirement	Pass ⊠			
	Part II Chemical test				
Oxidizable matter	The difference between testing solution and blank solution on total amount of potassium permanganate solution used[c(KmnO4=0.002mol/L)] shall not exceed 2.0ml	Pass ⊠			



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Report No. C16110	08	Report Date: Nov. 22, 2016	
Product Description	Leucocyte reduction filter with transfusion set	Sterile Batch No.	161108-1
Type/Code/Ref.	LRF-BB/ BBF2	Mfg. Date	2016.11
Batch No.	161107	- Reference	"Guide to the Preparation, Use and Quality Assurance of Blood
Batch Qty.	1300 pcs	1/CICICIICC	Components", ISO1135-4:2010

Total heavy metal	Total heavy metal≤1 µg /mL	Pass 🛚	
Acidity or alkalinity	PH difference between testing solution and blank solution ≤1.5	Pass ⊠	
Residue on evaporation	≤2mg/50mL	Pass 🗵	
UV-abs	≤0.3 within 250nm-320nm	Pass 🛚	
EO residue	EO residue should less than 2.0mg/set	Pass 🗵	
	Part III Biological test		
Bacterial endotoxin	<20EU/set	Pass 🛚	
Sterile	Bring up of the sterilized Biological indicator is negative and finished product with no growth of microbial	Pass 🛚	
	Part IV Performance test		
Residual white blood cells	ells < 1 x 10 ⁶ /unit		
Recover rate of RBC (%)	≥ 85	Pass 🗵	
Free hemoglobin	<300mg/L Pass [

Conclusion: The Leucocyte reduction filter with transfusion set with the Lot Number mentioned above has passed the test in accordance with the requirements of "Guide to the preparation, use and quality assurance of blood components "and ISO1135-4:2010.

