

# Product Testing Report

# demophorius

Report Date: 2019.05.25

HEALTHCARE

Product Description	Leucocyte reduction filter with transfusion set	Batch No.	1905010
Type/Code/Ref.	BBF	Mfg. Date	2019.05
Sterile Batch No.	S21905111	Exp. Date	2022.04
Batch Qty.	500pcs	Reference	"Guide to the Preparation, Use and Quality Assurance of Blood Components", ISO1135-4:2010

Testing Item	Criteria	Result
<b>Part I Physical test</b>		
Appearance	Filter chamber shall own smooth surface, keep clean inside and outside, without obvious impurity, weld smooth.	Pass <input checked="" type="checkbox"/>
Particles contamination	The number of particles shall be not exceed the contamination index.( $\leq 90$ )	Pass <input checked="" type="checkbox"/>
Sealing function	It shall no signs of air leakage.	Pass <input checked="" type="checkbox"/>
Linkage strength	The linkage of parts/fittings shall not break under 15N steady axial tension for 15s	Pass <input checked="" type="checkbox"/>
Close-piercing device	It shall be capable of piercing and penetrating the closuer of a fluid container without chip.	Pass <input checked="" type="checkbox"/>
Air-inlet device	The air-inlet device shall be provided with a protective cap over the Close-piercing device or needle	Pass <input checked="" type="checkbox"/>
	The Air-inlet device shall be provided with an air filter	Pass <input checked="" type="checkbox"/>
	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 <input checked="" type="checkbox"/>
Tubing	It should be Transparent or sufficiently Transparent	Pass <input checked="" type="checkbox"/>
	Inner diameter $3.5 \pm 0.1$ mm	Pass <input checked="" type="checkbox"/>
	Outer diameter $5.2 \pm 0.1$ mm	Pass <input checked="" type="checkbox"/>
Flow regulator	The flow regulator shall adjust the flow of the blood components between zero and maximum.	Pass <input checked="" type="checkbox"/>
Label	Meet the requirement	Pass <input checked="" type="checkbox"/>
Package	Meet the requirement	Pass <input checked="" type="checkbox"/>
<b>Part II Chemical test</b>		
Oxidizable matter	The difference between testing solution and blank solution on total amount of potassium permanganate solution used( $c(\text{KmnO}_4=0.002\text{mol/L})$ ) shall not exceed 2.0ml	Pass <input checked="" type="checkbox"/>
Total heavy metal	Total heavy metals $1 \mu\text{g/mL}$	Pass <input checked="" type="checkbox"/>
Acidity or alkalinity	PH difference between testing solution and blank solution $\leq 1.5$	Pass <input checked="" type="checkbox"/>

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Residue on evaporation	≤2mg/50mL	Pass <input checked="" type="checkbox"/>
UV-abs	≤0.3 within 250nm-320nm	Pass <input checked="" type="checkbox"/>
EO residue	EO residue should less than 1.0mg/set	Pass <input checked="" type="checkbox"/>

#### Part III Biological test

Bacterial endotoxin	<20EU/set	Pass <input checked="" type="checkbox"/>
Sterile	Bring up of the sterilized Biological indicator is negative and finished product with no growth of microbial	Pass <input checked="" type="checkbox"/>

#### Part IV Performance test

Residual white blood cells	< $\times 10^6$ /unit	Pass <input checked="" type="checkbox"/>
Recover rate of RBC (%)	≥ 85	Pass <input checked="" type="checkbox"/>
Free hemoglobin	<300mg/L	Pass <input checked="" type="checkbox"/>

**Conclusion:**

The Leucocyte reduction filter with transfusion set with the 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.

