DEMOPHORIUS
healthcare

Product Testing Report

Product Description	Leucocyte reduction filter with transfusion set	**Expiry. Date.**	08.2022
Type/Code/Ref.	BBF	**Mfg. Date**	2019.09
Batch No.	1909002	**Reference**	"Guide to the Preparation, Use and Quality Assurance of Blood Components", ISO1135-4:2010
Batch Qty.	pcs 1000		

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)	Pass
Sealing function	It shall no signs of air leakage.	Pass
Linkage strength	The linkage of parts/fittings shall not break under 15N steady axial tension for 15s	Pass
Close-piercing device	It shall be capable of piercing and penetrating the closuer of a fluid container without chip.	Pass
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
Tubing	It should be Transparent or sufficiently Transparent	Pass
	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

DEMOPHORIUS

demophorius limited | 196, Arch. Makarios III Ave. 3030 Limassol, Cyprus. | Tel. +357 25 749896 Fax. +357 25 749907 | info@demophorius.com www.demophorius.com

DEMOPHORIUS
healthcare

Product Testing Report

Product Description	Leucocyte reduction filter with transfusion set	**Expiry. Date.**	08.2022
Type/Code/Ref.	BBF	**Mfg. Date**	2019.09
Batch No.	1909002	**Reference**	"Guide to the Preparation, Use and Quality Assurance of Blood Components", ISO1135-4:2010
Batch Qty.	pcs 1000		

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	< 1 x 10 6 /unit	Pass
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.

DEMOPHORIUS LIMITED LIMASSOL

MICHALIS POLYDOROU
quality manager