

Solutran HEMO®

*Medical PVC for transfusional sector:
container for human blood and
blood component*

Solutran HEMO® PVC GRANULE

In compliance with the strictest ISO and GMP standards, Meditalia Srl produce **Solutran Hemo®**: medical granules in non-toxic soft, flexible, but extremely resistant PVC for the production of tubulars and extruded tubes used in the manufacturing of blood bags and blood component used in the transfusion sector.

The extremely high quality, non-toxic property and suitability for use of **Solutran Hemo®** is guaranteed:

- by the production of the PVC compound in a granulation unit which is completely automated and sealed to guarantee the purity of the finished product;
- by the rigorous use of suitable raw materials which are certified for medical use;
- by the specific and unique composition which gives the extruded **Solutran Hemo®** the collapse-resistant properties of the surfaces as well as all the mechanical properties required for final use as blood bags and blood component.

Solutran HEMO® PVC LAY FLAT TUBE, DOUBLE WOUND FLAT FILM AND TUBE

The **Solutran Hemo®** tubular and tube, non-toxic and biocompatible, flexible but resistant supply our customers with perfectly suitable and functional products to be used as blood containers and blood components, so its application is the transfusional sector.

Solutran Hemo® standard production has thickness 0,60 mm, width 240 mm, but we are able to manufacture it in varying thicknesses and widths to meet customers' requirements.

Solutran Hemo® tubular and tubes offer collapse-resistant properties of the surfaces, and give to the container all the technical properties required by Eu. Ph. Sez. 3.2.3 as resistences to centrifugation, to stretch, to leakage, to emptying under pressure, as well as to sudden changes in temperature ranging from freezing conditions to exposure to high temperatures.

Optimal gas permeability, O_2 TR = 680 cc/m²•24h•atm;
 CO_2 TR = 10205 cc/m²•24h•atm.

To safeguard against contamination, **Solutran Hemo®** tubulars and tubes are produced in specially protected areas (class ISO 8 cleaning room).

Modern and validated extrusion plants guarantee **Solutran Hemo®** correct destination use: the film stability, the quality of the rolling process, the constancy of its size parameters.



Via Della Piana 1
23030 Lovero V. (SO) - Italy
meditaliasrl.com

Tel. +39 0342 77 10 70
Fax. +39 0342 77 10 71
info@meditaliasrl.com

Solutran HEMO®

Technical sheet

Medical grade PVC granule - lay flat tube - double wound flat film - tube - container for transfusional sector, for human blood and blood component

CHEMICAL SPECIFICATIONS Eur. Ph. Sez. 3.1.1.1

FORMULATION

Poly(vinyl chloride)	> 55%
Plasticizer (DOP free)	< 40%
Epoxidised soya oil	< 5%
N,N'-diacylethylenediamines	< 1%
Calcium stearate	< 1%

TEST (tubular & container) LIMIT VALUE on S2 (tubular) LIMIT VALUE on S3 (container)

Vinyl chloride	1.0 ppm	NA
Appearance	Clear, colourless	NA
Alkalinity	1.0 ml HCl 0.01 M	0.8 ml HCl 0.01 M
Acidity	1.5 ml NaOH 0.01 M	0.4 ml NaOH 0.01 M
Residue on evaporation	0.3 %	3 mg
UV absorption on anticoagulant		0.5 250–350nm
Primary aromatic amines	20 ppm	
Reducing substances	2.0 ml Na ₂ S ₂ O ₃ 0.01M	2.0 ml Na ₂ S ₂ O ₃ 0.01 M
UV absorption	0.25 250–310nm	0.30 230–250nm 0.10 251–360nm
Barium	5.0 ppm	NA
Cadmium	0.6 ppm	NA
Heavy metals	50.0 ppm	NA
Calcium	0.07 %	NA
Tin	20.0 ppm	NA
Chlorides	NA	0.4 ppm
Ammonium	NA	2 ppm
Zinc	0.2 %	NA

PHYSICAL PROPERTIES - Typical test results on 60 ShA tubular

TEST	VALUE	UNIT	REFEREN.
Hardness	60	Shore A	ISO 868
Tensile strenght at break	130	Kg/cm ²	ISO R527
Elongation at break	370	%	ISO R527
Temperature of stiffening	-40	°C	ISO R458
Density	1.19	g/cm ³	ISO R1183

FUNCTIONAL TEST on container Eur. Ph. Sez. 3.2.3

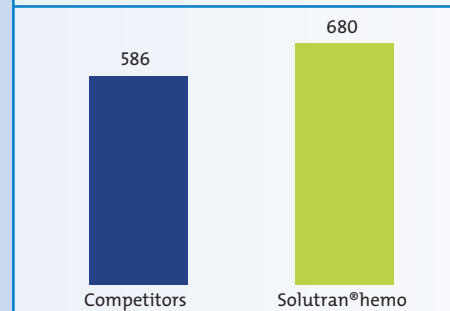
TEST	LIMIT VALUE
Resistance to centrifugation	In conformity
Resistance to stretch	In conformity
Leakage	In conformity
Vapour permeability	1%
Emptying under pressure	2 min
Speed of filling	In conformity
Resistance to temp. variations	In conformity

BIOLOGICAL REACTIVITY UNI EN ISO 10993

TEST	IN CONFORMITY
Irritation	Yes
Cytotoxicity	Yes
Implantation	Yes
Hemolysis	Yes
Systemic toxicity	Yes

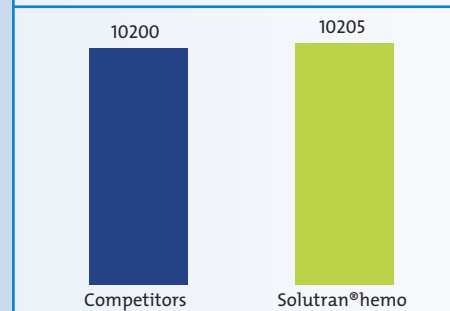
Test carried out in compliance with the European Pharmacopoeia, of Solutran®hemo plastic bags for plastic bag for platelet storage

Comparison of the coefficient of permeability to oxygen gas



O₂ TR (cc/m²•24h•atm)
ASTM D3985-05-Standard test method for oxygen gas transmission rate through plastic film sheeting using a coulometer sensor.

Comparison of the coefficient of permeability to carbon dioxide gas



CO₂ TR (cc/m²•24h•atm)
ASTM F2476-13-Standard test method for determination of carbon dioxide gas transmission rate (CO₂ TR) through barrier material using an infrared detector.

ITEM	TEST RESULT
Red cell hemolysis at the end of storage (42 days)	≤0.3%; n=3
Optimal Ph of platelets after 7 days of storage	6.88 - 7.12; n=3