

Solutran HEMO®

Technical sheet

Medical Grade PVC Granule-Lay Flat Tubing- Tube for Trasfusional Sector: Container 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'-diacetylenediamines | < 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

| 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

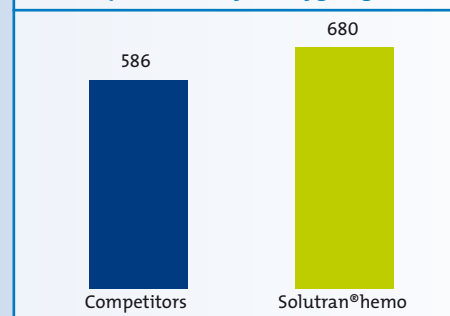
| TEST | LIMIT VALUE |
|--------------------------------|---------------|
| Resistance to Centrifugation | In conformity |
| Resistance to Stretch | In conformity |
| Leakage | In conformity |
| Vapour Permeability | 1% |
| Emptying under Pressure | 2 min |
| Speed of Filling | In conformity |
| Resistance to Temp. Variations | In conformity |

BIOLOGICAL RECTIVITY UNI EN ISO 30993

| TEST | IN CONFORMITY |
|-------------------|---------------|
| Irritation | Yes |
| Cytotoxicity | Yes |
| Implantation | Yes |
| Hermolysis | Yes |
| Systemic Toxicity | Yes |

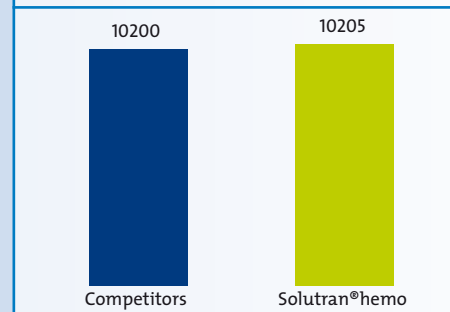
Test carried out in compliance with the European Pharmacopoeia, of Solutran®hemo plastic bags for plastic bag for platelet storage

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 |