

Medical Grade PVC Granule Lay Flat Tubes Tubes for Containers of Infusional Sector

CHEMICAL SPECIFICATIONS Eur. Ph. Sez. 3.1.1.1

FORMULATION

| | |
|-----------------------------|-------|
| Poly(vinyl chloride) | > 55% |
| Di(2-ethylhexyl)phthalate | < 40% |
| Epoxidised soya oil | < 5% |
| N,N'-diacylethylenediamines | < 1% |
| Calcium stearate | < 1% |

TEST

LIMIT VALUE

| | |
|------------------------|---|
| Vinyl chloride | 1,0 ppm |
| Appearance | Clear, Colourless |
| Alkalinity | 1,0 ml HCl 0.01 M |
| Acidity | 1,5 ml NaOH 0.01 M |
| Reducing Substances | 2,0 ml Na ₂ S ₂ O ₃ 0.01 M |
| UV Absorption | 0,25 250-310nm |
| Residue on Evaporation | 0,3% |
| Barium | 5,0 ppm |
| Cadmium | 0,6 ppm |
| Heavy Metals | 50,0 ppm |
| Calcium | 0,07% |
| Tin | 20,0 ppm |
| Zinc | 0,2% |

Small color differences depend only
from the color tone of the PVC resin

PHYSICAL PROPERTIES

| TEST | VALUE | UNIT | REFEREN. |
|---------------------------|---------------------|--------------------|-----------|
| Appearance | Omogeneous Granules | | |
| | Omogeneous Film | | |
| | Natural Colour | | |
| | Crystal Colour | | |
| | Contamination Free | | |
| | Burned Point Free | | |
| Hardness | 85 | Shore A | ISO 868 |
| Tensile strenght at break | 175 | Kg/cm ² | ISO R527 |
| Elongation at break | 290 | % | ISO R527 |
| Temperature of stiffening | -7 | °C | ISO R458 |
| Density | 1,25 | g/cm ³ | ISO R1183 |

BIOLOGICAL RECTIVITY UNI EN ISO 30993

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