

- Product name: STORAGE SOLUTION FOR PLATELETS SSP+ 300/250 mL
 - Packaging : MACOFLEX N : NO PVC Container 300 mL
 - Reference: SSP2130U
 - Batch number: 25110601F1
 - Date of Production: 06/11/2025
 - Expiry date: 11/2027
 - Released quantity: 18680 Bags
 - Country: UNIVERSEL

| | METHOD | RESULT | SPECIFICATION |
|---|-------------------------------|----------------|----------------------|
| TESTS | | | |
| pH | Eur.Ph. 2.2.3 | 7.3 | 7.0 - 7.5 |
| Osmolality | Eur.Ph. 2.2.35 | 293 | 280 - 320 mOsmol/kg |
| Extractable volume | Eur.Ph. 2.9.17 | Conform | ≥ 300 mL |
| Particulate contamination (particles ≥ 10 µm) | Eur.Ph. 2.9.19 Meth 1 | 0.80 | ≤ 25 particles/mL |
| Particulate contamination (particles ≥ 25 µm) | Eur.Ph. 2.9.19 Meth 1 | 0.00 | ≤ 3 particles/mL |
| Endotoxin test | Eur.Ph. 2.6.14 | <0.5 | < 0.5 IU/mL |
| Sterility test | Parametric release | Conform | Conform |
| ASSAY | | | |
| Magnesium | Ionic Chromatography | 1.5 | 1.4 - 1.5 mmol/L |
| Sodium | Ionic Chromatography | 180.7 | 174.7 - 193.1 mmol/L |
| Potassium | Ionic Chromatography | 4.9 | 4.8 - 5.2 mmol/L |
| Chloride | Silver nitrate titr. Or I.C.* | 76.7 | 72.0 - 79.5 mmol/L |
| Acetate | Ionic Chromatography | 32.6 | 30.9 - 34.0 mmol/L |
| Phosphate | Ionic Chromatography | 28.1 | 26.9 - 29.6 mmol/L |
| Citrate | Ionic Chromatography | 10.71 | 10.27 - 11.35 mmol/L |

*I.C. = Ionic Chromatography

These products comply with the requirements of the Medical Devices Directive (93/42/CE) and ISO 3826 standards.
 These products have been controlled according to the requirements of the current European Pharmacopoeia where applicable.

29/12/2025



Thibaud DOREMUS
Site Qualified Person