

- Product name: STORAGE SOLUTION FOR PLATELETS SSP+ 300/250 mL  
 - Packaging : MACOFLEX N : NO PVC Container 300 mL  
 - Reference: SSP2130U  
 - Batch number: 24022101F1  
 - Date of Production: 25/02/2024  
 - Expiry date: 02/2026  
 - Released quantity: 17620 Bags  
 - Country: UNIVERSEL

	METHOD	RESULT	SPECIFICATION
<b>TESTS</b>			
pH	Eur.Ph. 2.2.3	7.3	7.0 - 7.5
Osmolality	Eur.Ph. 2.2.35	296	280 - 320 mOsmol/kg
Extractible volume	Eur.Ph. 2.9.17	<b>Conform</b>	≥ 300 mL
Particulate contamination (particles ≥ 10 µm)	Eur.Ph. 2.9.19 Meth 1	1.81	≤ 25 particles/mL
Particulate contamination (particles ≥ 25 µm)	Eur.Ph. 2.9.19 Meth 1	0.05	≤ 3 particles/mL
Endotoxin test	Eur.Ph. 2.6.14	<b>&lt;0.5</b>	< 0.5 IU/mL
Sterility test	Parametric release	<b>Conform</b>	Conform
<b>ASSAY</b>			
Magnesium	Ionic Chromatography	1.5	1.4 - 1.5 mmol/L
Sodium	Ionic Chromatography	181.8	174.7 - 193.1 mmol/L
Potassium	Ionic Chromatography	4.9	4.8 - 5.2 mmol/L
Chloride	Silver nitrate titr. Or I.C.*	76.8	72.0 - 79.5 mmol/L
Acetate	Ionic Chromatography	32.7	30.9 - 34.0 mmol/L
Phosphate	Ionic Chromatography	29.3	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.

02/05/2024



Thibaud DOREMUS  
 Site Qualified Person