

- Product name: STORAGE SOLUTION FOR PLATELETS SSP+ 300/250 mL
 - Packaging : MACOFLEX N : NO PVC Container 300 mL
 - Reference: SSP2130U
 - Batch number: 24012301F1
 - Date of Production: 22/01/2024
 - Expiry date: 01/2026
 - Released quantity: 19020 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	294	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	0.57	≤ 25 particles/mL
Particulate contamination (particles ≥ 25 µm)	Eur.Ph. 2.9.19 Meth 1	0.09	≤ 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	184.2	174.7 - 193.1 mmol/L
Potassium	Ionic Chromatography	5.0	4.8 - 5.2 mmol/L
Chloride	Silver nitrate titr. Or I.C.*	75.4	72.0 - 79.5 mmol/L
Acetate	Ionic Chromatography	31.9	30.9 - 34.0 mmol/L
Phosphate	Ionic Chromatography	28.8	26.9 - 29.6 mmol/L
Citrate	Ionic Chromatography	10.59	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.

14/03/2024

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Pharmacien

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