CERTIFICAT DE CONFORMITE

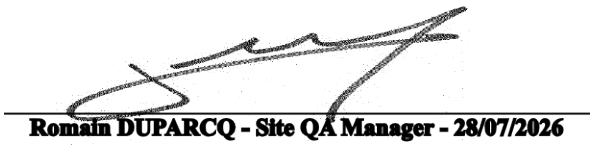
CE 0459

- Product name: PLATELET ADDITIVE SOLUTION - SSP+ 300 mL
- Packaging : NO PVC bag – Container 300 mL
- Reference: SSP4030U
- Batch number: 11566854AM
- Date of Production: 17/06/2026
- Expiry date: 06/2027
- Released quantity: 17180 Bags

	METHOD	RESULT	SPECIFICATION
TESTS			
pH	Eur.Ph. 2.2.3	7.2	7.0 - 7.5
Osmolality	Eur.Ph. 2.2.35	297	280 - 320 mOsmol/kg
Extractible volume	Eur.Ph. 2.9.17	**Conform**	≥ 300 mL
Particulate contamination (particles ≥ 10 µm)	Eur.Ph. 2.9.19 Meth 1	0.45	≤ 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	**<0.5**	< 0.5 IU/mL
Sterility test	Parametric release	**Conform**	Conform
ASSAY			
Magnesium	I.C* or A.A.S**	1.5	1.4 - 1.5 mmol/L
Sodium	I.C* or A.A.S**	179.9	174.7 - 193.1 mmol/L
Potassium	I.C* or A.A.S**	4.8	4.8 - 5.2 mmol/L
Chloride	Silver nitrate titr. Or I.C.*	76.0	72.0 - 79.5 mmol/L
Acetate	Ionic Chromatography	32.1	30.9 - 34.0 mmol/L
Phosphate	Ionic Chromatography	27.8	26.9 - 29.6 mmol/L
Citrate	Ionic Chromatography	10.60	10.27 - 11.35 mmol/L

*I.C. = Ionic Chromatography
**AAS = Atomic Absorption Spectrometry

These products comply with the requirements of the Regulation (EU) 2017/745.
These products have been controlled according to the requirements of the current European Pharmacopoeia where applicable.



Romain DUPARCQ - Site QA Manager - 28/07/2026