

***** **CERTIFICATE OF ANALYSIS** *****

Article: CompoFlow® 4F T&B CPD SAG-M RCC - PDS-V
Article number: CQ32250
Anticoagulant solution: 63 ml CPD
Preservation solution: 100 ml SAG-Mannitol
Batch number: 71XD15FC00 Quantity: 9720
Manufacturing date: 2025-04 Expiry date: 2027-03

Test results

1. CPD Anticoagulant solution

	Method ¹	Nominal value	Limits	Results
Sodium citrate.2H ₂ O	HPLC	26.3 g/l	25.0 - 27.6	25.2 g/l
Citric acid.1H ₂ O	HPLC	3.27 g/l	2.94 - 3.60	3.26 g/l
NaH ₂ PO ₄ .2H ₂ O	HPLC or Spectr. Ph.	2.51 g/l	2.38 - 2.64	2.39 g/l
Glucose.1H ₂ O ²	HPLC	25.5 g/l	24.2 - 26.8	25.1 g/l
5-HMF	HPLC		< 5 ppm	0.447 ppm
pH	Potent	5.6	5.3 - 5.9	5.6
Volume	Volumetr.	63 ml	57 - 69	65 ml

2. SAG-Mannitol Preservation solution

	Method	Nominal value	Limits	Results
Sodium chloride	Argent.	8.77 g/l	8.33 - 9.21	8.39 g/l
Adenine	HPLC	0.169 g/l	0.161-0.177	0.163 g/l
Glucose.1H ₂ O ²	HPLC	9.00 g/l	8.55 - 9.45	8.89 g/l
Mannitol	HPLC	5.25 g/l	4.99 - 5.51	5.17 g/l
5-HMF	HPLC		< 5 ppm	0.361 ppm
pH	Potent.	5	3.5 - 6.0	5.3
Volume	Volumetr.	100 ml	90 - 110	104 ml

¹⁾ The used test methods are equivalent or more accurate than the corresponding methods described in the Eur. Pharm.

²⁾ As total reducing sugars

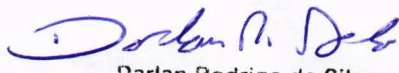
3. Characteristics: clear, colourless to faintly yellow solution practically free from visible particles conform
4. Physical control: in accordance with specifications conform
5. Sterility (Eur. Pharm.): sterile conform
6. Bacterial Endotoxines (Eur. Pharm.): CPD: < 5.56 EU/ml conform
SAGM: < 5.56 EU/ml conform
7. Used Filterbatch 90065/25 90066/25

Batch released by Quality Assurance.

Date:

02/07/2025

Name:



Darlan Rodrigo da Silva
Responsável Técnico

Signature:

CRF - SP. 30.802

Manufactured by:

Fresenius Kabi AG

Plant: Fresenius Hemocare Brasil Ltda

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