

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

Article:	CompoFlow® 4F T&B CPD SAG-M RCC - PDS-V		
Article number:	CQ32250		
Anticoagulant solution:	63 ml CPD	Quantity:	8800
Preservation solution:	100 ml SAG-Mannitol	Expiry date:	2026-01
Batch number:	71WB02FA00		
Manufacturing date:	2024-02		

Test results

1. CPD Anticoagulant solution

	Method ¹	Nominal value	Limits	Results
Sodium citrate.2H2O	HPLC	26.3 g/l	25.0 - 27.6	25.2 g/l
Citric acid.1H2O	HPLC	3.27 g/l	2.94 - 3.60	3.22 g/l
NaH2PO4.2H2O	HPLC or Spectr. Ph.	2.51 g/l	2.38 - 2.64	2.43 g/l
Glucose.1H2O ²	HPLC	25.5 g/l	24.2 - 26.8	24.6 g/l
5-HMF	HPLC		< 5 ppm	0.329 ppm
pH	Potent	5.6	5.3 - 5.9	5.7
Volume	Volumetr.	63 ml	57 - 69	67 ml


2. SAG-Mannitol Preservation solution

	Method	Nominal value	Limits	Results
Sodium chloride	Argent.	8.77 g/l	8.33 - 9.21	9.07 g/l
Adenine	HPLC	0.169 g/l	0.161-0.177	0.165 g/l
Glucose.1H2O ²	HPLC	9.00 g/l	8.55 - 9.45	8.79 g/l
Mannitol	HPLC	5.25 g/l	4.99 - 5.51	5.07 g/l
5-HMF	HPLC		< 5 ppm	0.187 ppm
pH	Potent.	5	3.5 - 6.0	5.3
Volume	Volumetr.	100 ml	90 - 110	107 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

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| 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
SAGM: < 5.56 EU/ml |
| 7. Used Filterbatch | conform
92771/23 |

<p><u>Batch released by Quality Assurance.</u></p> <p>Date: 18/03/2024</p> <p>Name: </p> <p>Signature: Darlan Rodrigo da Silva Gerente da Qualidade</p>	<p><u>Manufactured by:</u></p> <p>Fresenius Kabi AG Plant: Fresenius Hemocare Brasil Ltda.</p>
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