



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:	71UI08FB00	Quantity:	7896
Manufacturing date:	2023-09	Expiry date:	2025-08

Test results

1. CPD Anticoagulant solution

	Method ¹	Nominal value	Limits	Results
Sodium citrate.2H ₂ O	HPLC g/l	26.3 g/l	25.0 - 27.6	26.1
Citric acid.1H ₂ O	HPLC g/l	3.27 g/l	2.94 - 3.60	3.23
NaH ₂ PO ₄ .2H ₂ O	HPLC or Spectr. Ph. g/l	2.51 g/l	2.38 - 2.64	2.45
Glucose.1H ₂ O ²	HPLC g/l	25.5 g/l	24.2 - 26.8	24.6
5-HMF	HPLC ppm		< 5 ppm	0.313
pH	Potent	5.6	5.3 - 5.9	5.7
Volume	Volumetr. ml	63 ml	57 - 69	65

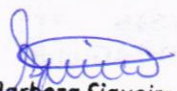
2. SAG-Mannitol Preservation solution

	Method	Nominal value	Limits	Results
Sodium chloride	Argent. g/l	8.77 g/l	8.33 - 9.21	8.87
Adenine	HPLC g/l	0.169 g/l	0.161-0.177	0.165
Glucose.1H ₂ O ²	HPLC g/l	9.00 g/l	8.55 - 9.45	8.81
Mannitol	HPLC g/l	5.25 g/l	4.99 - 5.51	5.07
5-HMF	HPLC ppm		< 5 ppm	0.184
pH	Potent.	5	3.5 - 6.0	5.3
Volume	Volumetr. ml	100 ml	90 - 110	106

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 | conform |
| SAGM: < 5.56 EU/ml | conform |

<p><u>Batch released by Quality Assurance.</u></p> <p>Date: 03.10.2023 </p> <p>Name: Vanessa Barboza Siqueira Responsável Técnica Substitua:</p> <p>Signature: CRF-SP. 111.974</p>	<p><u>Manufactured by:</u></p> <p>Fresenius Kabi AG Plant:</p>
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Form.no. 17-4224/5