



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

Article: CompoFlow® 4F T&B 63 ml CPD/100 ml SAGM - RCC - PDS-V  
 Article number: CQ32250  
 Anticoagulant solution: 63 ml CPD  
 Preservation solution: 100 ml SAG-Mannitol  
 Batch number: 85WA12FA00  
 Manufacturing date: 2024.01  
 Quantity: 22089  
 Expiry date: 2025.12

Test results

1. CPD Anticoagulant solution

	<b>Method<sup>1</sup></b>	<b>Nominal value</b>	<b>Limits</b>	<b>Results</b>
Sodium citrate.2H2O	Titration	26.3 g/l	25.0 - 27.6	25.7 g/l
Citric acid.1H2O	Titration	3.27 g/l	2.94 - 3.60	3.22 g/l
NaH2PO4.2H2O	UV	2.51 g/l	2.38 - 2.64	2.44 g/l
Glucose.1H2O <sup>2</sup>	HPLC	25.5 g/l	24.2 - 26.8	25.0 g/l
5-HMF	HPLC		< 5 ppm	0.4 ppm
pH	Potent	5.6	5.3 - 5.9	5.7
Volume	Volumetr.	63 ml	57 - 69	67 ml

2. SAG-Mannitol Preservation solution

	<b>Method</b>	<b>Nominal value</b>	<b>Limits</b>	<b>Results</b>
Sodium chloride	Argent.	8.77 g/l	8.33 - 9.21	8.64 g/l
Adenine	UV	0.169 g/l	0.161-0.177	0.168 g/l
Glucose.1H2O <sup>2</sup>	HPLC	9.00 g/l	8.55 - 9.45	8.87 g/l
Mannitol	HPLC	5.25 g/l	4.99 - 5.51	5.12 g/l
5-HMF	HPLC		< 5 ppm	0.3 ppm
pH	Potent.	5	3.5 - 6.0	5.2
Volume	Volumetr.	100 ml	90 - 110	106 ml

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

<sup>2)</sup> 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 23120803/23122501

<p><u>Batch released by Quality Assurance.</u></p> <p>Date: 31 Jan 2024</p> <p>Name: Xu Xiaoying</p> <p>Signature: <i>Xu Xiaoying</i></p>	<p><u>Manufactured by:</u></p> <p>Fresenius Kabi AG</p> <p>Plant: FKGZ</p>
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