

***** **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:	85WF17FB00	Quantity:	8272
Manufacturing date:	2024.06	Expiry date:	2026.05

Test results

1. CPD Anticoagulant solution

	Method¹	Nominal value	Limits	Results
Sodium citrate.2H ₂ O	Titration	26.3 g/l	25.0 - 27.6	25.6 g/l
Citric acid.1H ₂ O	Titration	3.27 g/l	2.94 - 3.60	3.22 g/l
NaH ₂ PO ₄ .2H ₂ O	UV	2.51 g/l	2.38 - 2.64	2.44 g/l
Glucose.1H ₂ O ²	HPLC	25.5 g/l	24.2 - 26.8	24.9 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

	Method	Nominal value	Limits	Results
Sodium chloride	Argent.	8.77 g/l	8.33 - 9.21	8.65 g/l
Adenine	UV	0.169 g/l	0.161-0.177	0.167 g/l
Glucose.1H ₂ O ²	HPLC	9.00 g/l	8.55 - 9.45	8.80 g/l
Mannitol	HPLC	5.25 g/l	4.99 - 5.51	5.13 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

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 | conform
conform |
| 7. Used Filterbatch | 24052104 |

<u>Batch released by Quality Assurance.</u> Date: 05 July 2024 Name: Xu Xiaoying Signature: 	<u>Manufactured by:</u> Fresenius Kabi AG Plant: FKGZ
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