

***** **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: 85UM01FA00
 Manufacturing date: 2023.12

Quantity: 22052
 Expiry date: 2025.11

Test results

1. CPD Anticoagulant solution

	Method¹	Nominal value	Limits	Results
Sodium citrate.2H2O	Titration	26.3 g/l	25.0 - 27.6	25.8 g/l
Citric acid.1H2O	Titration	3.27 g/l	2.94 - 3.60	3.24 g/l
NaH2PO4.2H2O	UV	2.51 g/l	2.38 - 2.64	2.44 g/l
Glucose.1H2O 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.1H2O ²	HPLC	9.00 g/l	8.55 - 9.45	8.84 g/l
Mannitol	HPLC	5.25 g/l	4.99 - 5.51	5.11 g/l
5-HMF	HPLC		< 5 ppm	0.3 ppm
pH	Potent.	5	3.5 - 6.0	5.4
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

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 23110801/23110802

<p><u>Batch released by Quality Assurance.</u></p> <p>Date: 28 Dec. 2023</p> <p>Name: Wei Yuchan</p> <p>Signature: <i>Wei Yuchan</i></p>	<p><u>Manufactured by:</u></p> <p>Fresenius Kabi AG</p> <p>Plant: FKGZ</p>
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