FRESENIUS KABI

***** **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:	85WA11FA00	Quantity:	16578
Manufacturing date:	2024.01	Expiry date:	2025.12

Test results

1. CPD Anticoagulant solution

	Method[1]	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	3.22 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	66 ml

2. SAG-Mannitol Preservation solution

	Method	Nominal value	Limits	Results
Sodium chloride	Argent.	8.77 g/l	8.33 - 9.21	8.62 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	8.85 g/l
Mannitol	HPLC	5.25 g/l	4.99 - 5.51	5.11 g/l
5-HMF	HPLC		< 5 ppm	0.4 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*

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

Batch released by Quality Assurance.	Manufactured by:
Date: 31 Jan. 2024	Fresenius Kabi AG
Name: Xu Xiaoying	Plant: FKGZ
Signature: Xu Xiaoying	