FRESENIUS KABI

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

Article:	COMPOFLOW®4F T&B-63 ML CPD/100 ML SAG-M-RCC+PDS-V		
Article number:	CQ32250		
Anticoagulant solution:	63 ml CPD		
Preservation solution:	100 ml SAG-Mannitol		
Batch number:	41WI08FA00	Quantity:	23 448
Manufacturing date:	10 September 2024	Expiry date:	2026-08

Test results

1. CPD Anticoagulant solution

	Method[1]	Nominal value	Limits	Results
Sodium citrate.2H2O	HPLC	26,3 g/l	25,0 – 27,6 g/l	25,6 g/l
Citric acid.1H2O	HPLC	3,27 g/l	2,94 – 3,60 g/l	3,15 g/l
NaH2PO4.2H2O	HPLC or Spectr.Ph.	2,51 g/l	2,38 – 2,64 g/l	2,48 g/l
Glucose.1H2O[2]	HPLC	25,5 g/l	24,2 – 26,8 g/l	24,5 g/l
5-HMF	HPLC		< 5 ppm	0,5 ppm
pH	Potent.	5,6	5,3 – 5,9	5,7
Volume	Volumetr.	63 ml	57 – 69 ml	66 ml

2. SAG-Mannitol Preservation solution

	Method	Nominal value	Limits	Results
Sodium chloride	Argent.	8,77 g/l	8,33 – 9,21 g/l	8,67 g/l
Adenine	HPLC	0,169 g/l	0,161 – 0,177 g/l	0,165 g/l
Glucose.1H2O[2]	HPLC	9,00 g/l	8,55 – 9,45 g/l	8,81 g/l
Mannitol	HPLC	5,25 g/l	4,99 – 5,51 g/l	5,15 g/l
5-HMF	HPLC		< 5 ppm	0,4 ppm
pH	Potent.	5	3,5 – 6,0	5,1
Volume	Volumetr.	100 ml	90 – 110 ml	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: 24RF024,24RF025,24RF026

Batch released by Quality Assurance.	Manufactured by:
Date: 01.10.2024	Fresenius Kabi AG Plant: Fresenius Kabi Horatev CZ s.r.o. Hořátev 104, 289 13 Czech Republic
Name: Tykva František	
Signature:	

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