



\*\*\*\*\* **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: 41UM11FA00  
 Manufacturing date: 15 December 2023  
 Quantity: 23 496  
 Expiry date: 2025-11

Test results

1. CPD Anticoagulant solution

	Method <sup>1</sup>	Nominal value	Limits	Results
Sodium citrate.2H <sub>2</sub> O	HPLC	26,3 g/l	25,0 – 27,6 g/l	25,4 g/l
Citric acid.1H <sub>2</sub> O	HPLC	3,27 g/l	2,94 – 3,60 g/l	3,18 g/l
NaH <sub>2</sub> PO <sub>4</sub> .2H <sub>2</sub> O	HPLC or Spectr.Ph.	2,51 g/l	2,38 – 2,64 g/l	2,46 g/l
Glucose.1H <sub>2</sub> O <sup>2</sup>	HPLC	25,5 g/l	24,2 – 26,8 g/l	24,8 g/l
5-HMF	HPLC		< 5 ppm	0,5 ppm
pH	Potent.	5,6	5,3 – 5,9	5,8
Volume	Volumetr.	63 ml	57 – 69 ml	67 ml


2. SAG-Mannitol Preservation solution

	Method	Nominal value	Limits	Results
Sodium chloride	Argent.	8,77 g/l	8,33 – 9,21 g/l	8,64 g/l
Adenine	HPLC	0,169 g/l	0,161 – 0,177 g/l	0,164 g/l
Glucose.1H <sub>2</sub> O <sup>2</sup>	HPLC	9,00 g/l	8,55 – 9,45 g/l	8,82 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	5,3
Volume	Volumetr.	100 ml	90 – 110 ml	108 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 23GY038,23RF063

Batch released by Quality Assurance.	Manufactured by:
Date: 08.01.2024	Fresenius Kabi AG
Name: Tykva František	Plant:
Signature: 	Fresenius Kabi Horatev CZ s.r.o.
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