

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

Article:	CompoFlow®4F T&B-66,5ml CPD/105ml SAG-M-RCC-PDS-V		
Article number:	CQ32R60		
Anticoagulant solution:	66,5 ml CPD		
Preservation solution:	105 ml SAG-Mannitol		
Batch number:	41UL07FB00	Quantity:	7 824
Manufacturing date:	9 November 2023	Expiry date:	2025-10

Test results

1. CPD Anticoagulant solution

	<b>Method<sup>1</sup></b>	<b>Nominal value</b>	<b>Limits</b>	<b>Results</b>
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	3,19 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	2,41 g/l
Glucose.1H <sub>2</sub> O <sup>2</sup>	HPLC	25,5 g/l	24,2 – 26,8 g/l	24,7 g/l
5-HMF	HPLC		< 5 ppm	0,5 ppm
pH	Potent.	5,6	5,3 – 5,9	5,7
Volume	Volumetr.	66,5 ml	61 – 72 ml	71 ml


2. SAG-Mannitol Preservation solution

	<b>Method</b>	<b>Nominal value</b>	<b>Limits</b>	<b>Results</b>
Sodium chloride	Argent.	8,77 g/l	8,33 – 9,21 g/l	8,65 g/l
Adenine	HPLC	0,169 g/l	0,161 – 0,177 g/l	0,165 g/l
Glucose.1H <sub>2</sub> O <sup>2</sup>	HPLC	9,00 g/l	8,55 – 9,45 g/l	8,80 g/l
Mannitol	HPLC	5,25 g/l	4,99 – 5,51 g/l	5,13 g/l
5-HMF	HPLC		< 5 ppm	0,4 ppm
pH	Potent.	5	3,5 – 6,0	5,2
Volume	Volumetr.	105 ml	95 – 115 ml	112 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

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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<br>SAGM: < 5,56 EU/ml | conform<br>conform |
| 7. Used Filterbatch  |   | 23RF058            |

<u>Batch released by Quality Assurance.</u>	<u>Manufactured by:</u>
Date: 27.11.2023	Fresenius Kabi AG
Name: Klímová Vladimíra	Plant: Fresenius Kabi Horatev CZ s.r.o.
Signature: 	Hořátev 104, 289 13 Czech Republic