

\*\*\*\*\* **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: 41XB01FA00  
Manufacturing date: 7 February 2025

Quantity: 23 472  
Expiry date: 2027-01

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 | 25,6 g/l |
| Citric acid.1H <sub>2</sub> O                       | HPLC                | 3,27 g/l      | 2,94 — 3,60 g/l | 3,22 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 | 2,42 g/l |
| Glucose.1H <sub>2</sub> O <sup>2</sup>              | HPLC                | 25,5 g/l      | 24,2 — 26,8 g/l | 24,5 g/l |
| 5-HMF                                               | HPLC                |               | < 5 ppm         | 0,4 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   | 8,60 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   | 8,74 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. | 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 24RF039,24RF041

|                                             |                                                                                     |                                  |  |
|---------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------|--|
| <u>Batch released by Quality Assurance.</u> |                                                                                     | <u>Manufactured by:</u>          |  |
| Date:                                       | 06.03.2025                                                                          | Fresenius Kabi AG                |  |
| Name:                                       | Tykva František                                                                     | Plant:                           |  |
| Signature:                                  |  | Fresenius Kabi Horatev CZ s.r.o. |  |
|                                             |                                                                                     | Hořátev 104, 289 13              |  |
|                                             |                                                                                     | Czech Republic                   |  |