FRESENIUS KABI

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

Article:	Compoflex®1F-63ml CPDA-1-PDS-V		
Article number:	PS11150		
Anticoagulant solution:	63 ml CPDA-1		
Batch number:	41UE18AA00	Quantity:	19 944
Manufacturing date:	16 May 2023	Expiry date:	2025-04

Test results

1. CPDA-1 Anticoagulant solution

	Method[1]	Nominal value	Limits				Results	
Sodium Citrate.2H2O	HPLC	26,3 g/l	25,0	–	27,6	g/l	25,2	g/l
Citric acid.1H2O	HPLC	3,27 g/l	2,94	–	3,60	g/l	3,21	g/l
NaH2PO4.2H2O	HPLC or Spectr.Ph.	2,51 g/l	2,38	–	2,64	g/l	2,44	g/l
Glucose.1H2O[2]	HPLC	31,9 g/l	30,3	–	33,5	g/l	30,8	g/l
Adenine	HPLC	0,275 g/l	0,261	–	0,289	g/l	0,269	g/l
5-HMF	HPLC			<	5	ppm	0,6	ppm
pH	Potent.	5,5	5,3	–	5,9		5,7	
Volume	Volumetr.	63 ml	57	–	69	ml	67	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*

2. Characteristics: clear, colourless to faintly yellow solution practically free from visible particles — conform

3. Physical control: in accordance with specifications — conform

4. Sterility (Eur. Pharm.): sterile — conform

5. Bacterial Endotoxines (Eur. Pharm.): < 5,56 EU/ml — conform

6. Used Filterbatch — -

Batch released by Quality Assurance.	Manufactured by:
Date: 05.06.2023	Fresenius Kabi AG Plant:
Name: Tykva František	Fresenius Kabi Horatev CZ s.r.o. Hořátev 104, 289 13
Signature:	Czech Republic

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