KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU/10 ML

Batch Number:	452308				
Code:	1013890				
Production Date:	02-2023	**Validity Start Date:**	02-2023	**Expiry Date:**	01-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Test	Method	Specification	Result
Characters	Ph. Eur.	White or pale yellow, hygroscopic powder or friable solid	Complies
Appearance (Solution)	Ph. Eur.	The preparation dissolves completely with gentle swirling within 10 min, giving a clear or slightly opalescent colourless or slightly yellow solution. The solution may show a few small flakes or particles after reconstitution. The filtered solution is clear or slightly opalescent.	Complies
Solubility	Ph. Eur.	≤ 600 s	190 s
Bacterial endotoxins	Ph. Eur.	Complies (< 0.03 E.U./I.U.)	Complies
Chloride	Potentiometric	90 - 140 mmol/L	108 mmol/L
Citrate	Enzymatic test	6 - 16 mmol/L	13 mmol/L
Factor VIII Potency	Ph. Eur.	400 - 600 I.U./vial	528 I.U./vial
Factor vWF potency	Ph. Eur.	N.A.	158 I.U./vial
Factor vWF:Ag	Immunochemical	N.A.	200 I.U./vial
Fibrinogen	Immunochemical	≤ 4.0 mg/vial	<1.4 mg/vial
Glycine	Kjeldhal	76 - 104 mg/vial	90 mg/vial
Haemagglutinins Anti-A1	Ph. Eur.	< 1:64	1:4
Haemagglutinins Anti-B	Ph. Eur.	< 1:64	1:2
Identity	Ph. Eur.	Complies	Complies
Osmolality	Ph. Eur.	≥ 240 mOsmol/kg	356 mOsmol/kg
pH	Ph. Eur.	6.5 - 7.5	6.9
Polisorbate 80	Spectrophotometric	≤ 100 ppm	<10 ppm
Sodium	Atomic emission spectrophotometry	120 - 180 mmol/L	147 mmol/L
Specific activity	N.A.	N.A.	182 IU/mg
Sterility	Ph. Eur.	Sterile	Sterile
Total Proteins	Bradford	≤ 7.2 mg/vial	2.9 mg/vial
Tri(n-butyl)phosphate	Gascromatographyc	≤ 5 ppm	<1 ppm
vWF:Rco/FVIII:C	N.A.	≥ 0.25	0.30
Water	Ph. Eur.	≤ 3 %	1 %

Reference: 108039
CoA: 1013890-STD
Certificate No.: 205637 Date: 27/04/2023 From: Database: LIMS_PROD

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU/10 ML

Batch Number:	452308				
Code:	1013890				
Production Date:	02-2023	**Validity Start Date:**	02-2023	**Expiry Date:**	01-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Certified By: Sara Del Carlo
Quality Control Manager
Date: 15/03/2023 17:02:26
This is an electronic signature

KEDRION
BIOPHARMA

Certificate for medicinal product

EMOCLOT 500 IU/10 ML

Batch Number:	452308				
Code:	1013890				
Production Date:	02-2023	**Validity Start Date:**	02-2023	**Expiry Date:**	01-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

The Human Plasma was collected from healthy donors according to European Guidelines, National Requirements and European Pharmacopoeia (Monograph 0853) with the aim of assuring the suitability of the individual donations. Every donation is tested and found non-reactive for:
- HBsAg, anti-HIV1/HIV2, anti-HCV.
- HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and Parvovirus B19-DNA by test NAT done by minipool testing. Units with a Parvovirus B19-DNA of elevated titer are excluded. The manufacturing plasma pools were tested and found to be non-reactive for HBsAg, anti-HIV1/HIV2 and by NAT for HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and tested for Parvovirus B -19 DNA. The manufacturing plasma pools used for the manufacture of the above batch were released from a European OMCL (Official Medicines Control Laboratory). I hereby certified that all manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and the requirements of the Marketing Authorization of the destination country/countries.

APPROVED

The Lot Is .....

Qualified Person: .....

Kedrion S.p.A.
Sara Del Carlo
Qualified Person
Bolognana Plant

28 APR 2023

Date: .....

Reference: 108039
CoA: 1013890-STD
Certificate No.: 205637 Date: 27/04/2023 From: Database: LIMS_PROD

KEDRION
BIOPHARMA

Material Code: 0006103761 *Inspection Lot: 030000033926*

CERTIFICATE OF ANALYSIS

N° 20220525095426

W.F.I. Solvent 10 ml

Batch Number: KA0522

Production Date: 04/2022

Expiry Date: 03/2027

Storage Temperature : Store at a temperature not higher than 25°C, protect from light. Do not freeze.

Tests	Methods	Requirements	Results
Appearance	Ph. Eur.	Clear, colourless liquid	Complies
Acidity/Alkalinity	Ph. Eur.	<=0,1 ml NaOH 0,01N/20 ml O <=0,15 ml HCl 0,01N/20 ml	Complies
Oxidisable Substances	Ph. Eur.	< 0,4 ml KMnO4 0,1N/100 ml The solution remains faintly pink	Complies
Chlorides (p.p.m.)	Ph. Eur.	<=0,5	< 0,5
Sterility	Ph. Eur.	Sterile	Sterile
Bacterial Endotoxin (E.U./ml)	Ph. Eur.	< 0,25	< 0,005
Nitrates (p.p.m.)	Ph. Eur.	<=0,2	< 0,2
Sulfates	Ph. Eur.	Absent/10ml	Absent
Ammonium (p.p.m)	Ph. Eur.	<=0,6	< 0,6
Calcium and Magnesium	Ph. Eur.	<=0,5 ml sodium edetate 0,01M/100 ml	Complies

KEDRION S.p.A.
Quality Assurance
Copia conforme all'originale - 1 -
Data 01/6/22 Firma C.)

Release O.M.C.L. N°: N.A. Date: N.A.

The Batch Is: APPROVED

Quality Control Manager : Ester Luciano **Date :** 25/05/2022

Qualified Person : Veronica De Rosa **Date :** 26/05/2022

KEDRION BIOPHARMA

Material Code: 0006103761 *Inspection Lot: 030000033926*

CERTIFICATE OF ANALYSIS

N° 20220525095426

W.F.I. Solvent 10 ml

Batch Number: KA0522

Production Date: 04/2022

Expiry Date: 03/2027

Storage Temperature : Store at a temperature not higher than 25°C, protect from light. Do not freeze.

Tests	Methods	Requirements	Results
Particulate contamination (>= 10 µm): Sub-visible particles (Particles/container)	Ph. Eur.	<=6000	18
Particulate contamination (>= 25 µm): Sub-visible particles (Particles/container)	Ph. Eur.	<=600	1
Residue on evaporation (%)	Ph. Eur.	<=0,004	0,002
Conductivity (µS/cm)	Ph. Eur.	<=25	2
Extractable volume (ml)	Ph. Eur.	>=10,0	10,0

KEDRION S.p.A.
Quality Assurance
Copia conforme all'originale -1-
Data 26/05/22 Firma

Release O.M.C.L. N°: N.A. Date: N.A.

The Batch Is: APPROVED

Quality Control Manager : ..... Date : 25/05/2022

Qualified Person : Veronica De Rose ..... Date : 26/05/2022

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU/10 ML

Batch Number:	452320				
Code:	1013892				
Production Date:	03-2023	**Validity Start Date:**	03-2023	**Expiry Date:**	02-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Test	Method	Specification	Result
Characters	Ph. Eur.	White or pale yellow, hygroscopic powder or friable solid	Complies
Appearance (Solution)	Ph. Eur.	The preparation dissolves completely with gentle swirling within 10 min, giving a clear or slightly opalescent colourless or slightly yellow solution. The solution may show a few small flakes or particles after reconstitution. The filtered solution is clear or slightly opalescent.	Complies
Solubility	Ph. Eur.	≤ 600 s	200 s
Bacterial endotoxins	Ph. Eur.	Complies (< 0.03 E.U./I.U.)	Complies
Chloride	Potentiometric	90 - 140 mmol/L	111 mmol/L
Citrate	Enzymatic test	6 - 16 mmol/L	11 mmol/L
Factor VIII Potency	Ph. Eur.	400 - 600 I.U./vial	503 I.U./vial
Factor vWF potency	Ph. Eur.	N.A.	128 I.U./vial
Factor vWF:Ag	Immunochemical	N.A.	159 I.U./vial
Fibrinogen	Immunochemical	≤ 4.0 mg/vial	<1.4 mg/vial
Glycine	Kjeldhal	76 - 104 mg/vial	93 mg/vial
Haemagglutinins Anti-A1	Ph. Eur.	< 1:64	1:4
Haemagglutinins Anti-B	Ph. Eur.	< 1:64	1:2
Identity	Ph. Eur.	Complies	Complies
Osmolality	Ph. Eur.	≥ 240 mOsmol/kg	355 mOsmol/kg
pH	Ph. Eur.	6.5 - 7.5	6.9
Polisorbate 80	Spectrophotometric	≤ 100 ppm	13 ppm
Sodium	Atomic emission spectrophotometry	120 - 180 mmol/L	147 mmol/L
Specific activity	N.A.	N.A.	144 IU/mg
Sterility	Ph. Eur.	Sterile	Sterile
Total Proteins	Bradford	≤ 7.2 mg/vial	3.5 mg/vial
Tri(n-butyl)phosphate	Gascromatographyc	≤ 5 ppm	<1 ppm
vWF:Rco/FVIII:C	N.A.	≥ 0.25	0.25
Water	Ph. Eur.	≤ 3 %	2 %

Reference: 109396
CoA: 1013892-STD
Certificate No.: 213438 Date: 22/06/2023 From: Database: LIMS_PROD

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU/10 ML

Batch Number:	452320				
Code:	1013892				
Production Date:	03-2023	**Validity Start Date:**	03-2023	**Expiry Date:**	02-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Certified By: Ilaria Rossi
Deputy Quality Control Manager
Date: 14/04/2023 16:43:34
This is an electronic signature

KEDRION
BIOPHARMA

Certificate for medicinal product

EMOCLOT 500 IU/10 ML

Batch Number:	452320				
Code:	1013892				
Production Date:	03-2023	**Validity Start Date:**	03-2023	**Expiry Date:**	02-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

The Human Plasma was collected from healthy donors according to European Guidelines, National Requirements and European Pharmacopoeia (Monograph 0853) with the aim of assuring the suitability of the individual donations. Every donation is tested and found non-reactive for:
- HBsAg, anti-HIV1/HIV2, anti-HCV.
- HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and Parvovirus B19-DNA by test NAT done by minipool testing. Units with a Parvovirus B19-DNA of elevated titer are excluded. The manufacturing plasma pools were tested and found to be non-reactive for HBsAg, anti-HIV1/HIV2 and by NAT for HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and tested for Parvovirus B -19 DNA. The manufacturing plasma pools used for the manufacture of the above batch were released from a European OMCL (Official Medicines Control Laboratory). I hereby certified that all manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and the requirements of the Marketing Authorization of the destination country/countries.

The Lot Is ..... APPROVED

Qualified Person: .....

Kedrion S.p.A.
Sara Del Carlo
Qualified Person
Bolognana Plant

Date: ..... 22 JUN 2023

Reference: 109396
CoA: 1013892-STD
Certificate No.: 213438 Date: 22/06/2023 From: Database: LIMS_PROD

KEDRION
BIOPHARMA

Material Code: 0006103761 *Inspection Lot: 030000034042*

CERTIFICATE OF ANALYSIS

N° 20220607152422

W.F.I. Solvent 10 ml

Batch Number: KA0822

Production Date: 05/2022

Expiry Date: 04/2027

Storage Temperature : Store at a temperature not higher than 25°C, protect from light. Do not freeze.

Tests	Methods	Requirements	Results
Appearance	Ph. Eur.	Clear, colourless liquid	Complies
Acidity/Alkalinity	Ph. Eur.	<=0,1 ml NaOH 0,01N/20 ml O <=0,15 ml HCl 0,01N/20 ml	Complies
Oxidisable Substances	Ph. Eur.	< 0,4 ml KMnO4 0,1N/100 ml The solution remains faintly pink	Complies
Chlorides (p.p.m.)	Ph. Eur.	<=0,5	< 0,5
Sterility	Ph. Eur.	Sterile	Sterile
Bacterial Endotoxin (E.U./ml)	Ph. Eur.	< 0,25	< 0,005
Nitrates (p.p.m.)	Ph. Eur.	<=0,2	< 0,2
Sulfates	Ph. Eur.	Absent/10ml	Absent
Ammonium (p.p.m)	Ph. Eur.	<=0,6	< 0,6
Calcium and Magnesium	Ph. Eur.	<=0,5 ml sodium edetate 0,01M/100 ml	Complies

KEDRION S.p.A.
Quality Assurance
Copia conforme all'originale
Data 08/06/22 Firma

Release O.M.C.L. N°: N.A. Date: N.A.

The Batch Is: APPROVED

Quality Control Manager : ..... Date : 07/06/2022

Qualified Person : Francesco De Rosa ..... Date : 07/06/2022

KEDRION
BIOPHARMA

Material Code: 0006103761 *Inspection Lot: 030000034042*

CERTIFICATE OF ANALYSIS

N° 20220607152422

W.F.I. Solvent 10 ml

Batch Number: KA0822

Production Date: 05/2022

Expiry Date: 04/2027

Storage Temperature : Store at a temperature not higher than 25°C, protect from light. Do not freeze.

Tests	Methods	Requirements	Results
Particulate contamination (> = 10 µm): Sub-visible particles (Particles/container)	Ph. Eur.	< =6000	21
Particulate contamination (> = 25 µm): Sub-visible particles (Particles/container)	Ph. Eur.	< =600	1
Residue on evaporation (%)	Ph. Eur.	< =0,004	0,002
Conductivity (µS/cm)	Ph. Eur.	< =25	2
Extractable volume (ml)	Ph. Eur.	> =10,0	10,0

KEDRION S.p.A.
Quality Assurance
Copia conforme all'originale
Data 28/06/22 Firma

Release O.M.C.L. N°: N.A. Date: N.A.

The Batch Is: APPROVED

Quality Control Manager : ..... Date : 07/06/2022

Qualified Person : ..... Date : 08/06/2022

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU 10 ML

Batch Number:	452317				
Code:	1013946				
Production Date:	03-2023	**Validity Start Date:**	03-2023	**Expiry Date:**	02-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Test	Method	Specification	Result
Characters	Ph. Eur.	White or pale yellow, hygroscopic powder or friable solid	Complies
Appearance (Solution)	Ph. Eur.	The preparation dissolves completely with gentle swirling within 10 min, giving a clear or slightly opalescent colourless or slightly yellow solution. The solution may show a few small flakes or particles after reconstitution. The filtered solution is clear or slightly opalescent.	Complies
Solubility	Ph. Eur.	≤ 600 s	190 s
Bacterial endotoxins	Ph. Eur.	Complies (< 0.03 E.U./I.U.)	Complies
Chloride	Potentiometric	90 - 140 mmol/L	107 mmol/L
Citrate	Enzymatic test	6 - 16 mmol/L	13 mmol/L
Factor VIII Potency	Ph. Eur.	400 - 600 I.U./vial	560 I.U./vial
Factor vWF potency	Ph. Eur.	N.A.	162 I.U./vial
Factor vWF:Ag	Immunochemical	N.A.	194 I.U./vial
Fibrinogen	Immunochemical	≤ 4.0 mg/vial	<1.4 mg/vial
Glycine	Kjeldhal	76 - 104 mg/vial	93 mg/vial
Haemagglutinins Anti-A1	Ph. Eur.	< 1:64	1:4
Haemagglutinins Anti-B	Ph. Eur.	< 1:64	1:2
Identity	Ph. Eur.	Complies	Complies
Osmolality	Ph. Eur.	≥ 240 mOsmol/kg	362 mOsmol/kg
pH	Ph. Eur.	6.5 - 7.5	7.0
Polisorbate 80	Spectrophotometric	≤ 100 ppm	11 ppm
Sodium	Atomic emission spectrophotometry	120 - 180 mmol/L	149 mmol/L
Specific activity	N.A.	N.A.	144 IU/mg
Sterility	Ph. Eur.	Sterile	Sterile
Total Proteins	Bradford	≤ 7.2 mg/vial	3.9 mg/vial
Tri(n-butyl)phosphate	Gascromatographyc	≤ 5 ppm	<1 ppm
vWF:Rco/FVIII:C	N.A.	≥ 0.25	0.29
Water	Ph. Eur.	≤ 3 %	1 %

Reference: 108730
CoA: 1013946-Egitto
Certificate No.: 213153 Date: 20/06/2023 From: Database: LIMS_PROD

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU 10 ML

Batch Number:	452317				
Code:	1013946				
Production Date:	03-2023	**Validity Start Date:**	03-2023	**Expiry Date:**	02-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Certified By: Ilaria Rossi
Deputy Quality Control Manager
Date: 04/04/2023 18:21:35

This is an electronic signature

KEDRION
BIOPHARMA

Certificate for medicinal product

EMOCLOT 500 IU 10 ML

Batch Number:	452317				
Code:	1013946				
Production Date:	03-2023	**Validity Start Date:**	03-2023	**Expiry Date:**	02-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

The Human Plasma was collected from healthy donors according to European Guidelines, National Requirements and European Pharmacopoeia (Monograph 0853) with the aim of assuring the suitability of the individual donations. Every donation is tested and found non-reactive for:
- HBsAg, anti-HIV1/HIV2, anti-HCV.
- HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and Parvovirus B19-DNA by test NAT done by minipool testing. Units with a Parvovirus B19-DNA of elevated titer are excluded. The manufacturing plasma pools were tested and found to be non-reactive for HBsAg, anti-HIV1/HIV2 and by NAT for HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and tested for Parvovirus B -19 DNA. The manufacturing plasma pools used for the manufacture of the above batch were released from a European OMCL (Official Medicines Control Laboratory). I hereby certified that all manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and the requirements of the Marketing Authorization of the destination country/countries.

APPROVED

The Lot is .....

Qualified Person: .....

Kedrion S.p.A.
Sara Del Carlo
Qualified Person
Bolognana Plant

Date: .....20 JUN 2023.....

Reference: 108730
CoA: 1013946-Egitto
Certificate No.: 213153 Date: 20/06/2023 From: Database: LIMS_PROD

KEDRION BIOPHARMA

Material Code: 0006103761 *Inspection Lot: 030000033695*

CERTIFICATE OF ANALYSIS

N° 20220513143718

W.F.I. Solvent 10 ml

Batch Number KA0122

Production Date 03/2022

Expiry Date 02/2027

Storage Temperature : Store at a temperature not higher than 25°C, protect from light. Do not freeze.

Tests	Methods	Requirements	Results
Appearance	Ph. Eur.	Clear, colourless liquid	Complies
Acidity/Alkalinity	Ph. Eur.	<=0,1 ml NaOH 0,01N/20 ml O <=0,15 ml HCl 0,01N/20 ml	Complies
Oxidisable Substances	Ph. Eur.	< 0,4 ml KMnO4 0,1N/100 ml The solution remains faintly pink	Complies
Chlorides (p.p.m.)	Ph. Eur.	<=0,5	< 0,5
Sterility	Ph. Eur.	Sterile	Sterile
Bacterial Endotoxin (E.U./ml)	Ph. Eur.	< 0,25	< 0,005
Nitrates (p.p.m.)	Ph. Eur.	<=0,2	< 0,2
Sulfates	Ph. Eur.	Absent/10ml	Absent
Ammonium (p.p.m)	Ph. Eur.	<=0,6	< 0,6
Calcium and Magnesium	Ph. Eur.	<=0,5 ml sodium edetate 0,01M/100 ml	Complies

KEDRION S.p.A.
Quality Assurance
Copia conforme all'originale -1-
Data 30/5/2022 Firma: C.

Release O.M.C.L. N°: N.A. Date: N.A.
The Batch Is: APPROVED

Quality Control Manager : ..... Date : 16/05/2022

Qualified Person : Gianluca De Rose ..... Date : 16/05/2022

KEDRION
BIOPHARMA

Material Code: 0006103761 *Inspection Lot: 030000033695*

CERTIFICATE OF ANALYSIS

N° 20220513143718 .

W.F.I. Solvent 10 ml

Batch Number: KA0122

Production Date: 03/2022

Expiry Date: 02/2027

Storage Temperature : Store at a temperature not higher than 25°C, protect from light. Do not freeze.

Tests	Methods	Requirements	Results
Particulate contamination (> = 10 µm): Sub-visible particles (Particles/container)	Ph. Eur.	< =6000	13
Particulate contamination (> = 25 µm): Sub-visible particles (Particles/container)	Ph. Eur.	< =600	0
Residue on evaporation (%)	Ph. Eur.	< =0,004	0,002
Conductivity (µS/cm)	Ph. Eur.	< =25	3
Extractable volume (ml)	Ph. Eur.	> =10,0	10,0

KEDRION S.p.A.
Quality Assurance
Copia conforme all'originale - 1
Data 30/05/22 Firma CJ

Release O.M.C.L. N°: N.A. Date: N.A.
The Batch Is: APPROVED

Quality Control Manager : ..... Date : 16/05/2022

Qualified Person : Veronica De Rose Date : 16/05/2022

KEDRION
BIOPHARMA

Material Code: 0006103761 *Inspection Lot: 030000033985*

CERTIFICATE OF ANALYSIS

N° 20220606111457

W.F.I. Solvent 10 ml

Batch Number
KA0722

Production Date
05/2022

Expiry Date
04/2027

Storage Temperature : *Store at a temperature not higher than 25°C, protect from light. Do not freeze.*

Tests	Methods	Requirements	Results
Appearance	Ph. Eur.	Clear, colourless liquid	Complies
Acidity/Alkalinity	Ph. Eur.	< =0,1 ml NaOH 0,01N/20 ml O < =0,15 ml HCl 0,01N/20 ml	Complies
Oxidisable Substances	Ph. Eur.	< 0,4 ml KMnO4 0,1N/100 ml The solution remains faintly pink	Complies
Chlorides (p.p.m.)	Ph. Eur.	< =0,5	< 0,5
Sterility	Ph. Eur.	Sterile	Sterile
Bacterial Endotoxin (E.U./ml)	Ph. Eur.	< 0,25	<0,01
Nitrates (p.p.m.)	Ph. Eur.	< =0,2	< 0,2
Sulfates	Ph. Eur.	Absent/10ml	Absent
Ammonium (p.p.m)	Ph. Eur.	< =0,6	< 0,6
Calcium and Magnesium	Ph. Eur.	< =0,5 ml sodium edetate 0,01M/100 ml	Complies

KEDRION S.p.A.
Quality Assurance
Copia conforme all'originale -1-
Data 28/06/22 Firma

Release O.M.C.L. N°: N.A. Date: N.A.
The Batch Is: APPROVED

Quality Control Manager : ..... Date : 06/06/2022

Qualified Person : ..... Date : 07/06/2022

KEDRION
BIOPHARMA

Material Code: 0006103761 *Inspection Lot: 030000033985*

CERTIFICATE OF ANALYSIS

N° 20220606111457

W.F.I. Solvent 10 ml

Batch Number
KA0722

Production Date
05/2022

Expiry Date
04/2027

Storage Temperature : *Store at a temperature not higher than 25°C, protect from light. Do not freeze.*

Tests	Methods	Requirements	Results
Particulate contamination (> = 10 µm): Sub-visible particles (Particles/container)	Ph. Eur.	< =6000	14
Particulate contamination (> = 25 µm): Sub-visible particles (Particles/container)	Ph. Eur.	< =600	1
Residue on evaporation (%)	Ph. Eur.	< =0,004	0,002
Conductivity (µS/cm)	Ph. Eur.	< =25	2
Extractable volume (ml)	Ph. Eur.	> =10,0	10,0

KEDRION S.p.A.
Quality Assurance
Copia conforme all'originale
Data 06/06/22 Firma Dott.ssa Debora Rossi

Release O.M.C.L. N°: N.A. Date: N.A.
The Batch Is: APPROVED

Quality Control Manager : ..... Date : 06/06/2022

Qualified Person : Veronica De Rose ..... Date : 07.06.2022

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU/10 ML

Batch Number:	452341				
Code:	1013976				
Production Date:	06-2023	**Validity Start Date:**	06-2023	**Expiry Date:**	05-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Test	Method	Specification	Result
Characters	Ph. Eur.	White or pale yellow, hygroscopic powder or friable solid	Complies
Appearance (Solution)	Ph. Eur.	The preparation dissolves completely with gentle swirling within 10 min, giving a clear or slightly opalescent colourless or slightly yellow solution. The solution may show a few small flakes or particles after reconstitution. The filtered solution is clear or slightly opalescent.	Complies
Solubility	Ph. Eur.	≤ 600 s	190 s
Bacterial endotoxins	Ph. Eur.	Complies (< 0.03 E.U./I.U.)	Complies
Chloride	Potentiometric	90 - 140 mmol/L	110 mmol/L
Citrate	Enzymatic test	6 - 16 mmol/L	11 mmol/L
Factor VIII Potency	Ph. Eur.	400 - 600 I.U./vial	497 I.U./vial
Factor vWF potency	Ph. Eur.	N.A.	166 I.U./vial
Factor vWF:Ag	Immunochemical	N.A.	215 I.U./vial
Fibrinogen	Immunochemical	≤ 4.0 mg/vial	<1.4 mg/vial
Glycine	Kjeldhal	76 - 104 mg/vial	91 mg/vial
Haemagglutinins Anti-A1	Ph. Eur.	< 1:64	1:4
Haemagglutinins Anti-B	Ph. Eur.	< 1:64	1:2
Identity	Ph. Eur.	Complies	Complies
Osmolality	Ph. Eur.	≥ 240 mOsmol/kg	358 mOsmol/kg
pH	Ph. Eur.	6.5 - 7.5	7.0
Polisorbate 80	Spectrophotometric	≤ 100 ppm	<10 ppm
Sodium	Atomic emission spectrophotometry	120 - 180 mmol/L	144 mmol/L
Specific activity	N.A.	N.A.	166 IU/mg
Sterility	Ph. Eur.	Sterile	Sterile
Total Proteins	Bradford	≤ 7.2 mg/vial	3.0 mg/vial
Tri(n-butyl)phosphate	Gascromatographyc	≤ 5 ppm	<1 ppm
vWF:Rco/FVIII:C	N.A.	≥ 0.25	0.33
Water	Ph. Eur.	≤ 3 %	1 %

Reference: 114370
CoA: 1013976-STD (L)
Certificate No.: 226130 Date: 04/10/2023 From: Database: LIMS_PROD

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU/10 ML

Batch Number:	452341				
Code:	1013976				
Production Date:	06-2023	**Validity Start Date:**	06-2023	**Expiry Date:**	05-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Certified By: Sara Del Carlo
Quality Control Manager
Date: 07/07/2023 09:08:32
This is an electronic signature

KEDRION
BIOPHARMA

Certificate for medicinal product

EMOCLOT 500 IU/10 ML

Batch Number:	452341				
Code:	1013976				
Production Date:	06-2023	**Validity Start Date:**	06-2023	**Expiry Date:**	05-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

The Human Plasma was collected from healthy donors according to European Guidelines, National Requirements and European Pharmacopoeia (Monograph 0853) with the aim of assuring the suitability of the individual donations. Every donation is tested and found non-reactive for:
- HBsAg, anti-HIV1/HIV2, anti-HCV.
- HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and Parvovirus B19-DNA by test NAT done by minipool testing. Units with a Parvovirus B19-DNA of elevated titer are excluded. The manufacturing plasma pools were tested and found to be non-reactive for HBsAg, anti-HIV1/HIV2 and by NAT for HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and tested for Parvovirus B -19 DNA. The manufacturing plasma pools used for the manufacture of the above batch were released from a European OMCL (Official Medicines Control Laboratory). I hereby certified that all manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and the requirements of the Marketing Authorization of the destination country/countries.

APPROVED

The Lot Is .....

Qualified Person: .....

Kedrion S.p.A.
Sara Del Carlo
Qualified Person
Bolognana Plant

04 OCT 2023

Date: .....

Reference: 114370
CoA: 1013976-STD (L)
Certificate No.: 226130 Date: 04/10/2023 From: Database: LIMS_PROD

KEDRION
BIOPHARMA

Material Code: 0006103761 *Inspection Lot: 030000034334*

CERTIFICATE OF ANALYSIS

N° 20220714100913

W.F.I. Solvent 10 ml

Batch Number
KA1722

Production Date
06/2022

Expiry Date
05/2027

Storage Temperature : Store at a temperature not higher than 25°C, protect from light. Do not freeze.

Tests	Methods	Requirements	Results
Appearance	Ph. Eur.	Clear, colourless liquid	Complies
Acidity/Alkalinity	Ph. Eur.	<=0,1 ml NaOH 0,01N/20 ml O <=0,15 ml HCl 0,01N/20 ml	Complies
Oxidisable Substances	Ph. Eur.	< 0,4 ml KMnO4 0,1N/100 ml The solution remains faintly pink	Complies
Chlorides (p.p.m.)	Ph. Eur.	<=0,5	< 0,5
Sterility	Ph. Eur.	Sterile	Sterile
Bacterial Endotoxin (E.U./ml)	Ph. Eur.	< 0,25	< 0,005
Nitrates (p.p.m.)	Ph. Eur.	<=0,2	< 0,2
Sulfates	Ph. Eur.	Absent/10ml	Absent
Ammonium (p.p.m)	Ph. Eur.	<=0,6	< 0,6
Calcium and Magnesium	Ph. Eur.	<=0,5 ml sodium edetate 0,01M/100 ml	Complies

KEDRION S.p.A.
Quality Assurance
Copia conforme all'originale -1-
Data 11/01/23 Firma (illegible)

Release O.M.C.L. N°: N.A. Date: N.A.
The Batch Is: APPROVED

Quality Control Manager : (illegible) Date : 15/07/2022

Qualified Person : Veronica De Rosa Date : 20/07/2022

KEDRION
BIOPHARMA

Material Code: 0006103761 *Inspection Lot: 030000034334*

CERTIFICATE OF ANALYSIS

N° 20220714100913

W.F.I. Solvent 10 ml

Batch Number: KA1722

Production Date: 06/2022

Expiry Date: 05/2027

Storage Temperature : Store at a temperature not higher than 25°C, protect from light. Do not freeze.

Tests	Methods	Requirements	Results
Particulate contamination (>= 10 µm): Sub-visible particles (Particles/container)	Ph. Eur.	<=6000	12
Particulate contamination (>= 25 µm): Sub-visible particles (Particles/container)	Ph. Eur.	<=600	0
Residue on evaporation (%)	Ph. Eur.	<=0,004	0,002
Conductivity (µS/cm)	Ph. Eur.	<=25	2
Extractable volume (ml)	Ph. Eur.	>=10,0	10,0

KEDRION S.p.A.
Quality Assurance
Copia conforme all'originale
Data 11/07/22 Firma CJ

Release O.M.C.L. N°: N.A. Date: N.A.

The Batch Is: APPROVED

Quality Control Manager : ..... Date : 15/07/2022

Qualified Person : ..... Date : 20/07/2022

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU/10 ML

Batch Number:	452326				
Code:	1013976				
Production Date:	04-2023	**Validity Start Date:**	04-2023	**Expiry Date:**	03-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Test	Method	Specification	Result
Characters	Ph. Eur.	White or pale yellow, hygroscopic powder or friable solid	Complies
Appearance (Solution)	Ph. Eur.	The preparation dissolves completely with gentle swirling within 10 min, giving a clear or slightly opalescent colourless or slightly yellow solution. The solution may show a few small flakes or particles after reconstitution. The filtered solution is clear or slightly opalescent.	Complies
Solubility	Ph. Eur.	≤ 600 s	210 s
Bacterial endotoxins	Ph. Eur.	Complies (< 0.03 E.U./I.U.)	Complies
Chloride	Potentiometric	90 - 140 mmol/L	110 mmol/L
Citrate	Enzymatic test	6 - 16 mmol/L	11 mmol/L
Factor VIII Potency	Ph. Eur.	400 - 600 I.U./vial	535 I.U./vial
Factor vWF potency	Ph. Eur.	N.A.	155 I.U./vial
Factor vWF:Ag	Immunochemical	N.A.	203 I.U./vial
Fibrinogen	Immunochemical	≤ 4.0 mg/vial	<1.4 mg/vial
Glycine	Kjeldhal	76 - 104 mg/vial	93 mg/vial
Haemagglutinins Anti-A1	Ph. Eur.	< 1:64	1:4
Haemagglutinins Anti-B	Ph. Eur.	< 1:64	1:2
Identity	Ph. Eur.	Complies	Complies
Osmolality	Ph. Eur.	≥ 240 mOsmol/kg	355 mOsmol/kg
pH	Ph. Eur.	6.5 - 7.5	7.1
Polisorbate 80	Spectrophotometric	≤ 100 ppm	13 ppm
Sodium	Atomic emission spectrophotometry	120 - 180 mmol/L	146 mmol/L
Specific activity	N.A.	N.A.	173 IU/mg
Sterility	Ph. Eur.	Sterile	Sterile
Total Proteins	Bradford	≤ 7.2 mg/vial	3.1 mg/vial
Tri(n-butyl)phosphate	Gascromatographyc	≤ 5 ppm	<1 ppm
vWF:Rco/FVIII:C	N.A.	≥ 0.25	0.29
Water	Ph. Eur.	≤ 3 %	1 %

Reference: 110957
CoA: 1013976-STD (L)
Certificate No.: 226129 Date: 04/10/2023 From: Database: LIMS_PROD

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU/10 ML

Batch Number:	452326				
Code:	1013976				
Production Date:	04-2023	**Validity Start Date:**	04-2023	**Expiry Date:**	03-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Certified By: Ilaria Rossi
Deputy Quality Control Manager
Date: 22/05/2023 11:52:05
This is an electronic signature

KEDRION
BIOPHARMA

Certificate for medicinal product

EMOCLOT 500 IU/10 ML

Batch Number:	452326				
Code:	1013976				
Production Date:	04-2023	**Validity Start Date:**	04-2023	**Expiry Date:**	03-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

The Human Plasma was collected from healthy donors according to European Guidelines, National Requirements and European Pharmacopoeia (Monograph 0853) with the aim of assuring the suitability of the individual donations. Every donation is tested and found non-reactive for:
- HBsAg, anti-HIV1/HIV2, anti-HCV.
- HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and Parvovirus B19-DNA by test NAT done by minipool testing. Units with a Parvovirus B19-DNA of elevated titer are excluded. The manufacturing plasma pools were tested and found to be non-reactive for HBsAg, anti-HIV1/HIV2 and by NAT for HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and tested for Parvovirus B -19 DNA. The manufacturing plasma pools used for the manufacture of the above batch were released from a European OMCL (Official Medicines Control Laboratory). I hereby certified that all manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and the requirements of the Marketing Authorization of the destination country/countries.

APPROVED

The Lot Is .....

Qualified Person: .....

Kedrion S.p.A.
Sara Del Carlo
Qualified Person
Bolognana Plant

04 OCT 2023

Date: .....

Reference: 110957
CoA: 1013976-STD (L)
Certificate No.: 226129 Date: 04/10/2023 From: Database: LIMS_PROD

KEDRION BIOPHARMA

Material Code: 0006103761 *Inspection Lot: 030000034150*

CERTIFICATE OF ANALYSIS

N° 20220624122722

W.F.I. Solvent 10 ml

Batch Number: KA1122

Production Date: 05/2022

Expiry Date: 04/2027

Storage Temperature : Store at a temperature not higher than 25°C, protect from light. Do not freeze.

Tests	Methods	Requirements	Results
Appearance	Ph. Eur.	Clear, colourless liquid	Complies
Acidity/Alkalinity	Ph. Eur.	<=0,1 ml NaOH 0,01N/20 ml O <=0,15 ml HCl 0,01N/20 ml	Complies
Oxidisable Substances	Ph. Eur.	< 0,4 ml KMnO4 0,1N/100 ml The solution remains faintly pink	Complies
Chlorides (p.p.m.)	Ph. Eur.	<=0,5	< 0,5
Sterility	Ph. Eur.	Sterile	Sterile
Bacterial Endotoxin (E.U./ml)	Ph. Eur.	< 0,25	< 0,005
Nitrates (p.p.m.)	Ph. Eur.	<=0,2	< 0,2
Sulfates	Ph. Eur.	Absent/10ml	Absent
Ammonium (p.p.m)	Ph. Eur.	<=0,6	< 0,6
Calcium and Magnesium	Ph. Eur.	<=0,5 ml sodium edetate 0,01M/100 ml	Complies

KEDRION S.p.A.
Quality Assurance
Copia conforme all'originale -1-
Data 27/06/22 Firma Dott.ssa De Rosa

Release O.M.C.L. N°: N.A. Date: N.A.

The Batch Is: APPROVED

Quality Control Manager : Dott. [illegible] Date : 27/06/2022

Qualified Person : Dott.ssa De Rosa Date : 27/06/2022

KEDRION BIOPHARMA

Material Code: 0006103761 *Inspection Lot: 030000034150*

CERTIFICATE OF ANALYSIS

N° 20220624122722

W.F.I. Solvent 10 ml

Batch Number: KA1122

Production Date: 05/2022

Expiry Date: 04/2027

***Storage Temperature** : Store at a temperature not higher than 25°C, protect from light. Do not freeze.*

Tests	Methods	Requirements	Results
Particulate contamination (>= 10 µm): Sub-visible particles (Particles/container)	Ph. Eur.	<=6000	13
Particulate contamination (>= 25 µm): Sub-visible particles (Particles/container)	Ph. Eur.	<=600	2
Residue on evaporation (%)	Ph. Eur.	<=0,004	0,002
Conductivity (µS/cm)	Ph. Eur.	<=25	3
Extractable volume (ml)	Ph. Eur.	>=10,0	10,0

KEDRION S.p.A.
Quality Assurance
Copia conforme all'originale - 1 -
Data 03/10/2022 Firma [signature]

Release O.M.C.L. N°: N.A. Date: N.A.

The Batch Is: APPROVED

Quality Control Manager : [signature] Date : 27/06/2022

Qualified Person : [signature] Date : 27/06/2022

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU/10 ML

Batch Number:	452344				
Code:	1013976				
Production Date:	06-2023	**Validity Start Date:**	06-2023	**Expiry Date:**	05-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Test	Method	Specification	Result
Characters	Ph. Eur.	White or pale yellow, hygroscopic powder or friable solid	Complies
Appearance (Solution)	Ph. Eur.	The preparation dissolves completely with gentle swirling within 10 min, giving a clear or slightly opalescent colourless or slightly yellow solution. The solution may show a few small flakes or particles after reconstitution. The filtered solution is clear or slightly opalescent.	Complies
Solubility	Ph. Eur.	≤ 600 s	230 s
Bacterial endotoxins	Ph. Eur.	Complies (< 0.03 E.U./I.U.)	Complies
Chloride	Potentiometric	90 - 140 mmol/L	111 mmol/L
Citrate	Enzymatic test	6 - 16 mmol/L	11 mmol/L
Factor VIII Potency	Ph. Eur.	400 - 600 I.U./vial	455 I.U./vial
Factor vWF potency	Ph. Eur.	N.A.	147 I.U./vial
Factor vWF:Ag	Immunochemical	N.A.	204 I.U./vial
Fibrinogen	Immunochemical	≤ 4.0 mg/vial	<1.4 mg/vial
Glycine	Kjeldhal	76 - 104 mg/vial	90 mg/vial
Haemagglutinins Anti-A1	Ph. Eur.	< 1:64	1:4
Haemagglutinins Anti-B	Ph. Eur.	< 1:64	1:2
Identity	Ph. Eur.	Complies	Complies
Osmolality	Ph. Eur.	≥ 240 mOsmol/kg	358 mOsmol/kg
pH	Ph. Eur.	6.5 - 7.5	7.0
Polisorbate 80	Spectrophotometric	≤ 100 ppm	10 ppm
Sodium	Atomic emission spectrophotometry	120 - 180 mmol/L	144 mmol/L
Specific activity	N.A.	N.A.	142 IU/mg
Sterility	Ph. Eur.	Sterile	Sterile
Total Proteins	Bradford	≤ 7.2 mg/vial	3.2 mg/vial
Tri(n-butyl)phosphate	Gascromatographyc	≤ 5 ppm	<1 ppm
vWF:Rco/FVIII:C	N.A.	≥ 0.25	0.32
Water	Ph. Eur.	≤ 3 %	1 %

Reference: 115029
CoA: 1013976-STD (L)
Certificate No.: 226950 Date: 10/10/2023 From: Database: LIMS_PROD

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU/10 ML

Batch Number:	452344				
Code:	1013976				
Production Date:	06-2023	**Validity Start Date:**	06-2023	**Expiry Date:**	05-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Certified By: Sara Del Carlo
Quality Control Manager
Date: 21/07/2023 13:05:53
This is an electronic signature

KEDRION
BIOPHARMA

Certificate for medicinal product

EMOCLOT 500 IU/10 ML

Batch Number:	452344				
Code:	1013976				
Production Date:	06-2023	**Validity Start Date:**	06-2023	**Expiry Date:**	05-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

The Human Plasma was collected from healthy donors according to European Guidelines, National Requirements and European Pharmacopoeia (Monograph 0853) with the aim of assuring the suitability of the individual donations. Every donation is tested and found non-reactive for:
- HBsAg, anti-HIV1/HIV2, anti-HCV.
- HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and Parvovirus B19-DNA by test NAT done by minipool testing. Units with a Parvovirus B19-DNA of elevated titer are excluded. The manufacturing plasma pools were tested and found to be non-reactive for HBsAg, anti-HIV1/HIV2 and by NAT for HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and tested for Parvovirus B -19 DNA. The manufacturing plasma pools used for the manufacture of the above batch were released from a European OMCL (Official Medicines Control Laboratory). I hereby certified that all manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and the requirements of the Marketing Authorization of the destination country/countries.

APPROVED

The Lot Is .....

Qualified Person: .....

10 OCT 2023

Date: .....

Kedrion S.p.A.
Barbara Giulianetti
Qualified Person
Bolognana Plant

Reference: 115029
CoA: 1013976-STD (L)
Certificate No.: 226950 Date: 10/10/2023 From: Database: LIMS_PROD

KEDRION BIOPHARMA

Material Code: 0006103761 *Inspection Lot: 030000034388*

CERTIFICATE OF ANALYSIS

N° 20220719143428

W.F.I. Solvent 10 ml

Batch Number KA1822

Production Date 06/2022

Expiry Date 05/2027

***Storage Temperature** : Store at a temperature not higher than 25°C, protect from light. Do not freeze.*

Tests	Methods	Requirements	Results
Appearance	Ph. Eur.	Clear, colourless liquid	Complies
Acidity/Alkalinity	Ph. Eur.	<=0,1 ml NaOH 0,01N/20 ml O <=0,15 ml HCl 0,01N/20 ml	Complies
Oxidisable Substances	Ph. Eur.	< 0,4 ml KMnO4 0,1N/100 ml The solution remains faintly pink	Complies
Chlorides (p.p.m.)	Ph. Eur.	<=0,5	< 0,5
Sterility	Ph. Eur.	Sterile	Sterile
Bacterial Endotoxin (E.U./ml)	Ph. Eur.	< 0,25	< 0,005
Nitrates (p.p.m.)	Ph. Eur.	<=0,2	< 0,2
Sulfates	Ph. Eur.	Absent/10ml	Absent
Ammonium (p.p.m)	Ph. Eur.	<=0,6	< 0,6
Calcium and Magnesium	Ph. Eur.	<=0,5 ml sodium edetate 0,01M/100 ml	Complies

KEDRION S.p.A.
Quality Assurance
Copia conforme all'originale
Data 12.01.2023 Firma

Release O.M.C.L. N°: N.A. Date: N.A.

The Batch Is: APPROVED

Quality Control Manager : ..... Date : 19/07/2022

Qualified Person : Jacopo De Rose ..... Date : 20/07/2022

KEDRION
BIOPHARMA

Material Code: 0006103761 *Inspection Lot: 030000034388*

CERTIFICATE OF ANALYSIS

N° 20220719143428

W.F.I. Solvent 10 ml

Batch Number: KA1822

Production Date: 06/2022

Expiry Date: 05/2027

Storage Temperature : Store at a temperature not higher than 25°C, protect from light. Do not freeze.

Tests	Methods	Requirements	Results
Particulate contamination (>= 10 µm): Sub-visible particles (Particles/container)	Ph. Eur.	<=6000	28
Particulate contamination (>= 25 µm): Sub-visible particles (Particles/container)	Ph. Eur.	<=600	3
Residue on evaporation (%)	Ph. Eur.	<=0,004	0,002
Conductivity (µS/cm)	Ph. Eur.	<=25	2
Extractable volume (ml)	Ph. Eur.	>=10,0	10,0

KEDRION S.p.A.
Quality Assurance
Copia conforme all'originale
Data 12.01.2023 Firma

Release O.M.C.L. N°: N.A. Date: N.A.

The Batch Is: APPROVED

Quality Control Manager : ..... Date : 19/07/2022

Qualified Person : Veronica De Rosa ..... Date : 20/07/2022