Medicines and Healthcare products Regulatory Agency

REGISTRATION OF MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ACTIVE SUBSTANCES TO BE USED AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

	Registrant Details
1. Registration Number	UK API 8801
2. Name or corporate name of registrant	BIO PRODUCTS LABORATORY LIMITED
3. Permanent or legal address of registrant	BIO PRODUCTS LABORATORY LIMITED, DAGGER LANE, ELSTREE, BOREHAMWOOD, HERTFORDSHIRE, WD6 3BX, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	BIO PRODUCTS LABORATORY LIMITED, DAGGER LANE, ELSTREE, BOREHAMWOOD, HERTFORDSHIRE, WD6 3BX, UNITED KINGDOM
5. National legal basis of registration	Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916)
6. Name of responsible officer of the competent authority of the member state validating the registration	Confidential
7. Date	06/02/2024

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in MHRA-GMDP.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

SCOPE OF REGISTRATION

Name and address of the site

BIO PRODUCTS LABORATORY LIMITED, DAGGER LANE, ELSTREE, BOREHAMWOOD, HERTFORDSHIRE, WD6 3BX, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance
PURIFIED FACTOR IX INTERMEDIATE
4000016645

B	Extraction of Active Substance from Natural Sources
	B.3 Human Source Extraction
E	General Finishing Steps

	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)
	F.4 Biological Testing

Active substance

HUMAN PROTHROMBIN COMPLEX

1000016178

B	Extraction of Active Substance from Natural Sources
	B.3 Human Source Extraction
E	General Finishing Steps
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)
	F.4 Biological Testing

Active substance

B+1 PASTE

1000017987

B	Extraction of Active Substance from Natural Sources
	B.3 Human Source Extraction
E	General Finishing Steps
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)
	F.4 Biological Testing

Active substance

FRACTION V

3000018085

B	Extraction of Active Substance from Natural Sources
	B.3 Human Source Extraction

E	General Finishing Steps
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)
	F.4 Biological Testing

Active substance

CRYOPRECIPITATE

1000017986

B	Extraction of Active Substance from Natural Sources
	B.3 Human Source Extraction
E	General Finishing Steps
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)
	F.4 Biological Testing

Active substance

FRACTION IV PASTE

1000017988

B	Extraction of Active Substance from Natural Sources
	B.3 Human Source Extraction
E	General Finishing Steps
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)
	F.4 Biological Testing

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

PURIFIED FACTOR IX INTERMEDIATE (4000016645)

HUMAN PROTHROMBIN COMPLEX (1000016178)

B+1 PASTE (1000017987)

FRACTION V (3000018085)

CRYOPRECIPITATE (1000017986)

FRACTION IV PASTE (1000017988)