Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 8801 Insp GMP 8801/18235-0042

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

Issued following an inspection in accordance with :
Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : BIO PRODUCTS LABORATORY LIMITED

Site address : BIO PRODUCTS LABORATORY LIMITED, DAGGER LANE, ELSTREE, BOREHAMWOOD, WD6 3BX, UNITED KINGDOM

Is an active substance manufacturer that has been inspected in accordance with Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 19/02/2024 , it is considered that it complies with

- The principles of GMP for active substances referred to in Regulation B17 and C17 of the Human Medicines Regulations 2012 (SI 2012/1916)

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

Manufacture of active substance. Names of substances subject to inspection :

- [4000016645] PURIFIED FACTOR IX INTERMEDIATE
- [1000016178] HUMAN PROTHROMBIN COMPLEX
- [1000017987] B+1 PASTE
- [3000018085] FRACTION V
- [1000017986] CRYOPRECIPITATE
- [1000017988] FRACTION IV PASTE

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

PURIFIED FACTOR IX INTERMEDIATE

3.2	Processing Activities of Active Substance from Natural Sources
	3.2.3 Human Source Extraction
3.5	General Finishing Steps
	3.5.2 Primary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)
	3.6.4 Biological Testing

HUMAN PROTHROMBIN COMPLEX

3.2	Processing Activities of Active Substance from Natural Sources
	3.2.3 Human Source Extraction
3.5	General Finishing Steps
	3.5.2 Primary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)
	3.6.4 Biological Testing

B+1 PASTE

3.2	Processing Activities of Active Substance from Natural Sources
	3.2.3 Human Source Extraction
3.5	General Finishing Steps
	3.5.2 Primary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)
	3.6.4 Biological Testing

FRACTION V

3.2	Processing Activities of Active Substance from Natural Sources
	3.2.3 Human Source Extraction
3.5	General Finishing Steps
	3.5.2 Primary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)
	3.6.4 Biological Testing

CRYOPRECIPITATE

3.2	Processing Activities of Active Substance from Natural Sources
	3.2.3 Human Source Extraction
3.5	General Finishing Steps
	3.5.2 Primary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)
	3.6.4 Biological Testing

FRACTION IV PASTE

3.2	Processing Activities of Active Substance from Natural Sources
	3.2.3 Human Source Extraction
3.5	General Finishing Steps
	3.5.2 Primary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)
	3.6.4 Biological Testing

25/07/2024	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency

Tel : Confidential