Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 29980 Insp GMP 29980/310043-0008[H]

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 : SPATONE LIMITED

Site address : SPATONE LIMITED, TREFRIW WELLS SPA, SNOWDONIA NATIONAL PARK, TREFRIW, LL27 0JS, UNITED KINGDOM
Other :
Manufacturer of products regarded as dietary supplements in EU (Non-pharmaceutical products)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 27/01/2025, it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended)

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

1. MANUFACTURING OPERATIONS

[1.4] Other products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.3] Other
Of an apple flavoured Iron rich water dietary supplement.

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.17] Other non-sterile medicinal products

Iron Rich water filtered and filled into sachets for use as a dietary supplement

[1.5.2] Secondary packaging

Restrictions or Remarks

This certificate is issued based on a desk-based assessment of GMP compliance information provided by the manufacturer. A risk-based site inspection programme remains in force.

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
				Certification applies only to products which are regarded as dietary supplements in UK/EU.

28/01/2025 Name and signature of the authorised person of the Competent Authority of United Kingdom

Confidential

Medicines and Healthcare products Regulatory Agency

Tel : Confidential