Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 8977

2: Name of authorisation holder ASPAR PHARMACEUTICALS LIMITED

3: Address(es) of manufacturing site(s)

ASPAR PHARMACEUTICALS LIMITED, ACREWOOD WAY, ST.

ALBANS, AL4 0JY, UNITED KINGDOM

ASPAR PHARMACEUTICALS LIMITED, 29-30 CAPITOL WAY, CAPITOL

WAY INDUSTRIAL PARK, COLINDALE, LONDON, NW9 0EQ, UNITED

KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

7: Name of responsible officer of the competent

4: Legally registered address of authorisation holder

authority of the member state granting the Confidential

manufacturing authorisation

8: Authorisation Date 09/10/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ASPAR PHARMACEUTICALS LIMITED, ACREWOOD WAY, ST. ALBANS, AL4 0JY, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.1] Capsules, hard shell

[1.2.1.8] Other solid dosage forms

[1.2.1.13] Tablets

[1.2.2] Batch certification

[1.4] Other products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.1] Herbal products

Issue Date: 09 Oct 2024

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.8] Other solid dosage forms

[1.5.1.13] Tablets

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.3] Chemical/Physical

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)

Herbal products

