Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 398

2: Name of authorisation holder STD PHARMACEUTICAL PRODUCTS LIMITED

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

STD PHARMACEUTICAL PRODUCTS LIMITED, PLOUGH LANE,

HEREFORD, HR4 0EL, UNITED KINGDOM

STD PHARMACEUTICAL PRODUCTS LIMITED, STD PHARMACEUTICAL

4: Legally registered address of authorisation holder PLOUGH LANE, HEREFORD, HEREFORD & WORCESTER, HR4 0EL,

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

authority of the member state granting the Confidential

manufacturing authorisation

8: Authorisation Date 26/09/2022

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

STD PHARMACEUTICAL PRODUCTS LIMITED, PLOUGH LANE, HEREFORD, HR4 0EL, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Products

[1.1.3] Batch certification

[1.6] Quality control testing

[1.6.3] Chemical/Physical

Issue Date: 26 Sep 2022