

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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| 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 |
| 4: Legally registered address of authorisation holder | STD PHARMACEUTICAL PRODUCTS LIMITED, STD PHARMACEUTICAL 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 manufacturing authorisation | Confidential |
| 8: Authorisation Date | 16/07/2024 |
| 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

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| 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 |