

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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|---|---|
| 1: Authorisation Number | UK MIA 1839 |
| 2: Name of authorisation holder | HAMOL LIMITED |
| 3: Address(es) of manufacturing site(s) | HAMOL LIMITED, NOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NG90 2DB, UNITED KINGDOM |
| 4: Legally registered address of authorisation holder | HAMOL LIMITED, 103-105 BATH ROAD, SLOUGH, SL1 3UH, 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 | 14/11/2024 |
| 9: Annexes attached | Annex 1 and/or Annex 2 |

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

HAMOL LIMITED, NOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NG90 2DB, UNITED KINGDOM

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| Human Medicinal Products |
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| Authorised Operations |
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| MANUFACTURING OPERATIONS (according to part 1) |
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Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile products

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

[1.2.1.8] Other solid dosage forms

[1.2.1.13] Tablets

[1.2.1.17] Other non-sterile medicinal products

Medicated Lozenges

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.2] Capsules, soft shell

[1.5.1.17] Other non-sterile medicinal products

Medicated Lozenges

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical