

Medicines and Healthcare products Regulatory Agency

REGISTRATION OF MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ACTIVE SUBSTANCES TO BE USED AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

Registrant Details

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| 1. Registration Number | UK API 21880 |
| 2. Name or corporate name of registrant | MEDREICH PLC |
| 3. Permanent or legal address of registrant | MEDREICH PLC, WARWICK HOUSE, PLANE TREE CRESCENT,
FELTHAM, TW13 7HF, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | MEDREICH PLC, WARWICK HOUSE, PLANE TREE CRESCENT,
FELTHAM, TW13 7HF, UNITED KINGDOM |
| 5. National legal basis of registration | Regulation 327 of The Human Medicines Regulations 2012 (SI
2012/1916) |
| 6. Name of responsible officer of the competent authority of the
member state validating the registration | Confidential |
| 7. Date | 17/05/2018 |

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in MHRA-GMDP.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

SCOPE OF REGISTRATION

Name and address of the site

MEDREICH PLC, WARWICK HOUSE, PLANE TREE CRESCENT, FELTHAM, TW13 7HF, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
HYDROXYZINE HYDROCHLORIDE (2000007325)	IPCA LABORATORIES LIMITED , P.O. SEJAVTA, RATLAM, MADHYA PRADESH, IN-457002, INDIA SYMED LABS LIMITED (UNIT ?II) , UNIT II, PLOT NO 25/B, PHASE III, IDA JEEDIMETLA, HYDERABAD, TELANGANA, IN-500055, INDIA	SYMED LABS LIMITED (UNIT ?II) , UNIT II, PLOT NO 25/B, PHASE III, IDA JEEDIMETLA, HYDERABAD, TELANGANA, IN-500055, INDIA

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B

Distribution

HYDROXYZINE HYDROCHLORIDE (2000007325)