

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 56021 |
| 2. Name or corporate name of registrant | TORBAY PHARMACEUTICALS LIMITED |
| 3. Permanent or legal address of registrant | TORBAY PHARMACEUTICALS LIMITED, WILKINS DRIVE, PAIGNTON,
TQ4 7FG, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | TORBAY PHARMACEUTICALS LIMITED, TORBAY PHARMACEUTICALS,
WILKINS DRIVE, PAIGNTON, TQ4 7FG, 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 | 25/06/2025 |

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

TORBAY PHARMACEUTICALS LIMITED, TORBAY PHARMACEUTICALS, WILKINS DRIVE, PAIGNTON, TQ4 7FG, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
METARAMINOL TARTRATE (2000008053)	MALLADI DRUGS & PHARMACEUTICALS LIMITED , PLOT NOS. 49, 50, 55, 56, IDA, GAJULAMANDYAM, ATTUR (P.O.), RENIGUNTA, ANDHRA PRADESH, IN-517 520, INDIA	MALLADI DRUGS & PHARMACEUTICALS LIMITED , PLOT NOS. 49, 50, 55, 56, IDA, GAJULAMANDYAM, ATTUR (P.O.), RENIGUNTA, ANDHRA PRADESH, IN-517 520, INDIA

CALCIUM GLUCONATE (2000011072)	GLOBAL CALCIUM PRIVATE LIMITED , 124, 125, 126 SIPCOT INDUSTRIAL COMPLEX, HOSUR, TAMIL NADU, IN-635126, INDIA	GLOBAL CALCIUM PRIVATE LIMITED , 124, 125, 126 SIPCOT INDUSTRIAL COMPLEX, HOSUR, TAMIL NADU, IN-635126, INDIA
CALCIUM SACCHARATE (1000006583)	GLOBAL CALCIUM PRIVATE LIMITED , 124, 125, 126 SIPCOT INDUSTRIAL COMPLEX, HOSUR, TAMIL NADU, IN-635126, INDIA	GLOBAL CALCIUM PRIVATE LIMITED , 124, 125, 126 SIPCOT INDUSTRIAL COMPLEX, HOSUR, TAMIL NADU, IN-635126, INDIA