

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

1. Registration Number UK API 48727
2. Name or corporate name of registrant BSPG LABORATORIES LIMITED
3. Permanent or legal address of registrant BSPG LABORATORIES LIMITED, DISCOVERY PARK HOUSE, RAMSGATE ROAD, SANDWICH, CT13 9ND, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place
BSPG LABORATORIES LIMITED, DISCOVERY PARK HOUSE, RAMSGATE ROAD, SANDWICH, CT13 9ND, UNITED KINGDOM
BSPG LABORATORIES LIMITED, SPITFIRE HOUSE, HUGIN LANE, DISCOVERY PARK, SANDWICH, CT13 9FG, 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 23/05/2023

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

BSPG LABORATORIES LIMITED, DISCOVERY PARK HOUSE, RAMSGATE ROAD, SANDWICH, CT13 9ND, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

CANNABIDIOL

1000000540

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction

	B.6 Purification of Extracted Substance - PLANT
E	General Finishing Steps
	E.1 Physical Processing Steps Multiple washing and recrystallisation
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution
CANNABIDIOL (1000000540)

Name and address of the site

BSPG LABORATORIES LIMITED, SPITFIRE HOUSE, HUGIN LANE, DISCOVERY PARK, SANDWICH, CT13 9FG, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

CANNABIDIOL
1000000540

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2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

MHRA-GMDP

MHRA

MHRA-GMDP

MHRA