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 32467
2. Name or corporate name of registrant	ASTRAZENECA PLC
3. Permanent or legal address of registrant	ASTRAZENECA PLC, 15 STANHOPE GATE, LONDON, W1K 1LN, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	ASTRAZENECA UK LIMITED, AVLON SITE, SEVERN ROAD, HALLEN, BRISTOL, BS10 7ZE, 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	27/06/2016

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

ASTRAZENECA UK LIMITED, AVLON SITE, SEVERN ROAD, HALLEN, BRISTOL, BS10 7ZE, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance
ROSUVASTATIN CALCIUM
2000006569

A	Manufacture of Active Substance by Chemical Synthesis
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) CRYSTALLISATION

E	General Finishing Steps
	E.1 Physical Processing Steps DRYING, MILLING
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

QUETIAPINE FUMARATE

2000005649

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) CRYSTALLISATION
E	General Finishing Steps
	E.1 Physical Processing Steps DRYING, MILLING
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing