Safeguarding public health

RESTRICTED – COMMERCIAL
Mr Maneesh Sapte
SVIZERA LABS PRIVATE LIMITED
PLOT NO. D-16/6
TTC INDUSTRIAL AREA
TURBHE
NAVI MUMBAI
IN-400703
INDIA

Medicines and Healthcare products Regulatory Agency
151 Buckingham Palace Road London SW1W 9SZ
T 0203 080 6000 www.mhra.gov.uk

Safeguarding public health

Certificate No: UK GMP 31876 Insp GMP 31876/382058-0003

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC.

The competent authority of the United Kingdom confirms the following:

The manufacturer	SVIZERA LABS PRIVATE LIMITED
Site address	PLOT NO. D-16/6 TTC INDUSTRIAL AREA TURBHE NAVI MUMBAI IN-400703 INDIA

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art.111(4) of Directive 2001/83/EC transposed in the following national legislation: Regulation 3(a) of the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations (SI 2005/2789) and Section 19(3) of the Medicines Act 1968 as amended.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 27/08/2012, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.

The authenticity of this certificate may be verified with the issuing authority.

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Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS			
1.1	**Sterile products**		
	1.1.1	*Aseptically prepared (list of dosage forms)*	
		1.1.1.1 Large volume liquids	Not Authorised
		1.1.1.2 Lyophilisates	Not Authorised
		1.1.1.3 Semi-solids	Not Authorised
		1.1.1.4 Small volume liquids	Not Authorised
		1.1.1.5 Solids and implants	Not Authorised
		1.1.1.6 Other aseptically prepared products	Not Authorised
	1.1.2	*Terminally sterilised (list of dosage forms)*	
		1.1.2.1 Large volume liquids	Not Authorised
		1.1.2.2 Semi-solids	Not Authorised
		1.1.2.3 Small volume liquids	Not Authorised
		1.1.2.4 Solids and implants	Not Authorised
		1.1.2.5 Other terminally sterilised prepared products	Not Authorised
	1.1.3	Batch certification only	Not Authorised

1.2	**Non-sterile products**		
	1.2.1	*Non-sterile products (list of dosage forms)*	
		1.2.1.1 Capsules, hard shell	Authorised
		1.2.1.2 Capsules, soft shell	Not Authorised
		1.2.1.3 Chewing gums	Not Authorised
		1.2.1.4 Impregnated matrices	Not Authorised
		1.2.1.5 Liquids for external use	Not Authorised
		1.2.1.6 Liquids for internal use	Not Authorised
		1.2.1.7 Medicinal gases	Not Authorised
		1.2.1.8 Other solid dosage forms	Authorised
		1.2.1.9 Pressurised preparations	Not Authorised
		1.2.1.10 Radionuclide generators	Not Authorised
		1.2.1.11 Semi-solids	Not Authorised
		1.2.1.12 Suppositories	Not Authorised
		1.2.1.13 Tablets	Authorised
		1.2.1.14 Transdermal patches	Not Authorised
		1.2.1.15 Intraruminal devices	Not Authorised
		1.2.1.16 Veterinary premixes	Not Authorised
		1.2.1.17 Other non-sterile medicinal product	Not Authorised
	1.2.2	*Batch certification only*	Not Authorised
1.3	**Biological medicinal products**		
	1.3.1	*Biological medicinal products*	
		1.3.1.1 Blood products	Not Authorised
		1.3.1.2 Immunological products	Not Authorised
		1.3.1.3 Cell therapy products	Not Authorised
		1.3.1.4 Gene therapy products	Not Authorised
		1.3.1.5 Biotechnology products	Not Authorised
		1.3.1.6 Human or animal extracted products	Not Authorised
		1.3.1.7 Other biological medicinal products	Not Authorised

	1.3.2	*Batch certification only (list of product types)*	
		1.3.2.1 Blood products	Not Authorised
		1.3.2.2 Immunological products	Not Authorised
		1.3.2.3 Cell therapy products	Not Authorised
		1.3.2.4 Gene therapy products	Not Authorised
		1.3.2.5 Biotechnology products	Not Authorised
		1.3.2.6 Human or animal extracted products	Not Authorised
		1.3.2.7 Other biological medicinal products	Not Authorised
1.4	**Other products or manufacturing activity**		
	1.4.1	*Manufacture of:*	
		1.4.1.1 Herbal products	Not Authorised
		1.4.1.2 Homoeopathic products	Not Authorised
		1.4.1.3 Biological active starting materials	Not Authorised
		1.4.1.4 Other	Not Authorised
	1.4.2	*Sterilisation of active substances/excipients/finished product:*	
		1.4.2.1 Filtration	Not Authorised
		1.4.2.2 Dry heat	Not Authorised
		1.4.2.3 Moist heat	Not Authorised
		1.4.2.4 Chemical	Not Authorised
		1.4.2.5 Gamma irradiation	Not Authorised
		1.4.2.6 Electron beam	Not Authorised
	1.4.3	Other	Not Authorised

1.5	**Packaging only**		
	1.5.1	*Primary packaging*	
		1.5.1.1 Capsules, hard shell	Not Authorised
		1.5.1.2 Capsules, soft shell	Not Authorised
		1.5.1.3 Chewing gums	Not Authorised
		1.5.1.4 Impregnated matrices	Not Authorised
		1.5.1.5 Liquids for external use	Not Authorised
		1.5.1.6 Liquids for internal use	Not Authorised
		1.5.1.7 Medicinal gases	Not Authorised
		1.5.1.8 Other solid dosage forms	Not Authorised
		1.5.1.9 Pressurised preparations	Not Authorised
		1.5.1.10 Radionuclide generators	Not Authorised
		1.5.1.11 Semi-solids	Not Authorised
		1.5.1.12 Suppositories	Not Authorised
		1.5.1.13 Tablets	Not Authorised
		1.5.1.14 Transdermal patches	Not Authorised
		1.5.1.15 Intraruminal devices	Not Authorised
		1.5.1.16 Veterinary premixes	Not Authorised
		1.5.1.17 Other non-sterile medicinal products	Not Authorised
	1.5.2	Secondary packaging	Authorised
1.6	**Quality control testing**		
	1.6.1	Microbiological: sterility	Not Authorised
	1.6.2	Microbiological: non-sterility	Authorised
	1.6.3	Chemical/Physical	Authorised
	1.6.4	Biological	Not Authorised

2. IMPORTATION OF MEDICINAL PRODUCTS			
2.1	**Quality control testing of imported medicinal products**		
	2.1.1	Microbiological: sterility	Not Authorised
	2.1.2	Microbiological: non-sterility	Not Authorised
	2.1.3	Chemical/Physical	Not Authorised
	2.1.4	Biological	Not Authorised
2.2	**Batch certification of imported medicinal products**		
	2.2.1	*Sterile Products*	
		2.2.1.1 Aseptically prepared	Not Authorised
		2.2.1.2 Terminally sterilised	Not Authorised
	2.2.2	Non-sterile Products	Not Authorised
	2.2.3	*Biological medicinal products*	
		2.2.3.1 Blood products	Not Authorised
		2.2.3.2 Immunological product	Not Authorised
		2.2.3.3 Cell therapy products	Not Authorised
		2.2.3.4 Gene therapy products	Not Authorised
		2.2.3.5 Biotechnology products	Not Authorised
		2.2.3.6 Human or animal extracted products	Not Authorised
		2.2.3.7 Other biological medicinal products	Not Authorised
	2.2.4	*Other importation activities*	
		2.2.4.1 Radiopharmaceuticals/Radionuclide generators	Not Authorised
		2.2.4.2 Medicinal gases	Not Authorised
		2.2.4.3 Herbal products	Not Authorised
		2.2.4.4 Homoeopathic products	Not Authorised
		2.2.4.5 Biological active starting materials	Not Authorised
		2.2.4.6 Other	Not Authorised

Manufacture of active substance. Names of substances subject to inspection:

ACTIVE NAME
N/A

EXCIPIENT NAME
N/A

Any restrictions or clarifying remarks related to the scope of this certificate:

N/A

1. Building(s)/Area(s)

   N/A

2. Room(s)

   N/A

3. Line(s) Equipment(s)

   N/A

4. QC testing

   N/A

5. Medicinal Product(s)/IMP(s)

   N/A

Name of the authorised person of the Competent Authority of the United Kingdom

Graeme McKilligan
GMP Inspector
graeme.mckilligan@mhra.gsi.gov.uk

Date: 13/12/2012