Certificate No: UK GMP 35697 Insp GMP 35697/1113679-0008

MHRA
Regulating Medicines and Medical Devices

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	SHARON BIO-MEDICINE LIMITED
Site address	CENTRAL HOPE TOWN SELAQUI INDUSTRIAL AREA DEHRADUN UTTARAKHAND IN-248 001 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: The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 24/04/2017, 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. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is only valid when presented with all pages and both parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear please contact the issuing authority.

NOTARY GANESH KALAM PANT DIST. MAHARASHTRA INDIA

BOMBAY CHAMBER OF COMMERCE AND INDUSTRY 1836

A copy of this document / CERTIFICATE has been recorded with the Chamber

Authorised Signatory
Bombay Chamber of Commerce and Industry
Regn. No. 5071 Date - 3 OCT 2017

MR. SANJAY MALHARRAO GAIKWAD
ASSISTANT MANAGER

Medicines and Healthcare Products Regulatory Agency

NOTARY GOVERNMENT OF INDIA GANESH R. KADAM B.A., LL.B., DLL ADVOCATE & NOTARY GOVT. OF INDIA

ATTESTED BY ME

- 3 OCT 2017

SHARON BIO-MEDICINE LTD.


भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
INDIA
This public document of the type
COMMERCIAL DOCUMENT
is issued to SHARON BIO-MEDICINE LTD.
has been signed by SANJAY MALHARRAO GAIKWAD
with the seal / stamp of ASSTT. MANAGER, BOMBAY CHAMBER OF COMMERCE AND INDUSTRY
Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 06-Oct-2017 at NEW DELHI, INDIA
with reference no. MHMC0035612617
Seal / Stamp
Signature
The Ministry of External Affairs accepts no responsibility for the contents of the above documents.
(DEBABRATA PAUL)
Section Officer (O.I.)
C.P.V. Division
Ministry of External Affairs
New Delhi

MHRA
Regulating Medicines and Medical Devices

Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

1.1 Sterile products

Not Authorised

1.2 Non-sterile products

1.2.1 Non-sterile products (processing operations for the following dosage forms)

1.2.1.1 Capsules, hard shell
1.2.1.13 Tablets

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

Not Authorised

1.5 Packaging

1.5.1 Primary packaging

1.5.1.1 Capsules, hard shell
1.5.1.13 Tablets

1.5.2 Secondary packaging

1.6 Quality control testing

1.6.2 Microbiological: non-sterility
1.6.3 Chemical/physical

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

Not Authorised

2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

Not Authorised

MHRA
Regulating Medicines and Medical Devices

3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis
Not Authorised

3.2 Processing Activities of Active Substance from Natural Sources
Not Authorised

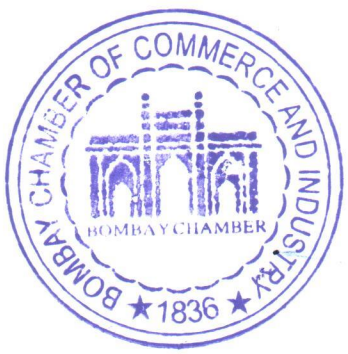
3.3 Manufacture of Active Substance using Biological Processes
Not Authorised

3.4 Manufacture of sterile active substance
Not Authorised

3.5 General Finishing Steps
Not Authorised

3.6 Quality Control Testing
Not Authorised

4 Other Activities
Not Authorised



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Regulating Medicines and Medical Devices

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

NOTARY GOVERNMENT OF INDIA GANESH R. KADAM THANE DIST. (MAHARASHTRA) REG. No. 5962 EXP. DT. 27/05/2018

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

Ian Harwood
GMP Inspector
Ian.Harwood@mhra.gsi.gov.uk

Date: 28/07/2017

BOMBAY CHAMBER OF COMMERCE AND INDUSTRY ★1836★ BOMBAY CHAMBER

SHARON BIO-MEDICINE LTD.