CERTIFICATE No. GIF-IW-N-4022/227/13

Główny Inspektor Farmaceutyczny

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

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

Main Pharmaceutical Inspector

/the Competent Authority of Poland/

confirms the following:

the manufacturer

Caplin Point Laboratories Limited

Guruvaraja kandigai Village, Sirupuzhalpettai Post, Gummidipoondi Taluk, Thiruvallur District, Pincode-601 201, Tamil Nadu, India

site address

Caplin Point Laboratories Limited

Unit IV, Survey No. : 895 & 897
Guruvarajakandigai Village, Sirupuzhalpettai Post, Gummidipoondi Taluk, Thiruvallur District, Pincode-601 201, Tamil Nadu, India

has been inspected in connection with marketing authorization(s) listing manufacturer located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Dz. U. z 2008 r. Nr 45 poz. 271)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **17-20/03/2015**, it is considered that it complies with the Good Manufacturing Practice requirements 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.

This certificate is valid only 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.

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

date: 2015 -07- 01

Main Pharmaceutical Inspectorate
12 Senatorska Street, 00-082 Warsaw, Poland
Tel. +48 22 635 99 51, fax. +48 22 635 99 57

Zofia Ulz
Main Pharmaceutical Inspector

CERTIFICATE No. GIF-IW-N-4022/227/13

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile Products**
	1.1.1 Aseptically prepared 1.1.1.4 Small volume liquids
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility ***1.6.3 Chemical/Physical*** ***1.6.4 Biological***

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

date: 2015 -07- 01

Main Pharmaceutical Inspectorate
12 Senatorska Street, 00-082 Warsaw, Poland
Tel. +48 22 635 99 51, fax. +48 22 635 99 57

Zofia Ulz
Main Pharmaceutical Inspector

The Main Pharmaceutical Inspectorate

CERTIFICATE NUMBER: ***GIF-IW-4022/227/13***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

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

The competent authority of Poland confirms the following:
The manufacturer: ***Caplin Point Laboratories Limited***
Site address: ***Unit IV, Survey No. : 895 & 897, Guruvarajakandigai Village, Sirupuzhalpettai Post, Gummidipoondi Taluk, Thiruvallur District, Tamil Nadu, India, Pincode-601 201, 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 .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2015-03-20*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

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 valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.3 Chemical/Physical* *1.6.4 Biological*

2015-07-01

Name and signature of the authorised person of the Competent Authority of Poland

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Confidential
The Main Pharmaceutical Inspectorate
Tel: ***Confidential***
Fax: ***Confidential***