GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

CHIEF PHARMACEUTICAL INSPECTOR

2024 -02- 15

ISF.405.20.2024.IP.1
WTC/0328_02_01/36

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

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

Chief Pharmaceutical Inspector

/the Competent Authority of Poland/

confirms the following:

the manufacturer and importer

J.S. HAMILTON POLAND Sp. z o. o.

ul. Chwaszczyńska 180, 81-571 Gdynia, POLAND

site address

J.S. HAMILTON POLAND Sp. z o. o.

ul. Chwaszczyńska 180, 81-571 Gdynia, POLAND

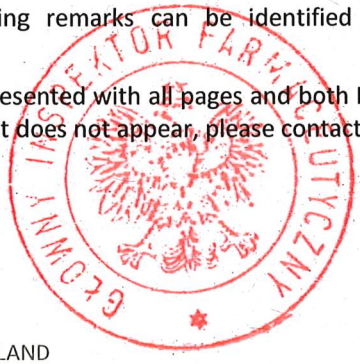
Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **097/0328/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2022, item 2301 as amended).

From the knowledge gained during inspection of this manufacturer and importer, the latest of which was conducted on **21-23/11/2023**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive (EU) 2017/1572.

This certificate reflects the status of the manufacturing and importation 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.

Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/).

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.



12 Senatorska str, 00-082 Warsaw, POLAND
phone 22 635 99 51
fax 22 635 99 57

www.gif.gov.pl
gif@gif.gov.pl

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

acting Chief Pharmaceutical Inspector

Marcin Wójtowicz

12 Senatorska str, 00-082 Warsaw, POLAND
phone 22 635 99 51
fax 22 635 99 57

www.gif.gov.pl
gif@gif.gov.pl

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

2024 -02- 15

CHIEF PHARMACEUTICAL INSPECTOR

ISF.405.20.2024.IP.2
WTC/0328_02_01/37

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 94(1) of Regulation No 2019/6

Chief Pharmaceutical Inspector
/the Competent Authority of Poland/

confirms the following:

the manufacturer

J.S. HAMILTON POLAND Sp. z o. o.

ul. Chwaszczyńska 180, 81-571 Gdynia, POLAND

site address

J.S. HAMILTON POLAND Sp. z o. o.

ul. Chwaszczyńska 180, 81-571 Gdynia, POLAND

Has been inspected under the national inspection programme in connection with manufacturing *authorisation no.* **097/0328/15** *in accordance with* Art. 88 *of Regulation* (EU) No 2019/6, Art. 38 and Art. 51a point 2 Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2022, item 2301 as amended).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **21-23/11/2023**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive 91/412/EEC.

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.

Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/).

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

12 Senatorska str, 00-082 Warsaw, POLAND
phone 22 635 99 51
fax 22 635 99 57

www.gif.gov.pl
gif@gif.gov.pl

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

Part 2

Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS	
1.6	Quality control testing
	1.6.3 Chemical/Physical

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

acting Chief Pharmaceutical Inspector

Marcin Wójtowicz

12 Senatorska str, 00-082 Warsaw, POLAND
phone 22 635 99 51
fax 22 635 99 57

www.gif.gov.pl
gif@gif.gov.pl