CHIEF PHARMACEUTICAL INSPECTOR

2024 -07- 11

ISF.405.80.2024.IP.1
WTC/0615_01_01/147

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

Dat Vi Phu Pharmaceutical Joint Stock Company (Davipharm)
Lot M7A, D17 Street, My Phuoc 1 Industrial Zone, Thoi Hoa Ward,
Ben Cat City, Binh Duong Province, 75911 Vietnam

site address

Dat Vi Phu Pharmaceutical Joint Stock Company (Davipharm)
Lot M7A, D17 Street, My Phuoc 1 Industrial Zone, Thoi Hoa Ward,
Ben Cat City, Binh Duong Province, 75911 Vietnam

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 (Journal of Laws from 2024, item 686).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **19/04/2024**, 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 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

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
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Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products 1.2.1.1 Capsules, hard shell 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary packing 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets **1.5.2 Secondary packing**
1.6	**Quality control testing**
	1.6.2 Microbiological: non sterility **1.6.3 Chemical/Physical**

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

Points: 1.2.1.1, 1.2.1.13, 1.5.1.1, 1.5.1.13 concern also manufacturing of medical products containing active substances for highly potent products.

The manufacture and packing of hard capsules and tablets in „non HP zone" and "HP zone" is approved.

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

acting Chief Pharmaceutical Inspector

Marcin Wójtowicz

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