CHIEF PHARMACEUTICAL INSPECTOR

2023 -07- 14 r.

IWSF.405.63.2023.IP.1.1
WTC/0614_01_01/124

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

Chief Pharmaceutical Inspector
/the Competent Authority of Poland/

confirms the following:

the manufacturer

Intas Pharmaceuticals Limited
Plot Nos. 5 to 14, Pharmez, Near Village Matoda, Sarkhej-Bavla National Highway, No. 8-A, Taluka: Sanand, Ahmedabad, Gujarat 382213, India

site address

Intas Pharmaceuticals Limited
Plot Nos. 5 to 14, Pharmez, Near Village Matoda, Sarkhej-Bavla National Highway, No. 8-A, Taluka: Sanand, Ahmedabad, Gujarat 382213, 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 as amended, transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2022. item 2301).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **27-31/03/2023**, 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. 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.

GŁÓWNY INSPEKTORAT 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

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile Products**
	1.1.1 Aseptically prepared 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids **1.1.2 Terminally sterilised** 1.1.2.3 Small volume liquids
1.2	**Non-sterile products**
	1.2.1 Non-sterile products 1.2.1.1 Capsules, hard shell 1.2.1.2 Capsules, soft shell 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary packing 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.13 Tablets **1.5.2 Secondary packing**
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility **1.6.2 Microbiological: non sterility** **1.6.3 Chemical/Physical** **1.6.4 Biological**

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

Points 1.1, 1.5, 1.6 concern medicinal products manufactured on production lines:
Block C (vial filling line 1, 2, 3, 4) Oncology Parenteral
and Block G (vial filling lines: 1, 2) (PFS Filling Line 3) General Parenteral.

Block B: points 1.2.1.1, 1.2.1.13, 1.5.1.1, 1.5.1.13;
Block C 2nd Floor Wing A: points 1.2.1.1, 1.2.1.2, 1.2.1.13, 1.5.1.1, 1.5.1.2, 1.5.1.13 also highly potent products;
Block G - only point 1.5

Chief Pharmaceutical Inspector
Ewa Krajewska

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fax 22 635 99 57
www.gif.gov.pl
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AL/48022.03

Notarial Declaration

The undersigned, Jan Hein Frederik Siemerink, LLM, civil-law notary in Amsterdam, the Netherlands,

herewith certifies:
that the attached copy is a fully identical photocopy of a document, consisting of two pages, which was shown to the undersigned and returned to the holder, after the attached photocopy was examined and found to be identical with the same.

This certification explicitly gives no opinion about the contents of the annexed document.

This certification may only be relied upon on the express condition that any issues of interpretation or liability there under will be governed by Dutch law and be brought exclusively before a Dutch Court.

All services provided by KB notarissen are subject to our general terms and conditions. Upon request we will send you our general terms and conditions. Our general terms and conditions are also available on our website or at the Chamber of Commerce.

Amsterdam, the Netherlands, 26 October 2023

mr. Jan Hein Frederik Siemerink * Notaris te Amsterdam *

J.H.F. Siemerink, LLM, civil-law notary

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: THE NETHERLANDS
   This public document
2. has been signed by **mr. J.H.F. Siemerink**
3. acting in the capacity of notary at Amsterdam
4. bears the seal/stamp of aforesaid notary

Certified

5. In Den Haag 6. on 27-10-2023
7. by the registrar of the district court of Den Haag
8. no. 2023/13418

9. Seal/stamp:

10. Signature:

S.M. Koegler



