



Chief Pharmaceutical Inspector

IWZJ.405.54.2018.MG.1

WTC/0393\_02\_01/108

## 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

**Prespack Jacek Karoński**

**ul. Św. Wawrzyńca 34, 60-541 Poznań, POLAND**

site address

**Prespack Jacek Karoński**

**ul. Sadowa 38, 60-185 Skórzewo, POLAND**

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **039/0393/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6<sup>th</sup> of September 2001 (Journal of Laws from 2017, item 2211).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **07-08/02/2018**, 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.

date: **2018 -04- 27**

Chief Pharmaceutical Inspectorate  
ul. Senatorska 12, 00-082 Warszawa, Poland  
Tel. +48 22 635 99 51, fax. +48 22 635 99 57



acting Chief Pharmaceutical Inspector

Zbigniew Niewójt

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Chief Pharmaceutical Inspector



## Part 2

Human Medicinal Products

### 1 MANUFACTURING OPERATIONS

1.1	<b>Sterile Products</b>
	1.1.3 Batch certification
1.2	<b>Non-sterile products</b>
	1.2.2 Batch certification
1.5	<b>Packaging</b>
	1.5.2 Secondary packing

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

Points 1.1.3 and 1.2.2 only in scope of certification of the repackaged finished product.



date: 2018 -04- 27

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