

***Agency for medicinal products and medical devices of the Republic of
Slovenia***

CERTIFICATE NUMBER: **409-6/2014-7**

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

Art. 15 of Directive 2001/20/EC

The competent authority of Slovenia confirms the following:

The manufacturer: ***Shilpa Medicare Limited***

Site address: ***Unit IV, Plot No. S-20 to S-24/A, Pharma SEZ, APIIC, Green Industrial Park, Polepally Village, Jedcherla Mandal, Mahaboobnagar-Dist., Telangana State, 509301, 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 and Art. 15(4) of Directive 2001/20/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2014-11-19** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC³

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.

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

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS

1.1 Sterile products

1.1.1 Aseptically prepared (processing operations for the following dosage forms)

1.1.1.1 Large volume liquids

1.1.1.2 Lyophilisates

1.1.1.4 Small volume liquids

1.1.2 Terminally Sterilised (processing operations for the following dosage forms)

1.1.2.1 Large volume liquids

1.1.2.3 Small volume liquids

1.1.3 Batch certification

1.2 Non-sterile products

1.2.1 Non-sterile products (processing operations for the following dosage forms)

1.2.1.1 Capsules, hard shell

1.2.1.13 Tablets

1.2.1.17 Other: Manufacture of intermediates (powders and granulates for further processing)(en)

1.2.2 Batch certification

1.5 Packaging

1.5.2 Secondary packing

1.5.1 Primary Packing

1.5.1.1 Capsules, hard shell

1.5.1.13 Tablets

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

Clarifying remarks (for public users)

The GMP certificate applies to oncology products/batches manufactured under contract manufacturing arrangements/agreements with Krka, d.d., Novo mesto, Slovenia.

2015-08-27

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

Confidential
Agency for medicinal products and medical devices of
the Republic of Slovenia
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