**Certificate No:**

**CERTIFICATE OF GMP COMPLIANCE OF MANUFACTURER**

**Part 1**

Issued following an inspection in accordance with current Good Manufacturing Practice Guidelines, and the Regulation on Manufacturing Plants of Medicinal Products for Human Use\* and the Law No 1262 on Pharmaceutical and Medicinal Preparations. These regulations are in line with the requirements of Pharmaceutical Inspection Co-operation Scheme (PIC/s) and the Directives of the European Commission.

Turkish Medicines and Medical Devices Agency confirms the following:

Manufacturer’s Name :

Head Office / Correspondence Address :

Site Address

Manufacturing Authorization Date :

Manufacturing Authorization Number :

or

Importer’ s Name :

Head Office / Correspondence Address :

Site Address :

Manufacturing Authorization Date :

Manufacturing Authorization Number :

Has been inspected in accordance with current Good Manufacturing Practice Guidelines, the Regulation on Manufacturing Plants of Medicinal Products for Human Use, the Law No 1262 on Pharmaceutical and Medicinal Products.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on …………/…………./………...., it is considered that it complies with the requirements of Good Manufacturing Practice (GMP).

This certificate reflects the status of the manufacturing site at the time of the inspection, and Turkish Medicines and Medical Devices Agency should be consulted to verify compliance of the manufacturing site with GMP requirements if more than 3 years have elapsed since the date of 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 by Turkish Medicines and Medical Devices Agency upon request.

\**This regulation is aligned with European Union Directive Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice for medicinal products for human use, and Directive 2001/83/EC on the Community code relating to medicinal products for human use.*

**Part 2**

Human Medicinal Products \*

Human Investigational Medicinal Products (for Phase I, II, III Clinical trials)\*

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| **1 MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS\*** | |
| *If the company is engaged in manufacture of products with special requirements, e.g. radiopharmaceuticals or products containing penicillin, sulphanomides, cytotoxics, cephalosporins, substances with hormonal activity or other potentially hazardous active ingredients, this should be stated under the relevant product type and dosage form.* | |
| **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  1.1.1.3 Semi-solids  1.1.1.4 Small volume liquids  1.1.1.5 Solids and implants  1.1.1.6 Other aseptically prepared products *(….free text)* |
|  | * + 1. Terminally sterilized (processing operations for the following dosage forms)   1.1.2.1 Large volume liquids  1.1.2.2 Semi-solids  1.1.2.3 Small volume liquids  1.1.2.4 Solids and implants  1.1.2.5 Other terminally sterilised prepared products *(….free text)* |
|  | 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  1.2.1.2 Capsules, soft shell  1.2.1.3 Chewing gums  1.2.1.4 Impregnated matrices  1.2.1.5 Liquids for external use  1.2.1.6 Liquids for internal use  1.2.1.7 Medicinal gasses  1.2.1.8 Other solid dosage forms  1.2.1.9 Pressurized preparations  1.2.1.10 Radionuclide generators  1.2.1.11 Semi-solids  1.2.1.12 Suppositories  1.2.1.13 Tablets  1.2.1.14 Transdermal patches  1.2.1.15 Other non-sterile medicinal products *(….free text)* |
|  | 1.2.2 Batch certification |
| **1.3** | **Biological medicinal products** |
|  | 1.3.1 Biological medicinal products  1.3.1.1 Blood products  1.3.1.2 Immunological products  1.3.1.3 Cell therapy products  1.3.1.4 Gene therapy products  1.3.1.5 Biotechnology products  1.3.1.6 Human or animal extract derived products  1.3.1.7 Tissue engineering products  1.3.1.8 Other biological medicinal products *(….free text)* |
|  | 1.3.2 Batch certification |
| **1.4** | **Other products or manufacturing activity** |
|  | 1.4.1 Other products  1.4.1.1 Herbal products  1.4.1.2 Homeopathic products  1.4.1.3 Other *(….free text)* |
|  | 1.4.2 Sterilization of active substances/excipients/finished products  1.4.2.1 Filtration  1.4.2.2 Dry heat  1.4.2.3 Moist heat  1.4.2.4 Chemical  1.4.2.5 Gamma irradiation  1.4.2.6 Electron beam |
|  | 1.4.3 Others *(….free text)* |
| **1.5** | **Packaging** |
|  | * + 1. Primary Packaging   1.5.1.1 Capsules, hard shell  1.5.1.2 Capsules, soft shell  1.5.1.3 Chewing gums  1.5.1.4 Impregnated matrices  1.5.1.5 Liquids for external use  1.5.1.6 Liquids for internal use  1.5.1.7 Medicinal gasses  1.5.1.8 Other solid dosage forms  1.5.1.9 Pressurized products  1.5.1.10 Radionuclide generators  1.5.1.11 Semi-solids  1.5.1.12 Suppositories  1.5.1.13 Tablets  1.5.1.14 Transdermal patches  1.5.1.15 Other non-sterile medicinal products *(….free text)* |
|  | 1.5.2 Secondary packaging |
| **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 testing |

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

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| **2 IMPORTATION OF MEDICINAL PRODUCTS\*** | |
| **2.1** | **Quality control testing of imported medicinal products** |
|  | 2.1.1 Microbiological: sterility |
|  | 2.1.2 Microbiological: non-sterility |
|  | 2.1.3 Chemical/Physical |
|  | 2.1.4 Biological |
| **2.2** | **Batch certification of imported medicinal products** |
|  | 2.2.1 Sterile Products  2.2.1.1 Aseptically prepared  2.2.1.2 Terminally sterilised |
|  | 2.2.2 Non-sterile products |
|  | 2.2.3 Biological medicinal products  2.2.3.1 Blood products  2.2.3.2 Immunological products  2.2.3.3 Cell therapy products  2.2.3.4 Gene therapy products  2.2.3.5 Biotechnology products  2.2.3.6 Human or animal extracted products  2.2.3.7 Tissue engineered products  2.2.3.8 Other biological medicinal products <free text > |
| **2.3** | **Other importation activities** |
|  | |  | | --- | | 2.3.1 Site of physical importation | |
| |  | | --- | | 2.3.2 Importation of intermediate which undergoes further processing | |  | |
| |  | | --- | | 2.3.3 Other *(….free text)* | |

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

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| **3 MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES** | |
|  | List of active substances manufactured:   1. ………. 2. ……….   ……….. |
| **3.1** | **General finishing steps** |
|  | 3.1.1 Physical processing steps (……..*specify) ( e.g. drying, milling/micronization, sieving*)  3.1.2 Primary packaging (*enclosing / sealing the active substance within a packaging material which is in direct contact with the substance*)  3.1.3 Secondary packaging (*placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance*)  3.1.4 Other |
| **3.2** | **Quality control testing** |
|  | 3.2.1 Microbiological testing (including sterility testing)  3.2.2 Microbiological testing (excluding sterility testing)  3.2.3 Chemical/physical testing  3.2.4 Biological testing |
| **4** **OTHER ACTIVITIES \***  *(free text)*………………………………………………………………………  ……………………………………………………………………………….... | |

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

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…..…../….....…/.....…….. *[date] ……………………..…..[number]*

*Name, surname and signature of the Authorized Person*

(\* ) Delete that which does not apply