TURKISH MINISTRY OF HEALTH
Turkish Medicines and Medical Devices Agency

CERTIFICATE OF GMP (GOOD MANUFACTURING PRACTICE) COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Good Manufacturing Practice Guidelines dated 12.08.2011, and the Regulation on Manufacturing Plants of Medicinal Products for Human Use *, numbered 28630 and dated 27.04.2013, issued based on Articles 27 and 40 of Decree Law #663 dated 11.10.2011 on the Organization and Mandate of the Ministry of Health and Its Subordinate Agencies, and Law #1262 dated 14.05.1928 on Pharmaceutical and Medicinal Products, in line with the requirements of World Health Organization.

Turkish Medicines and Medical Devices Agency confirms the following:

Manufacturer's Name: ……
Head Office / Correspondence Address: ……
Site Address: ……
Manufacturing Authorization
Date and Number: ……..

Has been inspected in accordance with Good Manufacturing Practice Guidelines dated 12.08.2011, and the Regulation on Manufacturing Plants of Medicinal Products for Human Use *, numbered 28630 and dated 27.04.2013, issued based on Articles 27 and 40 of Decree Law #663 dated 11.10.2011 on the Organization and Mandate of the Ministry of Health and Its Subordinate Agencies, and Law #1262 dated 14.05.1928 on Pharmaceutical and Medicinal Products, in line with the requirements of World Health Organization.

or

Active Substance Manufacturer's Name: ……
Head Office / Correspondence Address: ……
Site Address: ……
Manufacturing Authorization
Date and Number: ……..

Has been inspected in accordance with Good Manufacturing Practice Guidelines dated 12.08.2011, and the Regulation on Manufacturing Plants of Medicinal Products for Human Use *, numbered 28630 and dated 27.04.2013, issued based on Articles 27 and 40 of Decree Law #663 dated 11.10.2011 on the Organization and Mandate of the Ministry of Health and Its Subordinate Agencies, and Law #1262 dated 14.05.1928 on Pharmaceutical and Medicinal Products, in line with the requirements of World Health Organization.

Other (please specify):…….

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. The authenticity of this certificate may be verified with Turkish Medicines and Medical Devices Agency upon request.

*This regulation is aligned with European Union Directive 91/356/EEC 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)*

1 Manufacturing Operations of Human 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 *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 (products listed on the manufacturing authorization, if any)*
	1.1.2 Terminally sterilized *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 sterilized products (products listed on the manufacturing authorization, if any)*
	1.1.3 Batch certification only
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* *1.2.1.3 Tablets* *1.2.1.4 Semi-solids* *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 Pressurized preparations* *1.2.1.9 Radionuclide generators* *1.2.1.10 Suppositories* *1.2.1.11 Transdermal patches* *1.2.1.12 Other non-sterile medicinal products (products listed on the manufacturing authorization, if any)*
	1.2.2 Batch certification only
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 (products listed on the manufacturing authorization, if any)*
	1.3.2 Batch certification only
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)*

	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 …… (Other)
1.5	**Packaging**
	1.5.1 Primary Packaging *1.5.1.1 Capsules, hard shell* *1.5.1.2 Capsules, soft shell* *1.5.1.3 Tablets* *1.5.1.4 Semi-solids* *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 Pressurized products* *1.5.1.9 Radionuclide generators* *1.5.1.10 Suppositories* *1.5.1.11 Transdermal patches* *1.5.1.12 Other non-sterile medicinal products (products listed on the manufacturing authorization, if any)*
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological (including sterility testing) 1.6.2 Microbiological (excluding sterility testing) 1.6.3 Chemical/physical testing 1.6.4 Biological testing
2	**Manufacture of Active Substance***
	List of active substances manufactured:
2.1	**Manufacture of active substances by chemical synthesis**
	2.1.1 Manufacture of active substance intermediates 2.1.2 Manufacture of active substance raw materials 2.1.3 Formulation / Purification Stages (e.g. Crystallization) 2.1.4….(Other)
2.2	**Manufacture of active substances by extraction from natural sources**
	2.2.1 Manufacture of active substances by extraction from herbal sources 2.2.2 Manufacture of active substances by extraction from animal sources 2.2.3 Manufacture of active substances by extraction from human sources 2.2.4 Manufacture of active substances by extraction from mineral sources 2.2.5 Manufacture by modification of extracts 2.2.6 Manufacture by purification of extracts 2.2.7 ….(Other)
2.3	**Manufacture of active substances by biological processing**
	2.3.1 Fermentation 2.3.2 Cell cultivation (specify the type of cell, e.g. mammalian, bacterial) 2.3.3 Isolation/purification 2.3.4 Modification 2.3.5 …..(Other)
2.4	**Manufacture of sterile active substances** (complete sections 2.1, 2.2 and 2.3 where applicable)
	2.4.1 Aseptically prepared 2.4.2 Terminally sterilized

2.5	**General final steps of manufacturing**
	2.5.1 Physical processing steps (specify, e.g. drying, milling/micronization, sieving) 2.5.2 Primary packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 2.5.3 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) 2.5.4…..(Other)
2.6	**Quality control testing** 2.6.1 Microbiological testing (including sterility testing) 2.6.2 Microbiological testing (excluding sterility testing) 2.6.3 Chemical/physical testing 2.6.4 Biological testing
3	**Other operations*** ……..

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

……..

…../...../..... *[date]* ……*[number]*

Name, surname and signature of the Authorized Person

* Delete that which does not apply