

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:

Active Substance Manufacturer's Name:

WORLD MEDICINE İLAÇ SAN. VE TİC. A.Ş.

Head Office / Correspondence Address:

Evren Mah. Cami Yolu Cad. No:50 Güneşli
Bağcılar/İstanbul TURKEY

Site Address:

Evren Mah. Cami Yolu Cad. No:50 K:1b Zemin 4-5-6 Güneşli
Bağcılar/İstanbul TURKEY

Manufacturing Authorization Date and Number: **19/02/2015 TR/ÜY/2015/01**

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.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **12-14/11/2014** 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

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 <i>1.1.1.4 Small volume liquids (eye drop)</i>
	1.1.2 Terminally sterilized <i>1.1.2.3 Small volume liquids</i>
1.2	Non-sterile products
	1.2.1 Non-sterile products <i>1.2.1.1 Capsules, hard shell (capsule, micropellet capsule)</i> <i>1.2.1.2 Capsules, soft shell</i> <i>1.2.1.3 Tablets (tablet, film coated tablet, sugar coated tablet)</i> <i>1.2.1.6 Liquids for internal use (syrup, suspension, solution, ear drop, oral drop, nasal drop, nasal spray)</i> <i>1.2.1.8 Pressurized preparations (dry powder inhaler; measured dose inhaler)</i> <i>1.2.1.12 Other non-sterile medicinal products (products listed on the manufacturing authorization, if any)</i> <i>(Powder, granules, sachet)</i>
1.5	Packaging
	1.5.1 Primary Packaging <i>1.5.1.1 Capsules, hard shell</i> <i>1.5.1.2 Capsules, soft shell</i> <i>1.5.1.3 Tablets</i> <i>1.5.1.6 Liquids for internal use</i> <i>1.5.1.8 Pressurized products</i> <i>1.5.1.12 Other non-sterile medicinal products (products listed on the manufacturing authorization, if any)</i>
	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

26/03/2015 [date] TR/GMP/2015/67 [number]

Fatih TAN
Kurum Başkan Yardımcısı

