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:
İLKO İLAÇ SAN. VE TİC.A.Ş

Head Office / Correspondence Address:
Veysel Karani Mah. Çolakoğlu Sk. No:10 Kat:7-8-9 Sancaktepe
İstanbul / TURKEY

Site Address:
3.Organize Sanayi Bölgesi, Kuddusi Cad. 23 Sok. No:1 Selçuklu
Konya / TURKEY

Manufacturing Authorization
Date and Number: **22/06/2011 2011/07**

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 **22.01.2015** 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.	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products *1.2.1.1 Capsules, hard shell (capsule, controlled release capsule, enteric capsule)* *1.2.1.3 Tablets (tablet, coated tablet, controlled release tablet, film tablet, chewable tablet, enteric coated tablet)* *1.2.1.12 Other non-sterile medicinal products (products listed on the manufacturing authorization, if any) (granular powder)* 1.2.2 Batch certification only
1.5	**Packaging**
	1.5.1 Primary Packaging *1.5.1.1 Capsules, hard shell* *1.5.1.3 Tablets* *1.5.1.12 Other non-sterile medicinal products (granular powder)*
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological (excluding sterility testing) 1.6.3 Chemical/physical testing

26/01/2015 [date] TR/GMP/2015/71 [number]

Fatih TAN
Kurum Başkan Yardımcısı

Ministry of Health Republic of Turkey
Turkish Medicines and Medical Devices Agency