



AZƏRBAYCAN RESPUBLİKASI
SƏHIYYƏ NAZİRLİYİ
“ANALİTİK EKSPERTİZA MƏRKƏZİ” MMC

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04 iyun 2019 il

№ 03/6844

GMP inspection report № TUR2/02/2019/1

Inspected site(s)	Name	ATABAY İlaç Fabrikası A.Ş.
	Site address	Acıbadem Köftücü Sokak No.1 Kadıköy 34718, İstanbul - TÜRKİYE
	Phone	0 (90) 216 326 65 33 – 0 216 339 61 39
	Fax	0 (90) 216 340 13 77
Activities carried out by company	Manufacturing, quality control, packaging, storage, batch release, distribution and marketing of non-sterile: - tablet, coated tablet, capsule, powder filling, pomade, gel and suppository, syrup, suspension preparation The formulations manufactured at this site are for “Human use only”	
Inspection date(s)	• 18.02.2019 – 19.02.2019	
Inspector(s)	• Polad Hajibalayev (team leader) – Inspector of Department for Work with Pharmaceutical Entities – Analytical Expertise Center – Ministry of Health – Azerbaijan Republic; • Ulduz Eyvazova – registration specialist - Analytical Expertise Center – Ministry of Health – Azerbaijan Republic	
References	• European Union (EU) Guidelines for Good Manufacturing Practice (GMP) for Medicinal Products for Human and Veterinary Use • Other related guidelines and technical reports	
Brief report of the inspection activities	Scope of Inspection	• First time, planned, general GMP inspection of the manufacturer who is going to apply for the state registration of medicines in Azerbaijan Republic, according to the EU GMP and other related requirements.

	Activities and areas inspected	<ul style="list-style-type: none">• Pharmaceutical Quality System• Personnel• Premises and Equipment• Documentation• Production• Quality Control• Outsourced activities• Distribution, Complaints, Product Recalls• Self-inspection
Personnel met during the inspection		<ul style="list-style-type: none">• Vildan Tüzer (Qualified Person)• Fulya Sever (QA Manager)• Ercan Tokses (Production Manager)• Yasemin Acar (Quality Control)• Mehmet Gündoğdu (Packaging Supervisor)• Bora Kaymaz (Export Sales Manager).

