

TYPICAL NON-CONFORMITIES IDENTIFIED DURING THE GMP INSPECTION BY SCDMTE, RA

INSPECTION PERFORMED DURING 2022-2023



**The number of inspections
and geography of the
sites inspected**

**17 inspections and distant
assessments**

- **EUROPE– 13**
 - **including 2 API
manufacturers**
- **USA-2**
- **COUNTRIES SOUTH
EAST ASIA -2**

GUIDANCE DOCUMENTS APPLICABLE FOR CLASSIFICATION OF NON- CONFORMITIES



1. PI 040-1 3 Appendices 1 January 2019, PIC/S GUIDANCE ON CLASSIFICATION OF GMP DEFICIENCIES
2. Guidance on Classification of Observations for Inspection of Cells, Tissues and Organs Establishments (GUI-0101)
3. GMP deficiencies Version 1.0, August 2017 Last updated: 4 August 2017
4. **Relevant document from EUAU**

STATISTIC ON IDENTIFIED DEFICIENCIES



N	DEFICIENCY	СТАТИСТИКА ПО УЧАСТКАМ
1.	PHARMACEUTICAL QUALITY SYSTEM	10 (2 API production)
2.	PERSONNEL	5 (2 critical finding)
3.	PREMISES AND EQUIPMENT	10
4.	DOCUMENTATION	14
5.	PRODUCTION	15 (5 validation)
6.	QUALITY CONTROL	7
7.	OUTSOURCED ACTIVITY	3
8.	COMPLAINTS AND RECALL	1
9.	SELF-INSPECTION	5



VIII ALL-RUSSIA
GMP CONFERENCE

ORGANIZERS



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GEDEON RICHTER
Health is our mission

GENERAL INFO PARTNER



GENERAL INFO AND ANALYTICAL PARTNER

Фармацевтический
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**ФАРМ
МЕД
ПРОМ**