





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

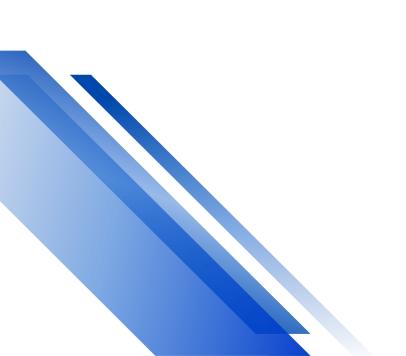


INSPECTION PERFORMED DURING 2022-2023

The number of inspections and geography of the sites inspected 17 inspections and distant

assessments

- EUROPE- 13
 - including 2 API manufacturers
- USA-2
- COUNTIRES 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



Ν	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

ORGANIZERS





S-GROUP

GENERAL PARTNER

STRATEGIC PARTNER





GEDEON RICHTER Health is our mission

GENERAL **INFO PARTNER**



GENERAL INFO AND ANALYTICAL PARTNER

Фармацевтический BECTHINK STRATEGIC **INFO PARTNER**

ΦΑΡΜ МЕД ΠΡΟΜ



VIII ALL-RUSSIA GMP CONFERENCE