GMP PHARMACEUTICAL ANALYSIS

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Zdravotní ústav se sídlem v Ústí nad Labem – kontrolní laboratoř č. 544 – Zkušební laboratoř Hradec Králové / The Health institute with headquarters in Ústí nad Labem - control laboratory No. 544 - Hradec Králové Test Laboratory – performs quality control of pharmaceutical substances (raw materials, active substances, medicinal products - see the final control page), including cytostatic products. Since 2003, the laboratory has been the holder of a permit to operate from the State Institute for Drug Control for human and human evaluated medicinal products in the scope of chemical and physical quality control. The laboratory is authorized to handle addictive substances and preparations containing them (the laboratory is on the specified list of persons according to Proclamation No. 28/2013 Coll.).

WHO IT IS INTENDED FOR

The service is intended for manufacturers, importers and distributors of medicines.

OFFER OF ANALYSIS AND SERVICES

- **quality control of pharmaceutical substances** (raw materials, active substances, medicinal products) is carried out in the scope of: **physical, physico-chemical and chemical tests**
- **development and validation of analytical methods**

EXAMPLES OF ANALYTICAL TECHNIQUES

Identity tests, purity tests and determination of content are carried out either as partial tests or as full certificates.

- limit tests
- titration
- determination of nitrogen by the Kjeldahl method
- microscopy (optical microscope, elektron microscope)
- relative density
- sulfate ash
- absorbance in UV-VIS
- IR spectrophotometry
- determination of water content according to Karl-Fisher (volumetric, coulometric)

- assessment of contamination with particles below the visibility limit in injection and infusion preparations - by the light shielding method according to Ph Eur. 2.9.19 – APSS-2000 device
- thin layer chromatography
- liquid chromatography with UV and RID detectors (determination: Related substances, impurity content and main component content)
- ion chromatography with conductivity detection
- gas chromatography (e.g.: proportion of fatty acids, trans-unsaturated fatty acids, omega-3, 6 and 9 unsaturated fatty acids, chromatographic profile of essential oils, volatile impurities, etc.) including Head space methods (e.g.: determination of ethylene oxide and dioxane, residual solvents)

LEGISLATION

Laboratories meet the requirements of Good Manufacturing Practice (GMP). Tests are performed according to the specifications of the valid pharmacopoeia (Czech pharmacopoeia. Ph.Eur., USP) or approved customer specifications, or using our own validated methods.

SAMPLES DOCUMENTATION AND OTHER INFORMATION

Service order – General

Quality systém – GMP certificates