

FEES GUIDE

A. Fees Guide

This Fees Guide shall be valid since 01.01.2020.

The Fees Guide issued on 01.09.2018 is hereby invalidated.

This Fees Guide determines the reimbursement of costs for the performance of expert activities upon request and reimbursement for the requested services provided by SIDC under the following law regulations:

Act No. 523/2004 Coll. on Budget Rules of the Public Service and on Amendment and Supplementing of Certain Acts

Act No. 362/2011 Coll. on Drugs and Medical Devices and on Amendment and Supplementing of Certain Acts

Act No. 139/1998 Coll. on Narcotics and Psychotropic Substances and Preparations as amended

Act No. 331/2005 Coll. on State Administrative Authorities in the matters of drug precursors and on Amendment and Supplementing of Certain Acts

Act No. 18/1996 Coll. on Prices as amended

The above services are not part of Act No. 145/1995 Coll. on Administrative Fees and on Amendment and Supplementing of Certain Acts

The price of a service is derived from cost of labor, the cost of the material and the operating costs needed for performing the service.

| LABORATORY CONTROL OF QUALITY OF MEDICINES | |
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| Description | price of service |
| Description, weighing and measurement of samples | |
| appearance and sensory tests | 8.50 € |
| clarity of liquids and solutions (per each analyte) | 2.00 € |
| weighting of medicines (per each weighed sample) | 2.00 € |
| weighting of capsule content (per each weighed sample) | 3.00 € |
| extractable volume test (per each analyte) | 8.50 € |
| Analysis preparation | |
| preparation of sample | 14.50 € - 85.00 € |
| preparation of special reagent | 20.00 € - 85.00 € |
| preparation of comparison sample | 40.00 € - 55.00 € |
| preparation of calibration curve | 25% of cost of used method |
| Disintegration of tablets and capsules (without determination) | |
| in water | 15.50 € |
| in gastric juice | 35.00 € |

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| in duodenal juice | 40.00 € |
| Dissolution tests for solid dosage forms (without determination) | |
| short-term dissolution | 45.00 € |
| long-term dissolution | 220.00 € |
| Determination of swelling number or foaming value | 20.00 € |
| Determination of water and moisture content | |
| drying at normal pressure | 40.00 € |
| determination of dry matter and residue | 55.00 € |
| semi micro determination of water (K.F.) | 155.00 € |
| Determination of ash or weighable residue | |
| total ash | 40.00 € |
| sulphated ash or more complex ashing | 55.00 € |
| determination of ash insoluble in hydrochloric acid | 75.00 € |
| Density and relative density | 35.00 € |
| UV-VIS spectrophotometry | |
| simple, at the specified wavelength | 80.00 € |
| complex, at multiple wavelengths | 100.00 € |
| Potentiometric titration | |
| automatic titration in aqueous medium | 60.00 € |
| automatic titration in non-aqueous medium | 110.00 € |
| determination with ion-selective electrodes | 70.00 € |
| Potentiometric determination of pH | 20.00 € |
| Conductivity | 25.00 € |
| Determination of identity, purity and content of substances by liquid chromatography | |
| simple determination | 400.00 € |
| complex determination | 450.00 € |
| Examination of identity and purity by color and precipitation reactions | |
| Presence of frequent ions | 15.00 € |
| Presence of infrequent ions | 30.00 € |
| Presence of organic substances | |
| frequent | 20.00 € |
| infrequent | 30.00 € |
| photo sensible substances | 35.00 € |
| Volumetric determination of substances | |
| simple titration (visual) | 30.00 € |
| simple titration (potentiometric) | 30.00 € |
| retrograde titration | 40.00 € |
| titration in anhydrous environment (without isolation) | 55.00 € |
| Content uniformity | 25 % of cost of used method |

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| Testing of purified water according to pharmacopoeia | |
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| for chemical purity | 125.00 € |
| for microbial purity | 70.00 € |
| Microbiological tests | |
| microbiological evaluation of non-sterile drugs (Ph. Eur. 5.1.4, 2.6.12, 2.6.13) | 60.00 € - 160.00 € |
| microbiological evaluation of herbal medicinal products for oral use (Ph. Eur. 5.1.8, 2.6.12, 2.6.13, 2.6.31) | 60.00 € - 160.00 € |
| any other specific microorganism (Ph. Eur. 2.6.13) | 16.00 € - 36.00 € |
| bacterial endotoxins – gel method, limit test | 75.00 € |
| bacterial endotoxins – gel method, semi-quantitative test | 80.00 € |
| bacterial endotoxins – turbidimetric kinetic method | 80.00 € |
| bacterial endotoxins – chromogenic kinetic method | 120.00 € |
| Standpoint of SIDC on the application for batch release of vaccines and products made from blood and human plasma on the Slovak market | 55.00 € |
| Issuance of laboratory test report | |
| Total analytical protocol | 55.00 € |

If the required method is not mentioned in the tariff, the price is determined from the price of the material, the price of the total labour and overall costs. The applicant is also charged the price for laboratory inspection in the supply laboratory, while he is always informed in advance and its content is required.

| INSPECTION (GMP, GDP, GPPTP) | |
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| Description | price of service |
| Issue of the Opinion in accordance with Act No. 362/2011 Coll. as amended for the applicant for a manufacturing authorization for production of human medicinal products and drugs under testing | 1,100.00 € |
| Issue of the Opinion in accordance with Act No. 362/2011 Coll. as amended for the applicant for an authorization for the preparation of blood products | 750.00 € |
| Issue of the Opinion in accordance with Act No. 362/2011 Coll. as amended for the applicant for a permission for a wholesale authorization of human medicines | 800.00 € |
| Issue of the Opinion in accordance with Act No. 362/2011 Coll. as amended for the applicant for a permission for a provision of health-care | 500.00 € |
| Issue of the Opinion in accordance with Act No. 362/2011 Coll. as amended for eye optics | 250.00 € |
| Issue of the Opinion in accordance with Act No. 139/1998 Coll. as amended for the applicant for an authorization for handling with narcotic and psychotropic substances | 200.00 € |

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| Issue of the Opinion in accordance with Act No. 331/2005 Coll. as amended for the applicant for an authorization for handling with controlled substances | 250.00 € |
| Issue of the Decision on approval of the quality control laboratories, excipients and human medicines | 800.00 € |
| Inspection of manufacturing facilities of manufacturer of human medicines in the third countries | 26,000.00 € |
| Issue of the Certificate of compliance with the requirements of Good manufacturing practice | 1 000.00 € |
| Issue of the Certificate of compliance with the requirements of Good distribution practice | 600.00 € |
| Issue of the Certificate for one product and one country – Certificate of Pharmaceutical Product (CPP) | 350.00 € |
| Issue of the Opinion on application for correction plan for differences in package and in PIL | 250.00 € |
| Submission of demand for parallel import of the medicinal product or submission of demand for an extension of a decision to authorize parallel import of medicinal product | 250.00 € |
| Submission of notification about brokering or sale of human medicines | 150.00 € |
| Insertion into list of online retailers | 100.00 € |
| Opinion on exemption for the affixing ad use data on outer and inner packing or in the package leaflet or its introduction in state language | 250.00 € |
| Refund of travel expenses | real costs |

| PHARMACOPOEIA | |
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| Description | price of service |
| Translation of pharmacopeial articles – 1 page | 30.00 € |

| CLINICAL TRIALS OF DRUGS | |
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| Description | price of service |
| Issue of the new Decision based on change of application | 135.00 € |

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| MEDICAL DEVICES | |
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| Description | price of service |
| Registration of Slovak manufacturer/ Slovak authorized representative of medical device | 700.00 € |
| Registration of Slovak manufacturer/ Slovak authorized representative of medical device in vitro | 700.00 € |
| Registration of Slovak manufacturer/ Slovak authorized representative of active implantable medical device | 700.00 € |
| Assessment of any other technical documentation of a medical device (registration of a new medical device) as part of the registration of the SK manufacturer / SK medical device authorized representative, in vitro diagnostic medical device, active implantable medical device | 400.00 € |
| Creating a medical device code in the medical device database (valid until May 26, 2020) | 7.00 € |
| Updating the medical device code in the medical device database (valid until May 26, 2020) | 4.00 € |
| New announcement of the medical device manufacturer | 20.00 € |
| Notification of the manufacturer about one change of medical device | 10.00 € |
| Notification of the manufacturer about more than one change of medical devices at the same time | 20.00 € |
| Withdrawal of the notification of the manufacturer of medical device | 5.00 € |

| REGISTRATION | |
|---|------------------|
| Description | price of service |
| Fee for submission and processing an application for withdrawal of marketing authorization of a human medicinal product | 50.00 € |
| Fee for a paper statement (1 page) about the SIDC codes for centrally authorized medicinal products | 2.00 € |
| Expert consultation related to one-hour insight into the registration documentation and search for the documentation (fee/1hour) | |
| paper documentation | 70.00 € |
| electronic documentation | 35.00 € |
| transfer of the documentation from Rovinka archive | 16.00 € |
| Expert consultation related to one-hour insight into the registration documentation and providing an printout from the documentation (fee/1hour) | |
| paper printout, print or copy of 1 page | 0.50 € |
| scan up to 100 pages | 35.00 € |
| scan over 100 pages | 70.00 € |

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| SCIENTIFIC RECOMMENDATION | |
|---|------------------|
| Description | price of service |
| Basic scientific advice | |
| pharmaceutical development | 2,000.00 € |
| non-clinical research | 2,000.00 € |
| clinical trial | 2,000.00 € |
| post- authorization safety study (PASS) | 2,000.00 € |
| Legal Status of the medicinal product | 1,500.00 € |
| Combined scientific advice | |
| pharmaceutical development and safety study | 2,800.00 € |
| clinical and non-clinical research | 2,800.00 € |
| safety studies and clinical trial | 2,800.00 € |
| Multidisciplinary scientific advice | |
| pharmaceutical and (non-) clinical and safety study | 3,500.00 € |

| GENERAL | |
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| Description | price of service |
| Expert consultation (oral, e-mail) related to the activities of the state institute, requested outside of the scope of administrative procedure, fee per each started ½ hour | 50.00 € |
| Manufacturing authorization in the European format | 300.00 € |

B. Fees guide for disclosure of information

Act No. 211/2000 Coll. on Free Access to Information and on Amendment and Supplementing of Certain Acts

| DISCLOSURE OF INFORMATION | |
|----------------------------------|-------------------------|
| Description | price of service |
| send by e-mail, fax, telephone | free |
| print or copy of 1 page (A4) | 0.20 € |
| print or copy of 1 page (A3) | 0.30 € |
| 1 pc CD/DVD | 2.00 € |
| postal fees | as per Slovak post fees |
| envelope | 0.20 € |