

FEES GUIDE

A. Fees Guide

This Fees Guide shall be valid since 01.03.2023.

The Fees Guide issued on 01.07.2022 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 | 10 € |
| clarity of liquids and solutions (per each analyte) | 2.00 € |
| weighing of samples (per each weighed sample) | 2.00 € |
| weighing of capsule content (per each weighed sample) | 3.00 € |
| extractable volume test (per each analyte) | 10 € |
| Analysis preparation | |
| preparation of sample | 17.00 € - 99.00 € |
| preparation of special reagent | 24.00 € - 99.00 € |
| preparation of reference sample | 47.00 € - 64.00 € |
| preparation of calibration curve | 25% of cost of used method |
| Disintegration of tablets and capsules (without determination) | |
| in water | 18.00 € |
| in gastric juice | 42.00 € |

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| in duodenal juice | 47.00 € |
| Dissolution tests for solid dosage forms (without determination) | |
| short-term dissolution | 52.00 € |
| long-term dissolution | 159.00 € |
| Determination of swelling index or foam index | 24.00 € |
| Determination of water and moisture content | |
| drying at normal pressure | 47.00 € |
| determination of dry matter and residue | 64.00 € |
| semi micro determination of water (K.F.) | 180.00 € |
| Determination of ash or weighable residue | |
| total ash | 47.00 € |
| sulphated ash or more complex ashing | 64.00 € |
| determination of ash insoluble in hydrochloric acid | 88.00 € |
| Density and relative density | 41.00 € |
| FTIR spectrophotometry | 214.00 € |
| UV-VIS spectrophotometry | |
| simple, at the specified wavelength | 96.00 € |
| complex, at multiple wavelengths | 118.00 € |
| Potentiometric titration | |
| automatic titration in aqueous medium | 70.00 € |
| automatic titration in non-aqueous medium | 130.00 € |
| determination with ion-selective electrodes | 81.00 € |
| Potentiometric determination of pH | 24.00 € |
| Conductivity | 30.00 € |
| Determination of identity, purity and assay by liquid chromatography | |
| simple determination | 450.00 € |
| complex determination | 500.00 € |
| Determination of identity and purity by colour and precipitation reactions | |
| Presence of frequent ions | 17.00 € |
| Presence of infrequent ions | 35.00 € |
| Presence of organic substances | |
| Frequent | 24.00 € |
| Infrequent | 35.00 € |
| photosensible substances | 41.00 € |
| Volumetric determination of samples | |
| simple titration (visual) | 35.00 € |
| simple titration (potentiometric) | 35.00 € |
| reserve titration | 46.00 € |
| titration in anhydrous medium (without isolation) | 64.00 € |
| Content uniformity | 20 % of cost of used method |

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| Testing of purified water according to pharmacopoeia | |
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| for chemical purity | 147.00 € |
| for microbiological purity | 83.00 € |
| Microbiological tests | |
| microbiological examination of non-sterile products (Ph. Eur. 5.1.4, 2.6.12, 2.6.13) | 72.00 € - 188.00 € |
| microbiological examination of herbal medicinal products for oral use (Ph. Eur. 5.1.8, 2.6.12, 2.6.13, 2.6.31) | 72.00 € - 188.00 € |
| any other specific microorganism (Ph. Eur. 2.6.13) | 17.00 € - 43.00 € |
| bacterial endotoxins – gel – clot method, limit test | 88.00 € |
| bacterial endotoxins – gel – clot method, quantitative test | 95.00 € |
| bacterial endotoxins – turbidimetric kinetic method | 95.00 € |
| bacterial endotoxins – chromogenic kinetic method | 141.00 € |
| The Permission to release vaccines and medicinal products derived from human blood and plasma on the market in Slovak Republic | 65.00 € |
| Issuance of laboratory test report | |
| Test protocol | 65.00 € |

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 | 1,250.00 € |
| 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 | 850.00 € |
| 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 | 1,020.00 € |
| 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 | 680.00 € |
| Issue of the Opinion in accordance with Act No. 362/2011 Coll. as amended for eye optics | 340.00 € |
| 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 | 340.00 € |

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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 | 340.00 € |
| 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 | 29,330.00 € |
| Inspection of manufacturing facilities of manufacturer of human medicines in the third countries - repeated | 14,670.00 € |
| Issue of the Certificate of compliance with the requirements of Good manufacturing practice | 1 130.00 € |
| Issue of the Certificate of compliance with the requirements of Good distribution practice | 910.00 € |
| Issue of the Certificate for one product and one country – Certificate of Pharmaceutical Product (CPP) | 450.00 € |
| Issue of a copy with authorization clause for valid Certificate of compliance with the requirements of Good manufacturing practice by the manufacturer and for the Registration form of manufacturers, importers and distributors of active substances | 12.00 € |
| Issue of the Opinion on application for correction plan for differences in package and in PIL | 300.00 € |
| 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 | 300.00 € |
| Insertion into the list of the subjects, performing online sales | 140.00 € |
| 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 | 310.00 € |
| Refund of travel expenses | real costs |

| PHARMACOPOEIA | |
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| Description | price of service |
| Translation of pharmacopeial articles – 1 page | 36.00 € |

| CLINICAL TRIALS OF DRUGS | |
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| Description | price of service |
| Issue of the new Decision based on change of application | 152.00 € |

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| MEDICAL DEVICES | |
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| Description | price of service |
| Assessment of technical documentation for the first announcement /registration of a medical device/ in vitro diagnostic medical device by the manufacturer or the authorized representative with registered place of business in the Slovak republic | 845.00 € |
| Assessment of any other technical documentation of medical device/ in vitro diagnostic medical device (registration of a new medical device) as part of the registration by the manufacturer /authorized representative registered place of business in Slovak republic | 485.00 € |
| Submission of creating a medical device/ in vitro diagnostic medical device <u>code</u> in the database of medical devices | 17.00 € |
| Submission of updating medical device/ in vitro diagnostic medical device code in the database of medical devices | 11.00 € |
| Submission of new notification of the medical device / in vitro diagnostic medical device | 23.00 € |
| Submission of one or more changes of medical device / in vitro diagnostic medical device | 40.00 € |
| Submission of request for permission of performance study in vitro diagnostic medical device | 500.00 € |
| Assessment of the announcement of substantial change of performance study in vitro diagnostic medical device | 500.00 € |
| Assessment of announcement of performance study in vitro diagnostic medical device with a label CE | 500.00 € |

| REGISTRATION | |
|---|------------------|
| Description | price of service |
| <i>Fee for submission and processing of Application for Withdrawal of a marketing authorisation for a human medicinal product</i> | 50.00 € |
| Fee for submission and processing of Notification of a Variation according to § 55(5) in accordance with Act. No. 362/2011 Coll (ref Article 61(3)) | 50.00 € |
| <i>Fee for a statement confirming (1 page/2 €) allocation of the SIDC codes for centrally authorised products (CAPs)</i> | 2.00 € |
| Expert consultation related to one-hour insight into the registration documentation and search for the documentation (fee/1hour) | |
| paper documentation | 75.00 € |
| electronic documentation | 38.00 € |

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| 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) | 50.00 € |
| paper printout, print or copy of 1 page | 1 € |
| scan up to 100 pages | 38.00 € |
| scan over 100 pages | 75.00 € |

| SCIENTIFIC RECOMMENDATION | |
|---|------------------|
| Description | price of service |
| Basic scientific advice | |
| pharmaceutical development | 2,100.00 € |
| non-clinical research | 2,100.00 € |
| clinical trial | 2,100.00 € |
| post- authorization safety study (PASS) | 2,100.00 € |
| Legal Status of the medicinal product | 1,600.00 € |
| Combined scientific advice | |
| pharmaceutical development and safety study | 3,000.00 € |
| clinical and non-clinical research | 3,000.00 € |
| safety studies and clinical trial | 3,000.00 € |
| Multidisciplinary scientific advice | |
| pharmaceutical and (non-) clinical and safety study | 3,700.00 € |

| 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 | 52.00 € |
| Manufacturing authorization in the European format | 355.00 € |
| Copy of the decision of manufacturers and wholesalers and EU format of the decision (for each copy) | 10.00 € |

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 | 2.50 € |
| postal fees | as per Slovak post fees |
| envelope | 0.20 € |