# INDIVIDUAL REGISTRATION CARD

## “XXXXXXXXXX”

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**Volunteer’s**

**initials:**

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| **Volunteer’s number** |  |  |

During screening:

### Randomization

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number:

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| --- | --- |
| Sponsor of the research | XXXXXXXXXX |
| **RESEARCH**  **ORGANIZATION** | ClinFarmInvest LLC, Russia |
| **CLINICAL CENTER** | Yaroslavl Region GAUZ Clinical hospital no.2 |
| **CHIEF RESEARCHER** | Professor, M.D. A. L. Hokhlov |

#### Yaroslavl, 2015.

##### GENERAL INSTRUCTIONS ON FILLING INDIVIDUAL

###### REGISTRATION CARD

1. Fill the IRC with black ball-point pen. Write with pressure, legibly, with block letters so that all the IRC pages could be readable.

2. Fill all the IRC sections completely and accurately. Use abbreviations “UNk”, “UNA”, or “EHO” if the information is unknown, unavailable, or if the examination hasn’t occurred respectively. Do not leave blank fields if otherwise is specified.

3. Any changes or corrections to the IRC must be crossed out without overlapping the original inscription, the corrections must be done along the initial entry; the researcher must indicate his/her initials and the entry date. (do not write on top of the previous entry, do not use the putty or eraser!).

4. The fields designed for dates shall be filled as follows: Write the date into the IRC in digits: day/month/year. Instead of unknown or incomplete dates, put a dash (for example, January 2013, | - | - | | 0 | 1 | | 2 | 0 | 1 | 3 |)

5. “Visit/procedure date”- Write down the actual visit/procedure date. These dates must be within the time periods specified in the protocol. If the visits took place beyond these time periods, the comments with the cause explanation are required (for example, violation of the visits schedule).

6. The comments shall be given only of necessity and must be short.

7. If the procedure, for example, assessment of all the crucial indicators, or only AD measuring, hasn’t occurred, write down “EHO” in the corresponding IRC section.

8. If the whole visit has not occurred, a diagonal line indicating the record absence, must be drawn at the corresponding IRC pages from one corner to the other.

9. If a volunteer quits the research prematurely, all the procedures specified for the post-clinical period, must be performed, and the obtained data must be recorded at the corresponding IRC pages “final visit” and “research completion”).

10. Continuous undesirable phenomena must be detected until their resolution, or, in the researcher’s opinion, clinical stabilization, until the volunteer completes his/her participation in the research.

11. Researcher must insure authenticity and precision of the registration information which contains in the IRC. Chief researcher or researcher (only a doctor) must sign and date the pages for UP (undesirable phenomena) and examinational results registration, as well as the pages containing the information on the research completion. Do not send these pages without signatures or dates.

12. IRC originals must be submitted to the monitor (the copies are to stay in the center).

SCREENING

DATE: |\_\_|\_\_| / |\_\_|\_\_| / |\_\_|\_\_|\_\_|\_\_|

Date, month, year

# VOLUNTEER’S INITIALS:|\_\_|\_\_|\_\_|NUMBER DURING SCREENING:|\_\_|\_\_|\_\_|

***INFORMED CONSENT: Please, pay attention: Written informed consent (the last page of patient’s information card) must be signed by the volunteer before commencement of any procedures and the actions related to the research.***

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| The volunteer was informed of the research in written and spoken form, had enough time to take a decision about taking part in the research. | □Yes □No | | | |
| Issuing date of the informed consent | |\_\_|\_\_|/|\_\_|\_\_| / |\_\_|\_\_|\_\_|\_\_|  Date, month, year | | | |
| The volunteer has asked all the important the questions and got concise replies. | □Yes □No | | | |
| Has the volunteer signed the informed consent? □\*Yes □No  \*Effective date: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  Date, month, year  *\* Note: If no, the volunteer can’t be included into the research* | | | |
| Has the consent signed and dated by the clinician? | | □Yes | □No |
| The copy of the signed Informed Consent form was handed over to the volunteer: | | □Yes | □No |
| The volunteer was handed over the original of insurance policy of the research participant: | | □Yes | □No |
| ***Note: The informed consent must be signed before any procedures specified in the research protocol, take place.*** | | | |

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| **Demographical data:** |
| Date of birth: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| Age: |\_\_|\_\_| Gender: Male □ Female □  Date, month, year  Race: Caucasian □ Other\*□  \*This parameter is the evidence that the volunteer does not comply with the inclusion/non-inclusion criteria.  Height (m): |\_\_|.|\_\_|\_\_| Weight (kg): |\_\_|\_\_|\_\_|.|\_\_| Body mass index (kg/m2): |\_\_|\_\_| . |\_\_|\*  \*Please, check the compliance with inclusion/non-inclusion criteria |

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| **Smoking:** |
| **Does the volunteer smoke?** \*Yes □ No □  Hasn’t smoked for the last three weeks Yes □ \*No □  *\** This parameter is the evidence that the volunteer does not comply with inclusion/non-inclusion criteria. |

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| **Alcohol:** |
| **Does the volunteer take alcohol?** \* Yes □ No □  \*If yes, more than 10 units per week? \* Yes □ No □  \*If more than 10 units per week*, it’s impossible to include him/her into the research!* |

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| **Taking medications:** |
| **Has the volunteer taken any medications (including depot-injections or implants of any preparations) for the last three month?**  \* Yes □ No □  \*List the preparations in the table bellow   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Preparation name** | **Active agent** | **Indications** | **Dosage** | **Starting date of the intake** | **End date of the intake** | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |

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| **Medical anamnesis:** |
| **Are there any diseases of the following organs and systems?**   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Code** | **System** | **\*Yes** | **No** |  | **Code** | **System** | **\*Yes** | **No** | |  | Cardiovascular |  |  |  | Nervous |  |  | |  | Bronchopulmonary |  |  |  | Psychical |  |  | |  | Lymphatic |  |  |  | Immune |  |  | |  | Gastrointestinal |  |  |  | Dermatologic |  |  | |  | Hepatic |  |  |  | Allergies |  |  | |  | Urino-genital |  |  |  | ENT organs |  |  | |  | Hematopoietic |  |  |  | Surgical operations |  |  | |  | Musculoskeletal |  |  |  | Other |  |  | |  | Endocrine |  |  |  |  |  |  |   **\*For those systems** where there was “Yes” reply, describe the case history and the state at the research moment in the table given bellow. |

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| **No.** | **Description of the disorders:** |
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| Physical examination**:** | | | |
| **Code** | **System** | **Norm** | **\*Deviation** |
|  | General condition |  |  |
|  | Head, neck |  |  |
|  | Heart |  |  |
|  | Lungs |  |  |
|  | Stomach |  |  |
|  | Musculoskeletal apparatus |  |  |
|  | Nervous system |  |  |
|  | Skin |  |  |
|  | Urinary system |  |  |
|  | Other |  |  |

\*In case of deviations, describe them in more details in the table given bellow.

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| **No.** | **Describe the deviation** |
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| **Main indicators of the organism state:** |
| **Measured in sitting position after 5-minute rest:**  \*Heart rate |\_\_|\_\_|\_\_| Beats per minute  \*Arterial pressure (in sitting position) |\_\_|\_\_|\_\_| / |\_\_|\_\_|\_\_| mm Mercury.  Body temperature |\_\_|\_\_|.|\_\_|°C  \*Please, check the compliance with inclusion/non-inclusion criteria |

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| **EKG in 12 abstractions:** |
| DATE: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| TIME: |\_\_|\_\_|:|\_\_|\_\_|  Date, month, year, hours, minutes  Norm □ \*Changes □  \*Please, describe  The changes\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

## Laboratory tests:

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| **General blood test:** | | | |
| Date of the blood specimen selection: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  date Date, month, year  Test Result Norm **\*Deviation** | | | |
| Red cells (1012/l) |  |  |  |
| Haemoglobin (g/l) |  |  |  |
| Platelets (109/l) |  |  |  |
| Leucocytes (109/l) |  |  |  |
| eosinophils (%) |  |  |  |
| Basocytes (%) |  |  |  |
| Neutrophile (%) |  |  |  |
| Lymphocytes (%) |  |  |  |
| Monocytes (%) |  |  |  |

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| **Biochemical blood test:** | | | |
| Date of blood specimen selection: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  date Date, month, year  Test Result Norm **\*Deviation** | | | |
| General protein (g/l) |  |  |  |
| alkaline phosphatase (Units/l) |  |  |  |
| ALT (Units/l) |  |  |  |
| AST (Units/l) |  |  |  |
| General bilirubin (mcmole/l) |  |  |  |
| creatinine (mcmole/l) |  |  |  |
| Glucose (мmole/l) |  |  |  |
| General cholesterol (mole/l) |  |  |  |
| triglycerides (mole/l) |  |  |  |

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| **General urine analysis:** | | | |
| Date of urine specimen selection: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  Date, month, year  Test Result Norm **\*Deviation** | | | |
| rN |  |  |  |
| Specific gravity |  |  |  |
| Protein (g/l) |  |  |  |
| Glucose (mole/l) |  |  |  |
| Ketone bodies (mole/l) |  |  |  |
| Bilirubin (mg/dl) |  |  |  |
| urobelinogen (mcmole/l) |  |  |  |
| Red cells (вin the field of view) |  |  |  |
| Leucocytes (in the field of view) |  |  |  |
| Epithelial cells (in the field of view) |  |  |  |
| Cylinders (in the field of view) |  |  |  |
| Yeast fungi (in the field of view) |  |  |  |
| Parasites (in the field of view) |  |  |  |
| Crystals (in the field of view) |  |  |  |

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| **Serologic examination:** | | |
| Date of blood specimen selection: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  Date, month, year  Test  **\***Positive Negative | | |
| HIV (form 50) |  |  |
| HbsAg |  |  |
| HCV |  |  |
| RW |  |  |

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| **Urine analysis on taking preparations which cause drug dependence:** | | |
| Date of urine specimen selection: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  Date, month, year  Test **\***Positive Negative | | |
| Opiates |  |  |
| Heroin |  |  |
| Morphine |  |  |
| Barbiturates |  |  |
| benzodiazepine |  |  |
| cannabinoid /Marijuana |  |  |
| Methamphetamine |  |  |
| Amphetamine |  |  |
| Cocaine |  |  |
| Methadone |  |  |
| Tricyclic antidepressants |  |  |
| 3,4-methylenedioxymethamphetamine |  |  |

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| **Cotinine Urine analysis:** |
| Date of urine specimen selection: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  Date, month, year  **\***Positive □ Negative □ |

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| **Pregnancy test (HCG):** |
| Date of urine specimen selection: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  Date, month, year  **\***Positive □ Negative □ |

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| **Inclusion criteria:** |  |
| 1. Healthy, nonsmoking women, or those women who had given up smoking not less than 3 months before the screening period, at the age of 18 to 45 years, white Caucasians with verified diagnosis: “healthy” by the record of standard clinical, laboratory and instrumental survey techniques | Yes □ *\*No* □ |
| 1. Body mass index (BMI): 18,5 ≤ BMI≤ 30 kg/m2; | Yes □ *\*No* □ |
| 1. Absence of lactation | Yes □ *\**No □ |
| 1. Negative pregnancy test | Yes □ *\*No* □ |
| 1. Wish to stick to adequate contraception methods during the whole research. Use of contraceptives during the whole period, from the moment of signing the Informed consent form, and up to seven days after the second period of the hospitalization is completed. Reliable contraception methods: a condom or a diaphragm +spermicide, whose use had started at least 14 days before the medication was taken, and the research started. If some peroral contraceptives have been used, they must be cancelled not later than 2 months before the research starts. Intrauterine hormone-free devices which were installed at least 4 weeks before the intake of the research preparations, can also be reliable contraceptive methods. | Yes □ *\**No □ |
| 1. The volunteer is capable of understanding the research requirements, signing the written informed consent, as well as agreeing to all the limitations imposed in the course of the research, and agreeing to come back to process the required researches | Yes □ *\**No □ |

*\*If a volunteer does not comply with one of the inclusion criteria, she can not be included into the research!*

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| **Non-inclusion criteria:** | |  |
| 1. Aggravated allergic history or allergic reactions to any active or additive agents contained in the both researched preparations | | *\**Yes □ No □ |
| 1. Intolerance to galactose, Lapp’s lactase deficiency and disorders of glucose/galactose absorption | | *\**Yes □ No □ |
| 1. Clinically significant diseases of cardiovascular, gastrointestinal, pulmonary, hematopoietic, immune, endocrine, urogenital system, renal and hepatic diseases, , including:  * Frequent headaches fits of migraines in the anamnesis; * Vaginal bleedings of unclear genesis in the anamnesis; * Multiple or pronounced risk factors of venous or arterial thrombosis, including complicated affections of valvular cardiac apparatus, auricular fibrillation; cerebrovascular or coronary artery diseases, venous or arterial thromboses or thromboembolisms in the anamnesis, including family anamnesis (deep vein thrombosis, thromboembolism of pulmonary artery, myocardial infarction, cerebrovascular disorders); * Hormone-dependent malignant diseases of genitals or mammal glands in the anamnesis, including family anamnesis (mother’s, sisters’); * dislipoproteinemia, hyperlipidemia, or hypertriglyceridemia currently or in anamnesis; * cholelithiasis; * diabetes mellitus with vascular complications | | *\**Yes □ No □ |
| 1. Surgical operations on gastrointestinal tract, excluding appendectomy | | *\**Yes □ No □ |
| 1. Anomaly of laboratory tests (general and biochemical blood test and urine analysis) | | *\**Yes □ No □ |
| 1. Positive pap test during the latest year | | *\**Yes □ No □ |
| 1. Acute infectious diseases less than within 4 weeks before the research | | *\**Yes □ No □ |
| 1. Other diseases which, in the researcher’s opinion, may influence the absorption, distribution, metabolism or excretion of the preparation, or increase the participation risk for the volunteer | | *\**Yes □ No □ |
| 1. HR less than 60 beats/min in the screening moment, or HR higher than 80 beats/min in the screening, or before the intake of the researched preparation in each research period | | *\**Yes □ No □ |
| 1. Clinically significant deviations in EKG, rate of systolic arterial pressure (SAP) measured in the sitting position lower than 90 mm of mercury, or higher than 130 mm of mercury, and/or diastolic arterial pressure (DAD) lower than 60 mm of mercury, or higher than 90 mm of mercury in each research period | | *\**Yes □ No □ |
| 1. Application of known hepatic function inhibitors or inductors, especially cytochrome R450 (example of inductors: barbiturates, carbamazepin, fentoin, glucocorticoids; example of inhibitors: antiviral preparations, clarithromycin, ciprofloxacin, gestoden, etc.) within 30 days before taking the first dosage | | *\**Yes □ No □ |
| 1. Application of any prescribed preparations with systemic absorption within 14 days before taking the first dosage | | *\**Yes □ No □ |
| 1. non-prescription preparations, including herbs and food additives within 7 days before taking the first dosage (including vitamins and natural food additives, phyto-additives, plant preparations such as Cat’s Claw, garden angelica, oenothera, pyrethrum, garlic, ginger, ginkgo, red clover, horse-chestnut, green tea, ginseng) | | *\**Yes □ No □ |
| 1. depot-injections or implants of any preparations within 3 months before taking the first dosage | | *\**Yes □ No □ |
| 1. if a volunteer uses peroral contraceptives- they must be cancelled not later than 2 months before the research starts | | *\**Yes □ No □ |
| 1. plasma or blood donorship (450 ml or more) less than 2 months before the research starts | | *\**Yes □ No □ |
| 1. taking more than 10 units of alcohol per week (1 unit of alcohol is equivalent to 1 liter of beer, 200 ml of wine, or 50 ml of spirit), or anamnestic information on, alcohol abuse, drug addiction, or drug misuse | | *\**Yes □ No □ |
| 1. smoking | | *\**Yes □ No □ |
| 1. participation in other clinical researches of preparations less than 3 months before the research starts | | *\**Yes □ No □ |
| 1. positive syphilis, hepatitis B, hepatitis C or HIV test during the screening | *\**Yes □ No □ |
| 1. positive pregnancy test during the screening and in every visit in the research period | *\**Yes □ No □ |
| 1. breast feeding | *\**Yes □ No □ |
| 1. positive test on the alcohol in the exhaled air in every visit for the research period | *\**Yes □ No □ |
| 1. positive urine analysis on use of preparations causing drug dependence during the screening and in every visit for the research period (opiates/morphine /heroin, methamphetamine, amphetamine, barbiturates, benzodiazepine, cannabinoids/marijuana, cocaine, methadone, tricyclic antidepressants, 3,4-methylenedioxymethamphetamine) and cotinine test | *\**Yes □ No □ |
| 1. the volunteers who are not intended to observe the routine of the research/or those who are untrustworthy, as well as the volunteers who evidently or likely, in the researcher’s opinion, are incapable of understanding and evaluating the information on this research in the frameworks of IC signing process, in particular, in respect of risk assessment and possible discomfort | *\**Yes □ No □ |
| 1. the volunteers who are expected to have problems with placing venous catheters or performing venipuncture; | *\**Yes □ No □ |
| 1. female volunteers with child bearing potential who had unprotected sexual intercourse with any unsterilized male partner within 14 days before taking the researched preparations. | *\**Yes □ No □ |
| 1. female volunteers in the first stage of menstrual cycle (from 1st to 15th day) at the batching moment. | *\**Yes □ No □ |

*\*If a volunteer complies with one non-inclusion criteria, he/she can not be included into the research!*

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| **Screening results (researcher’s conclusion):** | |
| Has the volunteer signed the patient’s informed list with Informed Consent form | Yes □ No □ |
| The volunteer has passed all the screening procedures | Yes □ No □ |
| The results of laboratory tests comply with normal values | Yes □ No □ |
| The volunteer conforms to all the inclusion/non-inclusion criteria | Yes □ No □ |
| The volunteer has been included into the research | Yes □ No □ |
| The volunteer has been informed of the participation rules. The volunteer agrees to observe these requirements. | Yes □ No □ |

Researcher’s name (full)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|

Date, month, year

**1st Research period**

**Day 1**

DATE: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| TIME OF THE VISIT TO THE CLINIC: |\_\_|\_\_|:|\_\_|\_\_|

Date, month, year, hours, minutes

|  |  |
| --- | --- |
| Have there been any undesirable phenomena since the last visit? | No □ **\***Yes □→ Please, check the inclusion/non-inclusion criteria. |
| Have there been any changes in medical history since the last visit? | No □ **\***Yes □ → Please, check inclusion/non-inclusion criteria. |
| Have there been any changes in the concurrent therapy since the last visit? | No □ \*\*Yes □ → Please, check inclusion/non-inclusion criteria and fill the concurrent therapy form. |
| Has the volunteer observed the limitations specified in the research protocol? | Yes □ No □→ Please, check inclusion/non-inclusion criteria. |

\* Complete the ‘undesirable phenomena registration’ form on p. 49

\*\* Complete ‘Concurrent therapy’ form on p. 51

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| **Test on alcohol in the exhaled air:** |
| Test date: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  Date, month, year  **\***Positive □ Negative □ |

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| **Pregnancy test (HCG):** |
| Date of urine specimen selection: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  Date, month, year  **\***Positive □ Negative □ |

\* If the result is positive, the volunteer is excluded from the research

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| **Urine analysis on the preparations which cause drug dependence:** | | |
| Date of urine specimen selection: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  date month year  Test **\***Positive Negative | | |
| Opiates/Heroin/Morphine |  |  |
| Barbiturates |  |  |
| benzodiazepine |  |  |
| Canabinoid/Marijuana |  |  |
| Methamphetamine |  |  |
| Amphetamine |  |  |
| Cocaine |  |  |
| Methadone |  |  |
| Tricyclic antidepressants |  |  |
| 3,4-methylenedioxymethamphetamine |  |  |

\*If the test is Positive, the volunteer is excluded from the research

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| **Main indicators of the organism state:** |
| **Measured in sitting position after 5-minute rest:**  Volunteer’s complaints: No □ **\***Yes □ (Please, check inclusion/non-inclusion criteria).  Heart rate |\_\_|\_\_|\_\_| Beats/min\*\*  Arterial pressure (in sitting position) |\_\_|\_\_|\_\_| / |\_\_|\_\_|\_\_| mm of mercury\*\*  Body temperature|\_\_|\_\_|.|\_\_|°C |

\* Complete ‘Undesirable phenomena registration’ form on p. 49

\*\*If systolic AP is < 90 mm of mercury or > 130 mm of mercury; diastolic AP is < 60 mm of mercury or > 90 mm of mercury; Heart rate is < 60 /1’ or > 90 /1’ - it is necessary to repeat arterial pressure measuring, complete the ‘Additional hemodynamic test measuring’ form on p. 28

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| **Physical examination:** | | | |
| **Code** | **System** | **Norm** | **\*Deviations** |
|  | General condition |  |  |
|  | Head, neck |  |  |
|  | Heart |  |  |
|  | Lungs |  |  |
|  | Stomach |  |  |
|  | Musculoskeletal apparatus |  |  |
|  | Nervous system |  |  |
|  | Skin |  |  |
|  | Urinary system |  |  |
|  | Other |  |  |

\*Complete the ‘Undesirable phenomena registration’ form on p. 49

**Has the volunteer still complied with all the inclusion/non-inclusion criteria?**

#### Yes □ No □

\*The volunteer can not continue participation in the research

## Has the volunteer been placed in a hospital?

Yes □ \*No □

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| **Randomization:** |
| |  |  |  | | --- | --- | --- | |  |  |  |   **Volunteer’s randomization code:** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Food and drink intake:** | | | |
| **Relative time** | **Real time** | **Food or drinks** | **Comments** |
| 1st day (at least 10 hours before taking the preparation) | \_\_\_\_\_:\_\_\_\_\_ | Supper |  |
| 1st day (-01:00) | \_\_\_\_\_:\_\_\_\_\_ | Intake of 200 ml of water (along with the preparation) |  |
| 1st day (00:00) | \_\_\_\_\_:\_\_\_\_\_ | Intake of 200 ml of water (along with the preparation) |  |
| 1st day (+02:00) | \_\_\_\_\_:\_\_\_\_\_ | Intake of 200 ml ofwater |  |
| 1st day (+04:00) | \_\_\_\_\_:\_\_\_\_\_ | Breakfast |  |
| 1st day (+06:00) | \_\_\_\_\_:\_\_\_\_\_ | Lunch |  |
| 1st day (+09:00) | \_\_\_\_\_:\_\_\_\_\_ | Dinner |  |
| 1st day (+13:00) | \_\_\_\_\_:\_\_\_\_\_ | Supper |  |
| 2nd day | \_\_\_\_\_:\_\_\_\_\_ | Breakfast |  |
| 2nd day | \_\_\_\_\_:\_\_\_\_\_ | Lunch |  |
| 2nd day | \_\_\_\_\_:\_\_\_\_\_ | Dinner |  |
| 2nd day | \_\_\_\_\_:\_\_\_\_\_ | Supper |  |

### Day 1

Date: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|

date month year

|  |
| --- |
| **Health state control before taking the preparation and placing the catheter:** |
| **Measured in sitting position after 5-minute rest:**  Volunteer’s complaints: No □ **\***Yes □ →Please, check inclusion/non-inclusion criteria).  Heart rate |\_\_|\_\_|\_\_| Beats/min \*\*  Arterial pressure (in sitting position) |\_\_|\_\_|\_\_| / |\_\_|\_\_|\_\_|mm of mercury \*\* |

• Complete the ‘Undesirable phenomena registration’ form on p. 49

\*\*If systolic AP is < 90 mm of mercury or > 130 mm of mercury; diastolic AP is < 60 mm of mercury or > 90 mm of mercury; the heart rate is < 60/1’ or > 90/1’, it is necessary to repeat arterial pressure measuring, complete the ‘Additional hemodynamic tests measuring’ form on p. 28

|  |  |  |  |
| --- | --- | --- | --- |
| **Physical examination:** | | | |
| **Code** | **System** | **Norm** | **\*Deviations** |
|  | General condition |  |  |
|  | Head, neck |  |  |
|  | Heart |  |  |
|  | Lungs |  |  |
|  | Stomach |  |  |
|  | Musculoskeletal apparatus |  |  |
|  | Nervous system |  |  |
|  | Skin |  |  |
|  | Urinary system |  |  |
|  | Other |  |  |

\*Complete the ‘Undesirable phenomena registration’ form on p. 75

|  |
| --- |
| **Taking the preparation:** |
| **Preparation:**  □ valsartan+ indapamide 160 mg/1,5 mg tablets (Gedeon Richter, Hungary)  □ diovan® tablets covered with film membrane (Novartis Pharma AG, Switzerland) and arifon® retard 1,5mg tablets with controlled release covered with film membrane (Servier Laboratory, France)   |  | | --- | | Planned dosage time  └─┴─┘:└─┴─┘  hh mm | | Real dosage time └─┴─┘:└─┴─┘  hh mm | | Deviations from the protocol while taking the preparation: YES □ NO □ |   **The preparation intake has been checked:** YES □ NO □  **The volunteer’s hands and mouth cavity were checked after the dosing:** YES □ NO □  **Signature of the person in charge: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

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| **Health state control in 8 hours after the preparation has been taken:** |
| **Measured in sitting position after 5-minute rest:**  Volunteer’s complaints: No □ **\***Yes □ →Please, check inclusion-non-inclusion criteria.  Heart rate |\_\_|\_\_|\_\_| Beats/min\*\*  Arterial pressure (in sitting position) |\_\_|\_\_|\_\_| / |\_\_|\_\_|\_\_| mm of mercury |

\* Complete the ‘Undesirable phenomena registration’ form on p. 49

\*\*If systolic AP is < 90 mm of mercury or > 130 mm of mercury; diastolic AP is < 60 mm of mercury or > 90 mm of mercury; Heart rate is < 60 /1’ or > 90 /1’ -, it is necessary to repeat arterial pressure measuring, complete the ‘Additional hemodynamic test measuring’ form on p. 28

|  |
| --- |
| **Health state control in 12 hours after taking the preparation:** |
| **Measured in sitting position after 5-minute rest:**  Volunteer’s complaints: No □ **\***Yes □ (Please, check inclusion/non-inclusion criteria).  Heart rate |\_\_|\_\_|\_\_| Beats/min\*\*  Arterial pressure (in sitting position) |\_\_|\_\_|\_\_| / |\_\_|\_\_|\_\_| mm of mercury\*\* |

\* Complete the ‘Undesirable phenomena registration’ form on p. 49

\*\*If systolic AP is < 90 mm of mercury or > 130 mm of mercury; diastolic AP is < 60 mm of mercury or > 90 mm of mercury; Heart rate is < 60 /1’ or > 90 /1’ - it is necessary to repeat arterial pressure measuring, complete the ‘Additional hemodynamic tests measuring’ form on p. 28

**Day2**

|  |  |  |  |
| --- | --- | --- | --- |
| **Health state control in 24 hours after taking the preparation:** | | | |
| **Measured in sitting position after 5-minute rest:**  Volunteer’s complaints: No □ \*Yes □ (Please, check inclusion/non-inclusion criteria).  Heart rate |\_\_|\_\_|\_\_| Beats/min\*\*  Arterial pressure (in sitting position) |\_\_|\_\_|\_\_| / |\_\_|\_\_|\_\_| mm of mercury\*\* | | | |
| \* Complete ‘Undesirable phenomena registration’ form on p. 49  \*\*If systolic AP is < 90 mm of mercury or > 130 mm of mercury; diastolic AP is < 60 mm of mercury or > 90 mm of mercury; Heart rate is < 60 /1’ or > 90/1’ - it is necessary to repeat arterial pressure measuring, complete the ‘Additional hemodynamic test measuring’ form on p. 28 | | | |
| **Physical examination:** | | | |
| **Code** | **System** | **Norm** | **\*Deviation** |
|  | General condition |  |  |
|  | Head, neck |  |  |
|  | Heart |  |  |
|  | Lungs |  |  |
|  | Stomach |  |  |
|  | Musculoskeletal apparatus |  |  |
|  | Nervous system |  |  |
|  | Skin |  |  |
|  | Urinary system |  |  |
|  | Other |  |  |

\*Complete the ‘Undesirable phenomena registration’ form on p. 49

|  |
| --- |
| **Health state control in 36 hours after taking the preparation:** |
| **Measured in sitting position after 5-minute rest:**  Volunteer’s complaints: No □ **\***Yes □ (Please, check inclusion/non-inclusion criteria).  Heart rate |\_\_|\_\_|\_\_| Beats/min\*\*  Arterial pressure (in sitting position) |\_\_|\_\_|\_\_| / |\_\_|\_\_|\_\_| mm of mercury\*\* |

\* Complete the ‘Undesirable phenomena registration’ form on p. 49

\*\*If sistolic AP is < 90 mm of mercury or > 130 mm of mercury; diastolic AP is < 60 mm of mercury or > 90 mm of mercury; Heart rate is < 60/1’ or > 90/1’ - it is necessary to repeat arterial pressure measuring, complete the ‘Additional hemodynamic test measuring’ form on p. 28

**Day 3**

|  |  |  |  |
| --- | --- | --- | --- |
| **Health state control in 48 hours after taking the preparation:** | | | |
| **Measured in sitting position after 5-minute rest:**  Volunteer’s complaints: No □ **\***Yes □ (Please, check inclusion/non-inclusion criteria).  Heart rate |\_\_|\_\_|\_\_| Beats/min\*\*  Arterial pressure (in sitting position) |\_\_|\_\_|\_\_| / |\_\_|\_\_|\_\_| mm of mercury\*\* | | | |
| \* Complete ‘Undesirable phenomena registration’ form on p. 49  \*\*If sistolic AP is < 90 mm of mercury or > 130 mm of mercury; diastolic AP is < 60mm of mercury or > 90 mm of mercury; Heart rate is < 60/1’ or > 90/1’ - it is necessary to repeat arterial pressure measuring, complete the ‘Additional hemodynamic test measuring’ form on p. 28 | | | |
| **Physical examination:** | | | |
| **Code** | **System** | **Norm** | **\*Deviation** |
|  | General condition |  |  |
|  | Head, neck |  |  |
|  | Heart |  |  |
|  | Lungs |  |  |
|  | Stomach |  |  |
|  | Musculoskeletal apparatus |  |  |
|  | Nervous system |  |  |
|  | Skin |  |  |
|  | Urinary system |  |  |
|  | Other |  |  |

\*Complete the ‘Undesirable phenomena registration’ form on p. 49

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sampling of blood specimen – 1st period** | | | | |
| **Time after the preparation intake, hrs** | **Time of blood sampling** | | | **Time deviations from the protocol** |
| **Planned** | | **Factual** |
| Before the preparation intake | |\_\_|\_\_|:|\_\_|\_\_| | | |\_\_|\_\_|:|\_\_|\_\_| | YES□ NO□Time: |\_\_|\_\_|:|\_\_|\_\_|Code: |\_\_| |
| Batching | |\_\_|\_\_|:|\_\_|\_\_| | | | |
| 0:30 hrs | |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|:|\_\_|\_\_| | | YES□ NO□ Time: |\_\_|\_\_|:|\_\_|\_\_|Code: |\_\_| |
| 0:45 hrs | |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|:|\_\_|\_\_| | | YES□ NO□ Time: |\_\_|\_\_|:|\_\_|\_\_|Code: |\_\_| |
| 1:00 hrs | |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|:|\_\_|\_\_| | | YES□ NO□ Time: |\_\_|\_\_|:|\_\_|\_\_|Code: |\_\_| |
| 1:30 hrs | |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|:|\_\_|\_\_| | | YES□ NO□ Time: |\_\_|\_\_|:|\_\_|\_\_|Code: |\_\_| |
| 2:00 hrs | |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|:|\_\_|\_\_| | | YES□ NO□ Time: |\_\_|\_\_|:|\_\_|\_\_| Code: |\_\_| |
| 1:30 hrs | |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|:|\_\_|\_\_| | | YES□ NO□ Time: |\_\_|\_\_|:|\_\_|\_\_| Code: |\_\_| |
| 1:45 hrs | |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|:|\_\_|\_\_| | | YES□ NO□ Time: |\_\_|\_\_|:|\_\_|\_\_| Code: |\_\_| |
| 2:00 hrs | |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|:|\_\_|\_\_| | | YES□ NO□ Time: |\_\_|\_\_|:|\_\_|\_\_|Code: |\_\_| |
| 2:40 hrs | |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|:|\_\_|\_\_| | | YES□ NO□ Time: |\_\_|\_\_|:|\_\_|\_\_| Code: |\_\_| |
| 3:00 hrs | |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|:|\_\_|\_\_| | | YES□ NO□ Time: |\_\_|\_\_|:|\_\_|\_\_| Code: |\_\_| |
| 4:00 hrs | |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|:|\_\_|\_\_| | | YES□ NO□ Time: |\_\_|\_\_|:|\_\_|\_\_|Code: |\_\_| |
| 6:00 hrs | |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|:|\_\_|\_\_| | | YES□ NO□ Time: |\_\_|\_\_|:|\_\_|\_\_| Code: |\_\_| |
| 9:00 hrs | |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|:|\_\_|\_\_| | | YES□ NO□ Time: |\_\_|\_\_|:|\_\_|\_\_| Code: |\_\_| |
| 12:00 hrs | |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|:|\_\_|\_\_| | | YES□ NO□ Time: |\_\_|\_\_|:|\_\_|\_\_|Code: |\_\_| |
| 16:00 hrs | |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|:|\_\_|\_\_| | | YES□ NO□ Time: |\_\_|\_\_|:|\_\_|\_\_|Code: |\_\_| |
| 24:00 hrs | |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|:|\_\_|\_\_| | | YES□ NO□ Time: |\_\_|\_\_|:|\_\_|\_\_| Code: |\_\_| |
| 36:00 hrs | |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|:|\_\_|\_\_| | | YES□ NO□ Time: |\_\_|\_\_|:|\_\_|\_\_| Code: |\_\_| |
| 48:00 hrs | |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|:|\_\_|\_\_| | | YES□ NO□ Time: |\_\_|\_\_|:|\_\_|\_\_| Code: |\_\_| |

**Time deviation codes from the research protocol:**

A – The volunteer hasn’t arrived at the appointed time

B – Due to technical problems

C – Difficulties with blood sampling

D – Undesirable phenomena

E – Other

F – Unknown reason

G – Time has not been recorded

|  |
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| **Out-patient visit, day 4:** |
| Date: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| TIME OF THE VISIT: |\_\_|\_\_|:|\_\_|\_\_|  date month year hours minutes   |  |  | | --- | --- | | Have there been any undesirable phenomena since the last visit? | No □ **\***Yes □→Please, check inclusion/non-inclusion criteria). | | Have there been any changes in the medical history since the last visit? | No □ **\***Yes □ (Please, check inclusion/non-inclusion criteria). | | Have there been any changes in the concurrent therapy since the last visit? | No □ \*\*Yes □ (Please, check inclusion/non-inclusion criteria) and complete concurrent therapy form. | | Has the volunteer observed the limitations specified in the protocol? | Yes □ No □(Please, check inclusion/non-inclusion criteria). |   **\***Complete the ‘Undesirable phenomena registration’ form on p. 49  \*\*Complete ‘concurrent therapy’ form on p. 51   |  | | --- | | **Main indicators of the organism state:** | | **Measured in sitting position after 5-minute rest:**  Volunteer’s complaints: No □ **\***Yes □ (Please, check inclusion/non-inclusion criteria).  Heart rate |\_\_|\_\_|\_\_| Beats/min\*\*  Arterial pressure (in sitting position) |\_\_|\_\_|\_\_| / |\_\_|\_\_|\_\_| mm of mercury\*\*  Body temperature |\_\_|\_\_|.|\_\_|°C |   \* Complete ‘Undesirable phenomena registration’ form on p. 49  \*\*If sistolic AP is < 90 mm of mercury or > 130 mm of mercury; diastolic AP is < 60 mm of mercury or > 90 mm of mercury; Heart rate is < 60/1’ or > 90/1’ - it is necessary to repeat arterial pressure measuring, complete the ‘Additional hemodynamic test measuring’ form on p. 28   |  |  |  |  | | --- | --- | --- | --- | | **Physical examination:** | | | | | **Code** | **System** | **Norm** | **\*Deviation** | |  | General condition |  |  | |  | Head, neck |  |  | |  | Heart |  |  | |  | Lungs |  |  | |  | Stomach |  |  | |  | Musculoskeletal apparatus |  |  | |  | Nervous system |  |  | |  | Skin |  |  | |  | Urinary system |  |  | |  | Other |  |  |   **\***Complete the ‘Undesirable phenomena registration’ form on p. 49   |  |  |  |  | | --- | --- | --- | --- | | **Blood speciman selection:** | | | | | **Time after the preparation intake, hrs** | **Time of blood sampling** | | **Time deviation from the protocol** | | **Planned** | **Factual** | | 72:00 hrs | |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|:|\_\_|\_\_| | YES□ NO□ Time: |\_\_|\_\_|:|\_\_|\_\_|  Code: |\_\_| | |

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| --- |
| **Additional hemodynamic test measuring:** |
| **Date:** |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| **Time:** |\_\_|\_\_|:|\_\_|\_\_|  date month year hours minutes  **Measured in sitting position after 5-minute rest:**  Volunteer’s complaints: No □ **\***Yes □ (Please, check inclusion/non-inclusion criteria).  Heart rate |\_\_|\_\_|\_\_| Beats/min\*\*  Arterial pressure (in sitting position) |\_\_|\_\_|\_\_| / |\_\_|\_\_|\_\_| mm of mercury\*\* |
| **Date:** |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| **Time:** |\_\_|\_\_|:|\_\_|\_\_|  date month year hours minutes  **Measured in sitting position after 5-minute rest:**  Volunteer’s complaints: No □ **\***Yes □ (Please, check inclusion/non-inclusion criteria).  Heart rate |\_\_|\_\_|\_\_| Beats/min\*\*  Arterial pressure (in sitting position) |\_\_|\_\_|\_\_| / |\_\_|\_\_|\_\_| mm of mercury\*\* |
| **Date:** |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| **Time:** |\_\_|\_\_|:|\_\_|\_\_|  date month year hours minutes  **Measured in sitting position after 5-minute rest:**  Volunteer’s complaints: No □ **\***Yes □ (Please, check inclusion/non-inclusion criteria).  Heart rate |\_\_|\_\_|\_\_| Beats/min\*\*  Arterial pressure (in sitting position) |\_\_|\_\_|\_\_| / |\_\_|\_\_|\_\_| mm of mercury\*\* |
| **Date:** |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| **Time:** |\_\_|\_\_|:|\_\_|\_\_|  date month year hours minutes  **Measured in sitting position after 5-minute rest:**  Volunteer’s complaints: No □ **\***Yes □ (Please, check inclusion/non-inclusion criteria).  Heart rate |\_\_|\_\_|\_\_| Beats/min\*\*  Arterial pressure (in sitting position) |\_\_|\_\_|\_\_| / |\_\_|\_\_|\_\_| mm of mercury\*\* |
| **Date:** |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| **Time:** |\_\_|\_\_|:|\_\_|\_\_|  date month year hours minutes  **Measured in sitting position after 5-minute rest:**  Volunteer’s complaints: No □ **\***Yes □ (Please, check inclusion/non-inclusion criteria).  Heart rate |\_\_|\_\_|\_\_| Beats/min\*\*  Arterial pressure (in sitting position) |\_\_|\_\_|\_\_| / |\_\_|\_\_|\_\_| mm of mercury\*\* |
| **Date:** |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| **Time:** |\_\_|\_\_|:|\_\_|\_\_|  date month year hours minutes  **Measured in sitting position after 5-minute rest:**  Volunteer’s complaints: No □ **\***Yes □ (Please, check inclusion/non-inclusion criteria).  Heart rate |\_\_|\_\_|\_\_| Beats/min\*\*  Arterial pressure (in sitting position) |\_\_|\_\_|\_\_| / |\_\_|\_\_|\_\_| mm of mercury\*\* |

\* Complete the ‘Undesirable phenomena registration’ form on p. 49

\*\*If sistolic AP is < 90 mm of mercury or > 130 mm of mercury; diastolic AP is < 60 mm of mercury or > 90 mm of mercury; Heart rate is < 60/1’ or > 90/1’ , it is necessary to complete the ‘undesirable phenomena registration’ form on p. 49

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| --- |
| **Final medical examination:** |
| **Date:** |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| **Time:** |\_\_|\_\_|:|\_\_|\_\_|  date month year hours minutes  **Measured in sitting position after 5-minute rest:**  Volunteer’s complaints: No □ **\***Yes □ (Please, check inclusion/non-inclusion criteria).  Heart rate |\_\_|\_\_|\_\_| Beats/min\*\*  Arterial pressure (in sitting position) |\_\_|\_\_|\_\_| / |\_\_|\_\_|\_\_| mm of mercury\*\*  \* Complete the ‘Undesirable phenomena registration’ form on p. 49  \*\*If sistolic AP is < 90 mm of mercury or > 130 mm of mercury; diastolic AP is < 60 mm of mercury or > 90 mm of mercury; Heart rate is < 60/1’ or > 90 /1’ , it is necessary to complete the ‘Undesirable phenomena registration’ form on p. 49  **Has the volunteer had any undesirable phenomena since the moment of the preparation intake?**  \*YES □ NO □  If “YES”, please, complete the ‘Undesirable phenomena registration’ form on p. 75 and ‘Concurrent therapy’ (if required) on p. 77  **HAS THE VOLUNTEER FINISHED THE RESEARCH PREMATURELY?**  YES\*□ NO□  If “YES», please, do all the final visit procedures and complete the page 46 |

|  |
| --- |
| **Final medical examination:** |
| **Date:** |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| **Time:** |\_\_|\_\_|:|\_\_|\_\_|  date month year hours minutes  **Measured in sitting position after 5-minute rest:**  Volunteer’s complaints: No □ **\***Yes □ (Please, check inclusion/non-inclusion criteria).  Heart rate |\_\_|\_\_|\_\_| Beats/min\*\*  Arterial pressure (in sitting position) |\_\_|\_\_|\_\_| / |\_\_|\_\_|\_\_| mm of mercury \*\*  \*Complete the ‘Undesirable phenomena registration’ form on p. 75  \*\*If sistolic AP is < 90 mm of mercury or > 130 mm of mercury; diastolic AP is < 60 mm of mercury or > 90 mm of mercury; Heart rate is < 60/1’ or > 90/1’ , it is necessary to complete the ‘Undesirable phenomena registration’ form on p. 75   |  |  |  |  | | --- | --- | --- | --- | | **Physical examination:** | | | | | **Code** | **System** | **Norm** | **\*Deviation** | |  | General condition |  |  | |  | Head, neck |  |  | |  | Heart |  |  | |  | Lungs |  |  | |  | Stomach |  |  | |  | Musculoskeletal apparatus |  |  | |  | Nervous system |  |  | |  | Skin |  |  | |  | Urinary system |  |  | |  | Other |  |  |   **\*Complete the ‘Undesirable phenomena registration’ form on p**. 75  **Has the volunteer had any undesirable phenomena since the moment of the preparation intake?**  \*YES □ NO□  If “YES”, please, complete the ‘Undesirable phenomena registration’ form on p. 75 and ‘Concurrent therapy’ (if required) on p. 77  **HAS THE VOLUNTEER FINISHED THE RESEARCH PREMATURELY?**  YES\*□ NO □  If “YES”, please, do all the final visit procedures and complete p. 72 |

##### Laboratory tests on the research completion:

|  |  |  |  |
| --- | --- | --- | --- |
| **General blood test:** | | | |
| Date of blood specimen sampling: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  date month year  Test Result Norm **\*Deviation** | | | |
| Red cells (1012/l) |  |  |  |
| Haemoglobin (g/l) |  |  |  |
| Platelets (109/) |  |  |  |
| Leucocytes (109/л) |  |  |  |
| eosinophils (%) |  |  |  |
| Basocytes (%) |  |  |  |
| Neutrophile (%) |  |  |  |
| Lymphocytes (%) |  |  |  |
| Monocytes (%) |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Biochemical blood test:** | | | |
| Date of blood specimen selection: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  date month year  Test Result Norm **\*Deviation** | | | |
| General protein (g/l) |  |  |  |
| alkaline phosphatase (Units/l) |  |  |  |
| ALT (units/l) |  |  |  |
| AST (Units/l) |  |  |  |
| General bilirubin (mcmole/l) |  |  |  |
| Creatinine (mcmole/l) |  |  |  |
| Glucose (mole/l) |  |  |  |
| General cholesterol (mole/l) |  |  |  |
| triglycerides (mole/l) |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **General urine analysis:** | | | |
| Date of urine specimen selection: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  date month year  Test Result Norm **\*Deviation** | | | |
| rN |  |  |  |
| Specific gravity |  |  |  |
| Protein (g/l) |  |  |  |
| Glucose (mole/l) |  |  |  |
| Ketone bodies (mole/l) |  |  |  |
| Bilirubin (mg/dl) |  |  |  |
| Urobilinogen (mcmole/l) |  |  |  |
| Red cells (in the field of view) |  |  |  |
| Leucocytes (in the field of view) |  |  |  |
| Epithelial cells (in the field of view) |  |  |  |
| Cylinders (in the field of view) |  |  |  |
| Yeast fungi (in the field of view) |  |  |  |
| Parasites (in the field of view) |  |  |  |
| Crystals (in the field of view) |  |  |  |

|  |
| --- |
| **Research completion:** |
| **Date:** |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| **Time:** |\_\_|\_\_|:|\_\_|\_\_|  date month year hours minutes  **The volunteer has completely finished participation in the research:** YES □ \*NO □  \*By which reason**?**:  □ non-observance of the protocol requirements or a serious violation of the protocol  □ development of an undesirable phenomena, or any other condition which, in the researcher’s opinion, does not insure safe participation in this research for this probationer  □ positive test on alcohol in the exhaled air  □ positive pregnancy test  □ the volunteer’s wish to quit the research  □positive urine analysis on the preparations which cause drug dependence  □ Occurrence of nausea in the volunteer within 5 hours since the moment of the preparation intake  □ occurrence of diarrhea in the volunteer (in case of 3 watery stool episodes within 2 hours)  □a severe disease or intolerance of the researched preparation  □another reason:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| --- |
| **Deviations from the protocol:** |
| **Have there been any deviations from the protocol during the research?**  **YES\*□ NO□**  \*If YES, please, describe:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **A check phone call in 7 days:** |
| **Date:** |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  date month year  **Has the volunteer had any undesirable phenomena since the moment of the preparation intake?**  \*YES □NO □  \*Complete the ‘Undesirable phenomena registration’ form on p.49  And ’concurrent therapy’ (if required) on p. 51 |

### Researcher’s name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|

date month year

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| No concurrent diseases and/or undesirable phenomena | Degree of severity |  | Severity codes | |
| 1 = Slight  2 =Moderate  3 =Severe |  | 1 =Death  2 =Dangerous for life  3 = Hospitalization  4 = Hospitalization prolongation | 5 = Disability  6 = congenital malformation |

Undesirable phenomena registration

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| No. | Disease/undesirable phenomenon description | Starting date (Day / month/ year) Time | Severity | Measures taken | Connection with the researched preparation | Is the UP serious? If YES, specify the code() | Result |
| Finishing date (Day / month/ year) |
|  |  | \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_  \_\_\_\_:\_\_\_\_ |  | **🞏** No | -Particular  -Probable  Possible  Doubtful  Conditional  Generalized | **n** No  If Yes, specify the severity code(s)  \_\_\_\_\_\_\_\_\_\_\_ | - Complete resolution  - Incomplete resolution  - The result is unknown  - Death |
| **🞏Other**: |
| \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ |
|  |  | \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_  \_\_\_\_:\_\_\_\_ |  | **🞏** No. | - Particular  - Probable  - Possible  -Doubtful  - Conditional  - Generalized | **n** No  If Yes, specify the severity code(s)  \_\_\_\_\_\_\_\_\_\_\_ | - Complete resolution  - Incomplete resolution  - The result is unknown  - Death |
| **🞏Other**: |
| \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ |
|  |  | \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_  \_\_\_\_:\_\_\_\_ |  | **🞏** No. | - Particular  - Probable  -Possible  - Doubtful  - Conditional  - Generalized | nNo  If Yes, specify the severity code(s)  \_\_\_\_\_\_\_\_\_\_\_ | - Complete resolution  - Incomplete resolution  - The result is unknown  - Death |
| **🞏Other**: |
| \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ |

Hereby I certify that all the information has been registered completely and accurately.

Date: «\_\_\_\_»\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 201 Chief researcher’s signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| No concurrent diseases and/or undesirable phenomena | Degree of severity |  | Severity codes | |
| 1 = Slight  2 =Moderate  3 =Severe |  | 1 =Death  2 =Dangerous for life  3 = Hospitalization  4 = Hospitalization prolongation | 5 = Disability  6 = Congenital malformation |

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| --- | --- | --- | --- | --- | --- | --- | --- |
| No. | The disease/undesirable phenomenon description | Starting date (Day / month/ year) Time | Severity | Measures taken | Connection with the researched preparation | Is the UP serious? If YES, specify the code(s) | Result |
| Finishing date (Day / month / year) |
|  |  | \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_  \_\_\_\_:\_\_\_\_ |  | **🞏** No. | - Particular  - Probable  - Possible  - Doubtful  - Conditional  - Generalized | **n** No  If Yes, specify the severity code(s)  \_\_\_\_\_\_\_\_\_\_\_ | - Complete resolution  - Incomplete resolution  - The result is unknown  - Death |
| **🞏Other**: |
| \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ |
|  |  | \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_  \_\_\_\_:\_\_\_\_ |  | **🞏** No. | - Particular  - Probable  - Possible  - Doubtful  - Conditional  - Generalized | **n** No  If Yes, specify the severity code(s)  \_\_\_\_\_\_\_\_\_\_\_ | - Complete resolution  - Incomplete resolution  - The result is unknown  - Death |
| **🞏Other**: |
| \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ |
|  |  | \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_  \_\_\_\_:\_\_\_\_ |  | **🞏** No. | - Particular  - Probable  - Possible  - Doubtful  - Conditional  - Generalized | **n** No  If Yes, specify the severity code(s)  \_\_\_\_\_\_\_\_\_\_\_ | - Complete resolution  - Incomplete resolution  - The result is unknown  - Death |
| **🞏Other**: |
| \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ |

Hereby I certify that all the information has been registered completely and accurately.

Date: «\_\_\_\_»\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 201 Chief researcher’s signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

##### If there is a serious undesirable phenomenon, it is necessary to complete the form of SUP notification!

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Noconcurrent therapy. Concurrent therapy. | | | | | |
| Indications for a preparation intake. | Brand name. | Daily dosage. | Application method\*. | Starting date (day/month/year). | Finishing date  (day/month/year) |
|  |  |  |  |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  🞏Continues. |
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|  |  |  |  |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  🞏Continues. |
| \*1- Peroral; 2- Intravenously; 3- Intramuscularly; 4- Hypodermic; 5- Rectal; 6- Local; 7- Inhalation; 8- Other. | | | | | |
| Please, check inclusion/non-inclusion/exclusion criteria. | | | | | |
|  | | | | | |

Researcher’s name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|

Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­\_\_\_\_\_\_\_\_\_\_\_