MINISTRY OF HEALTH OF UKRAINE
National University of Pharmacy

"APPROVED"
First Vice-Rector of NUPh
Professor I. S. Gritsenko
<Signature>

«01» 09 2006
<Seal: Ministry of Health of Ukraine; National University of Pharmacy; No. 02010936>

PROGRAM
of Clinical Testing

of Medical-Purpose Item
"AMP Noninvasive Hemogram Analyzer as per Specification ТУ У 33.1-22716816-001:2006"
Code 9018 19 90 10 under Ukrainian Index of Export-Import Products (UKTZED)
Manufactured by Research and Production Complex "Biopromin" Ltd (Ukraine)

«AGREED»
Executive Manager:
[Signature] S. B. Popov
«1» 09 2006
«AGREED»
Method Developer,
Chief Researcher of Neurology, Psychiatry and Addictology Institute of Academy of Medical Sciences of Ukraine, M.D.
[Signature] A. V. Malykhin
«1» 09 2006
«AGREED»
Director of RPC "Biopromin" Ltd.
[Signature] A. A. Pulavsky
«1» 09 2006

[Seal:
Ukraine, Kharkiv No. 22716816
Limited Liability Company Research and Production Complex "Biopromin"]

Kharkiv - 2006

1. Grounds for Performing Clinical Testing (CT)

1.1. Clinical testing (CT) is performed in conformity with the Assignment of the State Service of Medical Products and Medical-Purpose Items No. 6 BM - 1789/н dated August 03, 2006

1.2. Applicant's inquiry on the possibility of performing CT:

□ yes

□ no

2. Subject of Clinical Testing (SCT): "AMP Noninvasive Hemogram Analyzer as per Specification ТУ У 33.1-22716816-001:2006" UKTZED Code 9018 19 90 10

2.1.SCT data:

2.1.1. SCT full name: "AMP Noninvasive Hemogram Analyzer as per Specification ТУ У 33.1-22716816-001:2006" UKTZED Code 9018 19 90 10 manufactured by Research and Production Complex "Biopromin" Ltd (Ukraine)

2.1.2. Short name: "AMP Noninvasive Hemogram Analyzer as per Specification ТУ У 33.1-22716816-001:2006" UKTZED Code 9018 19 90 10

2.1.3. Manufacturer: Research and Production Complex "Biopromin" Ltd (Ukraine)

2.2. Designation: SCT is designed for obtaining patient's complete blood count (quantity of erythrocytes, quantity of hemoglobin, quantity of leucocytes, quantity of lymphocytes) without taking blood sample with further processing by USPIH software

2.3. Major principle: automatic noninvasive determination of blood count by the results of taking the temperature with special micropocessor sensors on "reference" points on the surface of the human body (duration 180 to 720 sec. depending on the state of patient) and processing the results with a specialized program.

2.4. Number of specimens tested: 1 specimen

3. Objective of Clinical Testing:

3.1. SCT operation safety evaluation.

3.2. MPI performance evaluation: complete blood count research results accuracy evaluation comparing with the results obtained by means of the certified hematology analyzer.

3.3. Discovery of unforeseen adverse effects of SCT operation.

3.4. Evaluation of expediency of product use in Ukraine.

4. Arrangements for Performing Clinical Testing:

4.1. Basis for performing CT: Department of Clinical Pharmacy and Pharmaceutical Care of the National University of Pharmacy, Kharkiv

4.2. Personnel for performing CT (doctors – qualification, speciality, number of people):

- general practitioners– 2 people
- specialists on clinical laboratory diagnostics – 2 people

4.3.List of official documents:

- ✓ Assignment of the State Service of Medical Products and Medical-Purpose Items No. 6 BM - 1789/н dated August 03, 2006

- ✓ Declaration Patent for Useful Model 7 A61B5/02.
- ✓ Expert Conclusion No. 204/06 dated February 22, 2006 on conformity with UKT ZED code.
- ✓ Conclusion of the Sanitary & Epidemiological Examination No. 05.03.02-07/12739 dated March 22, 2006.
- ✓ Program and procedure of technical acceptance testing.
- ✓ Protocol No. 0-4/2260-2006 of MPI acceptance technical testing.
- ✓ Report No. 4/2260-2006 dated August 01, 2006 of MPI technical acceptance testing.
- ✓ Protocol No. 772 of preclinical examination dated March 20, 2006
- ✓ MPI operating manual.
- ✓ State registration certificate of Research and Production Complex "Biopromin" Ltd.
- ✓ VAT Payer registration certificate of Research and Production Complex "Biopromin" Ltd.

4.4. Language of documents: Ukrainian

4.5. Conditions of performing CT:
Testing will be performed in usual environment of a medial establishment with 30 men and 30 women. Total number of testing participants – 60 people. Testing will include healthy volunteers without inflammatory diseases of internals, symptoms of anemic, allergic and oncologic states. Data on clinical blood cell count, obtained with AMP Noninvasive Hemogram Analyzer, will be compared with the results obtained by means of the certified hematology analyzer.

4.6. Additional conditions required for performing CT:
- temperature requirements: N/A;
- humidity requirements: N/A;
- atmospheric pressure: N/A;
- illumination level: N/A;
- noise level: N/A;
- SCT sensitivity to external technical obstructions: N/A;
- need of earthing and special requirements for voltage and current frequency: N/A;
- need of water pipe-lines: N/A.

4.7. Responsible for performing CT: (full name, position):
S.B.Popov, M.D., Professor, Department of Clinical Pharmacy and Pharmaceutical Care of National University of Pharmacy.

4.8. Terms of performing CT:
September 01, 2006 – December 20, 2006.

5. Amount and Contents of Medical and Operational Testing.

5.1. Major spheres of SCT application: Clinical laboratory diagnostics of human diseases.

5.2.SCT characteristics:
- safety – economic feasibility – reliability – convenience – other.

5.3. Criteria of evaluating operating and accompanying documents quality:
- language – information amount – convenience – presentation

5.4. Criteria of evaluation of general operation features of SCT:
- completeness
- Time for:
    - Sterilisation:
      □ not required

□ required
- Desinfection
□ not required
□ required
- switching to operation mode:
□ not required
□ required
- compatibility with other equipment:
□ yes
□ no

6. Scope and Contents of Clinical Testing (CT).

6.1. Need for performing introductory training:
□ yes
□ no

6.2. Types of illnesses for diagnostics and treatment of which SCT is designed:
Illnesses, requiring complete blood count.

6.3. Experiments types:

6.3.1. The following laboratory blood indices have been determined during open and comparative researches of SCT:
Quantity of erythrocytes, x 10^{12}/l;
Quantity of hemoglobin, g/l;
Quantity of leucocytes, Ч10^{9}/l;
Quantity of lymphocytes, %.
Indicators have been determined in comparison as per two methods

- by means of a certified "SYSMEX N-2000" hematology analyzer (Japan). Venous blood for testing with certified hematology analyzer is obtained by means of venepuncture of an median cubital vein.
- By means of AMP noninvasive hemogram analyzer. Specially designed microprocessor sensors are applied to "reference" points (after preliminary degreasing of skin and sensors): blue sensor is applied to the area of carotid artery bifurcation (to the internal and external areas) on the left, green sensor – on the right; yellow sensor – to the left armpit, violet sensor – to the right armpit; red sensor – to the abdominal area (in the middle of umbilical cavity).

6.3.2. Side effects found at MPI operation

6.3.2.1. Side effects definition
Side effect means any undesirable event, found during MPI testing irrespective of its relation to application of the MPI. Side effects also include such cases as: injuries, toxic and allergic reactions, undesired clinical or laboratory changes.

Side effects are subdivided into serious and non-serious
The following side effects are considered to be serious:
- threaten a patient's life or health;
- require admission to hospital or prolonging hospitalization;
- lead to disabilities.
Non-serious – all undesirable events, which don't meet the above-mentioned criteria. Side effects are also subdivided into **expected (predicted)** and **unexpected.**

Illnesses, symptoms or signs and/or laboratory factors, out of line with norms noted in the beginning of testing, are not considered to be side effects if they are discovered during testing, with the exception of cases of increasing intensity or frequency.
If side reactions appeared in the result of using several measurement devices, it is necessary to define cause-and-effect relation of observed side effects with the measurement device being tested (absent, distant, possible, likely).

6.3.2.2. Registration of side effects.
All side effects observed by a patient and/or a doctor in the examination process, including events without direct relation with the tested measurement device, should be registered in a case-record of the individual registration form of a research participant.
Each case of a side effect is recorded in a side effects registration card, which is submitted to the Pharmaceutical Control Department of the State Pharmacological Center of Ministry of Health of Ukraine (address: 01042, Kyiv, Chigorina Str., 18).

6.3.2.3. Notification on serious side effects
In case a serious side effect appears, researchers should take all medical measures for arresting adverse effects and to notify the Customer, the Pharmaceutical Control Department of the State Pharmacological Center of the Ministry of Health of Ukraine (tel: (044) 268-25-00) and the Department of Clinical Testing Arrangement and Control of the Ministry of Health of Ukraine (tel: (044) 483-21-43) within 24 hours.

6.3.3. Criteria for MPI efficiency evaluation.
Efficiency of AMP Noninvasive Hemogram Analyzer will be evaluated by comparing with the results obtained by means of the certified hematology analyzer. Comparative evaluation will be performed with the use of parametric methods of variational statistics. Probability of discrepancies between mean values will be defined in conformity with the Student t-criteria. Results at $p < 0,05$ will be considered as significant.

6.4.Additional measures related to SCT operation:
No additional measures related to utilization or preventing SCT-related injuries among patients or personnel are envisaged.

6.5.Additional terms for performing CT:
□ yes
□ no

7. Methods of testing:

7.1. Clinical; 7.2. Instrumental; 7.3. Laboratory; 7.4. Morphological; 7.5. Radiological; 7.6. Ultrasound; 7.7. Statistic; 7.8. Other; 7.9. Expert evaluation.

8. Reporting

8.1. Protocol of clinical testing

□ yes
□ no

8.2. Report of clinical testing

□ yes
□ no

8.3.Register of clinical testing

□ yes
□ no

8.4. Individual registration forms of testing participants

□ yes
□ no

9. Conclusions.

9.1. SCT operation safety:

□ yes
□ no

9.2. SCT conformity to its designation:

□ yes
□ no

9.3. SCT operation efficiency:

□ yes
□ no

9.4. SCT operation recommendations:

□ yes
□ no

9.5. SCT operation drawbacks and difficulties, discovered during testing:

□ yes
□ no

Executive Manager		
Doctor of Medical Science, Professor	*[Signature]*	**S. B. Popov**
Co-executives		
Pharmaceutics Candidate, Assistant Professor	*[Signature]*	**S. V. Misyuryova**
Pharmaceutics Candidate, Assistant Professor	*[Signature]*	**V. V. Propisnova**

<Overleaf>: This document contains 6 (six) sheets, numbered, stitched and sealed
First Vice-Rector of NUPh [Signature] Professor I.S. Gritsenko
<Seal: Ministry of Health of Ukraine; National University of Pharmacy; No. 02010936>
<Seal: Ministry of Health of Ukraine; National University of Pharmacy; No. 02010936>