

NATIA KVIZHINADZE, NINO INTSKIRVELI, DAVID TOPURIA,  
NANA DUGHASHVILI, NODAR SULASHVILI

## GSP AND ITS FEATURES IN MEDICAL AND PHARMACEUTICAL INSTITUTIONS

Social and Clinical Pharmacy, Tbilisi State Medical University, Tbilisi, Georgia

Doi: <https://doi.org/10.52340/jecm.2023.04.03>

*ნათია კვიციანიძე, ნინო ინტსკირველი, დავით თოფურია, ნანა დუღაშვილი, ნოდარ სულაშვილი*  
**GSP და მისი მახასიათებლები სამედიცინო და ფარმაცევტულ დაწესებულებებში**  
თბილისის სახელმწიფო სამედიცინო უნივერსიტეტი, თბილისი, საქართველო

### რეზიუმე

კარგი შენახვის პრაქტიკის წყალობით (GSP), ბიზნესს შეუძლია პროდუქტის მიწოდება საბოლოო მომხმარებელამდე უფრო სწრაფად. ეს ნიშნავს, როგორც დროის დაზოგვას, ასევე მიწოდება-მოთხოვნის ბალანსის შენარჩუნებას. კარგი შენახვის პრაქტიკის კურსი შედგება ფართო დღის წესრიგისგან, რომელიც ასახავს გადამწყვეტ პირობებს, რეგულაციებსა და მოთხოვნებს, რომლებიც დაკავშირებულია ჩართულ პერსონალთან და მათ პასუხისმგებლობებთან, არსებით განმარტებებთან, შენობებთან და ობიექტებთან, შენახვის პირობებთან და ა.შ.

კარგი სადისტრიბუციო პრაქტიკა და შენახვის კარგი პრაქტიკა უზრუნველყოფს, რომ განაწილებული პროდუქცია იყოს ავტორიზებული შესაბამისი კანონმდებლობის შესაბამისად; მუდმივად შენარჩუნებულია შენახვის შესაბამისი პირობები, მათ შორის საქონლის გადაადგილება სადისტრიბუციო ქსელის სხვადასხვა ნაწილებს შორის; სხვა პროდუქტებით დაბინძურება არის აცილებული; ხდება მარაგების სათანადო ბრუნვა; და რომ პროდუქტები მთელი განაწილების ჯაჭვში ინახება უსაფრთხო და დაცულ ადგილებში.

**Introduction:** Good Storage Practice (GSP) and Good Distribution Practice (GDP) describe human, veterinary and investigational drug substance and drug product supply chain procedures and standards for assurance of the biological/pharmaceutical product identity, strength, purity, efficacy and quality after storage, transportation and distribution operations up to the point of use, i.e. to the point where the patient or end-user receives the product.

The GSP (Good Storage Practices for Pharmaceuticals) standard covers all the essentials for proper storage and transportation of pharmaceutical products. These measures may be adapted to the specific situation, if necessary, provided that all quality standards are met. Its main principle is to establish a uniform conformity between the stability of medical products and the storage modes indicated on the labels, which must be adhered to in the drug distribution system.

Proper storage of medicines and medical products (materials, products) is especially important in the activities of a pharmaceutical institutions (base, pharmacy, etc.). The proper storage conditions, quality of both, the prepared and the ready-made drug forms and their effectiveness are highly dependent on it and is very important. Medicines are misplaced due to improper storage, leading to significant material loss, and the use of unsuitable medicines can lead to undesirable and sometimes life-threatening consequences for the patient.

The quality of medical products can be assured if the rules of its circulation, in particular pre-clinical and clinical trials, manufacturing, wholesale and retail sale of pharmaceutical products, are strictly adhered to at all stages of the medicinal life cycle.

In addition, the recommendations of international medical and pharmaceutical organizations (WHO, FIP, etc.) play an important role, including the recommendations of the GSP, which establishes relevant authority and approves national standards for pharmaceutical storage, including in the work of the pharmaceutical staff.

**Aim of the study:** The aim of the study was to find out whether the conditions of storage of a national pharmaceutical product are in line with the requirements of the GSP of the International Pharmaceutical Federation in order to develop national recommendations for appropriate storage for pharmaceutical establishments.

**Materials and Methods:** The study subject was pharmaceutical institutions and pharmacy staff. The survey was conducted using pre-filled questionnaires, with complete anonymity.

In a store, relative humidity should not be above 65% (there are several devices for humidity measurement). Air is a factor of deterioration due to its content of oxygen and humidity. All containers should remain closed. In airtight and opaque containers (hospital type), drugs are protected against air and light.

The methodology known as “Plan-Do-Check-Act” can be applied to all processes. It can be briefly described as follows: Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the warehouse’s policies.

**Do:** implement the processes.

**Check:** monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

**Act:** take actions to continually improve process performance [6].

**Results:** According to the study results GSP standards are met in Georgia in case of only 7 %. On the question: what extent are your facilities (pharmacy, clinic, hospital, pharmaceutical warehouse) hygienic-sanitary standards and pharmaceutical order? – most of the respondent-pharmacists answered the positively (72%). In 98% the pharmacists did not receive an oral instruction from a supervisor to sell an expired or incorrect storage drug and fortunately, they have never had a sale of an unsuitable drug due to expired or incorrect storage at the pharmacy. Only 26% of respondents are familiar with GSP (Good Storage Practices for pharmaceuticals) recommendations for proper storage practices for pharmaceuticals.

Some developing countries export highly competitive products, which do not need preferences to successfully access world markets. In this case, GSP is withdrawn from these product sectors through a graduation mechanism [2]:

- when the average value of imports from a GSP beneficiary country (divided by the total value of all GSP imports for that Section) over 3 years exceeds the general threshold of 57%
- for vegetable products, animal or vegetable oils, fats and waxes and mineral products graduation applies when the percentage share referred to exceeds 17.5%
- for textiles graduation applies when the percentage share referred to exceeds 47.2%

### **Conclusions:**

- GSP recommendations are not incorporated into national pharmaceutical activities;
- Most pharmacists are not aware of the recommendations of the GSP;
- In our opinion, we consider it necessary for the Ministry of Labor, Health and Social Affairs of Georgia to set up a commission so that they can adopt the relevant by-law to implement the national recommendations of the GSP;
- Pharmacy staff training according to GSP to enhance their qualifications is essential.

As pharmaceutical and biotechnology industry operations became globalized (due to manufacturers’ interest in keeping low production costs), more APIs/DSs (active pharmaceutical ingredient/drug substance) and drug products are being manufactured in one region and then transported/imported/exported to other regions worldwide.

As a result, supply chain safety, validation and GSP and GDP have become much more critical and relevant. Uncontrolled or unsafe supply chain steps may lead to huge risks related to product safety and quality that can easily lead to product recalls or risks to patients’ health.

### **References:**

1. Good Storage and Distribution Practice (GSP-GD), Good Chain Safety and Validation; <https://eranyona.com/good-storage-and-distribution-practice-gsp-gdp/2>.
2. Generalized Scheme of Preferences Plus (GSP+); <https://trade.ec.europa.eu/access-to-markets/en/content/generalised-scheme-preferences-plus-gsp>
3. <https://www.fda.gov/wp-content/uploads/2021/04/Administrative-Order-No.-2013-0027.pdf>

4. Generalized System of Preferences (GSP), Office of USA trade representative: <https://ustr.gov/issue-areas/trade-development/preference-programs/generalized-system-preference-gsp>
5. Good storage and Distribution practices for medical products (August 2019); WHO Drug Information, Vol 33, No. 2, 2019; <https://apps.who.int/iris/bitstream/handle/10665/330887/DI332-194-225-eng.pdf>
6. ISO 9001:2008, quality management systems requirements

*NATIA KVIZHINADZE, NINO INTSKIRVELI, DAVID TOPURIA,  
NANA DUGHASHVILI, NODAR SULASHVILI*

#### **GSP AND ITS FEATURES IN MEDICAL AND PHARMACEUTICAL INSTITUTIONS**

Social and Clinical Pharmacy, Tbilisi State Medical University, Tbilisi, Georgia

#### **SUMMARY**

Businesses can deliver products completely safe to the consumer. This means both saving time and maintaining the supply-demand balance. Good Storage Practice course consists of a wide-ranging agenda that outlines crucial terms, regulations and requirements related to the personnel involved and their responsibilities, essential definitions, premises and facilities, storage conditions etc.

The Good Distribution practices and Good Storage Practices ensure that the distributed products are authorized in accordance with the relevant legislation; appropriate storage conditions are maintained at all times, including movement of goods between various parts of the distribution network etc.

**Keywords:** GSP, pharmacy, Georgia, supply, storage

