Software Requirements Specification

for

PHADEC-01 Decision Support System,

Version 1.13

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Definition, acronyms, and abbreviations

Term	Definition
ATC	ATC (Anatomical Therapeutic Chemical) is a special code given to a drug, based on the organ or system it affects and how it functions [1].
CSS	It is a simple design language intended to simplify the process of making web pages.
DDI	Drug-drug interactions
EHR	An electronic health record (EHR) is a digitally recorded systematized collection of patient and population health information. [2].
ERD	Entity Relationship Diagram
FDA	The Food and Drug Administration (FDA) is a federal agency of the Department of Health and Human Services that is in charge of preserving and promoting public health by controlling and supervising food safety, dietary supplements, and prescription and over-the-counter pharmaceutical medications [3].
FDI	Food-drug interactions
HIE	Health information exchange is the electronic interchange of clinical and administrative information between healthcare providers [4].
HIPAA	Health Insurance Portability and Accountability Act (HIPAA) is a piece of American legislation that establishes data privacy and security safeguards for medical records [5].

HTML	It is a typical markup language used to create web pages.
iOS	An operating system used in Apple phones.
NDC	The National Drug Code (NDC) is an FDA standard for uniquely identifying drug items marketed in the United States [6].
OS	An operating system (OS) is part of system software that controls computer components such as hardware and software resources and offers standard services to programs.
OTC	Over-the-counter is a drug that is available without a prescription.
PBM	Pharmacy benefits managements (PBMs) create, implement, and manage outpatient drug benefit plans for employers, managed care organizations, and other third-party payers [7].
PDSS	Pharmacy Decision Support System.
Rule-Based System	A rule-based system is a particular kind of expert system that consists of a series of if-then rules and is used as a decision support system in many fields, including security, transportation, and healthcare [8].
SGK Medula	SGK Medula is an integrated system between general health insurance and health facilities in Turkey, created to electronically collect billing information and pay for services without interfering with the internal processes of health facilities.
SRS	Software Requirements Specification

Stakeholder	A person, group, or organization whose interests are affected by the success or failure of a project or business initiative.
UI	User Interface.
Web-Based Application	Any software that is accessed via a network connection using HTTP rather than being stored in a device's memory is referred to as a web-based application.

1. Introduction

1.1 Purpose

In this section of the report, the importance and purpose of the software requirements specification (SRS) will be touched upon and explained in detail. SRS is a detailed document in terms of containing the crucial phases of the project. It describes the product's functionality in terms of fulfilling the needs of all stakeholders. In addition, SRS is one of the most important stages of a project, especially in terms of guiding and informing the developers about the phases of the project. Consequently, SRS studies are an important phase that minimizes the loss of time and money for the project teams.

Therefore, the main purpose of this document is to explain what the system's characteristics are, how it should be built, and how it will respond in various situations along with diagrams related to the system. Moreover, the functional and non-functional requirements of the system will be touched upon and evaluated separately. Consequently, this document is prepared based on the findings of an interview with pharmacists and will be used for stages of the project such as design, testing, and implementation phases.

1.2 Scope

The aim of this project is to solve the difficulties in verifying and controlling the suitability of drug-drug (DDI) interactions, and food-drug (FDI) with a systematic decision mechanism. The “Pharmacy Decision Support and Tracking System” is a web-based application to benefit both patients and pharmacists.

The application will identify drug interactions and display a warning to the pharmacist. Furthermore, by considering interactions such as DDI and FDI, the system should be able to forecast which prospective dietary supplements and OTC (over-the-counter) medications could be preventive and protective for each patient's disease. Correspondingly, the rule-based system will make recommendations to pharmacists by predicting and listing the most profitable products according to their ATC (Anatomical Therapeutic Chemical) codes for the product group available to the pharmacist. As a result, the system will be able to safely improve pharmacists' profitability by recommending products to their patients more effectively and precisely. Moreover, patients will be able to use the safest and most effective medications for their diseases.

1.3 Overview

The remaining parts of the SRS document include two sections that contain a detailed and comprehensive definition of the requirements for the project. The next section touches upon various crucial topics such as system overview, features, stakeholders, and their relationship with the system. Furthermore, this section also includes a detailed description of the product's assumptions and dependencies and system constraints.

The third section of the document provides technical information in terms of specific requirements and covers the functional and non-functional requirements topics. Moreover, this section also includes detailed information about different system interfaces such as hardware, software, and user interfaces.

2. Overall Description of The Project

2.1 Product perspective

The system aims to determine the drug-drug and drug-nutrient interactions of drugs sold in pharmacies and to recommend food supplements suitable for the patient's disease according to the profit margin of the pharmacy. This feature allows us to determine whether drug-drug interactions reduce the risks associated with these interactions. Also, the system must make predictions accordingly to the patient's disease and recommended supplements (nutrients). It stores the interaction data of drugs and nutrients on the web server. Accordingly, the data can be accessed from anywhere. The pharmacist accesses the ATC codes in the database and issues an alert for interacting drugs or nutrients. It also gives food supplement information to the patient according to the ATC code. Pharmacists guide the patient by accessing the warnings on the screen by accessing the web interface. Therefore, using the data from the database, the system will suggest the best medications for the patient.

2.2 Product functions

The system shall have the listed features below:

- Login, Register
- Alert Message
- View results
- Create, View, Modify, and Delete Patient
- Insert, Delete, Modify, and View Prescriptions Info
- Allergy Checking
- Drug Interaction Checking
- Medication Reconciliation
- Formulary Management
- Clinical Decision Support

2.3 User characteristics

Admin: The system administrator, known as Admin, has the authority to add, remove, or change the information on patient and pharmacist user accounts. This account has all the same rights as a pharmacist's account. Thus, it may be used for managing and monitoring patients and their interactions.

Admin is the system administrator who is allowed to create/delete/modify user accounts including pharmacists and patients. This account can be used for both managing and keeping track of patients and their interactions as it has all the privileges of a pharmacist’s account.

Pharmacist: Pharmacists are responsible for drug-drug and drug-nutrient interactions of patients. A patient can be added or removed by pharmacists from the list of interactions. Via our web interface, pharmacists may see the outcomes of patient interaction.

Patient: Patients can enter the prescription code into the web-based interface that opens on the pharmacist's screen, namely the medulla. According to the ATC codes in the database, they can learn drug or nutrient recommendations and restrictions from the pharmacist. Patients can also give rights to pharmacists for accessing his/her data.

2.4 Constraints

- The pharmacists shall have computers capable of running web-based apps.
- Pharmacists shall be trained on how to use the application.
- Data quality: The accuracy and completeness of data used in PDSS can impact the reliability of recommendations made by the system.
- Integration: PDSS must be integrated with other electronic systems in the pharmacy, such as electronic health records (EHRs), to ensure that patient information is accurate and up-to-date.
- Usability: The user interface of the PDSS must be easy to use and understand to enable pharmacists to quickly and efficiently access information and make informed decisions.
- Customization: PDSS must be customized to meet the specific needs of the pharmacy and its patients, which may vary based on the pharmacy's size, patient population, and other factors.
- Data security: PDSS must comply with applicable privacy and security regulations to protect patient information from unauthorized access or disclosure.
- Cost: PDSS can be expensive to implement and maintain, and the benefits of the system must justify the cost.
- Human factors: The effectiveness of PDSS may be influenced by factors such as the pharmacist's cognitive workload, experience, and training.

2.5 Assumptions and Dependencies

- The operation of the system depends on updates being made in the pharmacies' database inventory to update the availability of drugs as the system requests are accepted.
- Data availability: PDSS assumes that the necessary data is available in the pharmacy's electronic systems, such as electronic health records (EHRs), medication history, and laboratory results.
- Data accuracy: PDSS assumes that the data used in the system is accurate and up-to-date. If the data is incomplete or inaccurate, the recommendations made by the system may not be reliable.
- System integration: PDSS is dependent on other electronic systems in the pharmacy, such as EHRs and medication dispensing systems, to ensure that patient information is accurate and up-to-date.
- Clinical guidelines: PDSS is designed to provide recommendations based on established clinical guidelines. Therefore, the system assumes that the clinical guidelines used in the system are up-to-date and evidence-based.
- User interaction: PDSS assumes that the pharmacist will interact with the system appropriately and will use the information provided by the system to make informed decisions about patient care.
- System maintenance: PDSS requires regular maintenance and updates to ensure that it remains up-to-date and effective.
- Regulatory compliance: PDSS must comply with applicable regulatory requirements, such as privacy and security regulations, to protect patient information from unauthorized access or disclosure.

3. Specific Requirements

3.1 External interface requirements

3.1.1 User Interfaces

- The system UI must be simple to use for users.
- The system UI must be responsive to make ease to use for users. (Desktop and mobile layouts must be different)
- The system shall include light/dark mode.
- The system shall display the interactions within a popup to inform the pharmacist.

3.1.2 Hardware Interfaces

- Drug-drug, drug-food, and drug-disease interaction information should be kept in a database.
- The model should recommend the best drugs for the patient according to the information that is kept in the database.
- The user Interface should connect to the server to check drug interactions.
- The system must respond to a pharmacist about drug interactions within a popup.

3.1.3 Software Interfaces

3.1.3.1 Web server

- The server should keep information about drug interactions.
- The server should identify the type of request. For example, if the request is about getting drug information, the system should identify the request is coming from SGK Medulla Pharmacy Interface and send a response according to the type.
- The system database should be accessible from our model to make decisions and send the “decision results” response to the related UI.

3.1.3.2 Patient Interface

- The web server should be able to fetch patient information and inform the patient about his/her prescription.

3.1.3.3 SGK Medulla Pharmacy Interface

- Pharmacists should be able to fill out the prescription form and submit it.
- The system should get form data from SGK Medulla Pharmacy and analyze it for a recommendation.
- On the same page, a popup should appear to inform the pharmacist about interactions.

3.1.4 Communication Interfaces

- The web server should inform pharmacists if there is a risky situation about interactions.

3.2 Functional Requirements

Designed to provide comprehensive information and support for both patients and healthcare providers. Pharmacy Decision Support System should be user-friendly, easy to navigate and provide accurate, reliable, and up-to-date information to improve patient safety and quality of care. The functional requirements of the system and the use cases to which the requirements belong are indicated in this section.

- Drug Database: The system should have an extensive database of drugs and their corresponding information such as indications, contraindications, dosages, side effects, and drug interactions.
- The system should have a comprehensive database that includes information on drug-food interactions, including the specific foods that interact with each medication. This database should be regularly updated with the latest information.
- The PDSS should have the capability to provide disease-specific recommendations for medication to ensure that the prescribed medications do not exacerbate the patient's condition or interact negatively with other medications or foods. This feature will help healthcare professionals make informed decisions about medication management and ultimately improve patient outcomes. By taking into account the patient's specific

disease or condition, the PDSS can suggest medications that are more likely to be effective and safe for that particular patient.

- Clinical Decision Support: The system should provide real-time clinical decision support for pharmacists based on the patient's information such as age, weight, medical history, allergies, lab results, and current medications.
- The system provides detailed information on drug formulations, dosages, pharmacokinetics, pharmacodynamics, drug-drug, drug-food, and drug-disease interactions, as well as the effects of drugs on different populations such as pregnant or lactating women, and pediatric and geriatric patients.
- Users can search for medications by National Drug Code (NDC) number and access drug monographs with comprehensive information on drug indications, dosages, contraindications, and precautions.
- The system manages patient medication information and provides useful recommendations to prevent harmful interactions and allergies.
- The system alerts users of any possible drug interactions and allergies and provides real-time alerts to avoid harmful combinations.
- The system also allows users to customize drug interaction alerts based on severity, relevance, and preference.
- Drug Interaction Alerts: The system should provide drug interaction alerts when a patient is prescribed a medication that may interact with other medications the patient is taking.
- Adverse Drug Reaction Monitoring: The system should monitor adverse drug reactions and alert the pharmacist if the patient experiences any adverse reactions.
- Patient Education: The system should provide patient education materials such as medication guides, drug information leaflets, and dosage instructions.
- Materials on medication use and side effects, medication administration, and dosing guidelines for healthcare providers are also available, along with information on medication alternatives, including cost, risks, and benefits.
- Prescription Tracking: The system should track prescriptions.

- Electronic Prescription Processing: The system should enable electronic prescribing and processing of prescriptions.
- Reporting and Analytics: The system should generate reports and analytics to track medication usage, patient outcomes, and pharmacy operations.
- The system provides various reports, including drug interaction reports, adverse drug event reports, and medication error reports.
- Users can also view medication history, drug information such as side effects and interactions.
- The system allows users to create and manage patient profiles.
- Integration with EHR: The system should be integrated with the Electronic Health Record (EHR) system used by the healthcare provider to access patient information and update the patient's medication record.
- These features provide healthcare providers with a comprehensive medication management tool to enhance patient care and safety.

This requirement document outlines the need for the system to have medication tracking and inventory management features. Additionally, it should provide medication cost-effectiveness analysis and allow users to create and manage medication formularies for individual patients.

3.3 Non-Functional requirements

- Security: Only authorized pharmacists should have access to the system, and they must verify the username and password to log in.
- Performance: When pharmacists use the system, the system should be fast and increase the number of procedures performed by keeping the procedure process short.
- Availability: The downtime of the system should be as low as possible, and the maintenance hours of the system should be selected during the hours when the pharmacist is not busy or even not working during the day.

- Compatibility: The application is available on different operating systems (Windows, Linux, macOS, etc.) and must be able to work on and in different browsers (Google Chrome, Mozilla Firefox, Internet Explorer, Safari, etc.) should be able to work.

- Innovation: The system should be innovative and develop itself under the leadership of feedback received from pharmacists.

- Testability: The system should allow a pharmacist to test it to check whether the system is working properly.

- Interoperability: The system should be interoperable with other healthcare systems such as Electronic Health Record (EHR), Health Information Exchange (HIE), and Pharmacy Benefit Management (PBM) systems to share data and improve patient care coordination.

- Usability: The system should be easy to use, intuitive, and require minimal training for pharmacists and other healthcare professionals to use efficiently.

- Compliance: The system should comply with relevant regulatory standards such as HIPAA, FDA, and other state and federal regulations governing healthcare data privacy and security.

- Maintenance: The system should be easy to maintain and support, with regular updates, bug fixes, and enhancements to improve its functionality, usability, and performance.

- Cost: The system should be cost-effective to implement, maintain, and support, with minimal hardware and software requirements, and a low total cost of ownership.

3.3.1 OS (operating system) non-functional requirements

- Stability: The system should be clear and understandable, not to make pharmacists hesitate about drug-drug interaction, which can be reliable.

- Resource utilization: Sources should be the most reliable, well-known certified sources in the field of pharmacy.

- Ease of use: The system should be easy to use and clear from the pharmacist's point of view.

3.3.2 Database non-functional requirements

- Data consistency: Even if this web application is running on different platforms, it should show the current number of medicines available in the stock of the specified pharmacy.

- Scalability: When new products are added to the pharmacy database, the database should be able to adapt to the changes and the pharmacy database should be minimally affected by system density in terms of performance.

- Backup and recovery: The information should be uploaded to the database version by version and the previous version should be easy to view if a problem is encountered.

3.3.3 Programming environment non-functional requirements

- Support for programming languages and libraries: The system should support languages such as HTML, CSS, and JavaScript at the front end.

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