Ontology-based Expert System for a Generic Drug Production of Pharmaceutical Dosage Forms

Software Requirement Specification

By

**Mr. Narongrit Saisuwan 542115017**

**Mr. Panupak Wichaidit 542115047**

Department of Software Engineering

College of Arts, Media and Technology

Chiang Mai University

Project Advisor

………………………………………..

**Dr. Chartchai Doungsa-ard**

# Document History

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Document Name** | **Version** | **Status** | **Date** | **Viewable** | **Reviewer** | **Responsible** |
| **Documents** | | | | | | |
| **Ontology-based Expert System for a Generic Drug Production of Pharmaceutical Dosage Forms –Software Requirement v.0.1.docx** | **0.1**   * Introduction * Use case diagram * User scenario * User Requirement Specification (URS) * System Requirement Specification (SRS) | Draft | April 1, 2014 | NS, PW, CD | NS, PW | NS, PW |
| **Ontology-based Expert System for a Generic Drug Production of Pharmaceutical Dosage Forms –Software Requirement v.0.2.docx** | **0.2**   * Use case diagram * User Requirement Specification (URS) * System Requirement Specification (SRS) | Draft | April 12, 2014 | NS, PW, CD | NS, PW | NS, PW |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

Table of Contents

[Document History 1](#_Toc386098286)

[Chapter 1 | Introduction 3](#_Toc386098287)

[Chapter 2 | User Scenario 3](#_Toc386098288)

[Chapter 3 | Requirement Specification 5](#_Toc386098289)

[3.1 Functional Requirement 5](#_Toc386098290)

[3.1.1 User Requirement Specification (URS) 5](#_Toc386098291)

[3.1.2 User Requirement Description 6](#_Toc386098292)

[3.1.3 System Requirement Specification (SRS) 32](#_Toc386098293)

[3.2 Non - Functional Requirement 38](#_Toc386098294)

# Chapter 1 | Introduction

Software Requirement describes the requirement specification of Ontology-base expert system for generic drug production of pharmaceutical dosage form. The Software Requirement is composed of the User requirement Specification (URS), User requirement description, System Requirement Specification (SRS) and non- functional requirement. The purpose of this document are making the same understanding of the stakeholder and supporting the future development.

# Chapter 2 | User Scenario

The client want to use the Ontology-base expert system for generic drug production of pharmaceutical dosage form on the tablet computer. The client need login before using the program. The program should show the current user after the user login to the system. The first page of program should be a menu which consists of the history, evaluate case, manage a case and calculate drug reformulation as a generic version. The client need 3 types of the user. The first one is general pharmacists. The general pharmacists can register as member by sending the request to the administrator. The general pharmacist can use the system for evaluation and calculate drug reformulation. They also view their drug reformulate history. The drug reformulate history can search by drug’s name and date. The second type of user is an administrator. The administrator can manage the member, drug formulation cases and excipient in the program. They can approve the member register and change authorize status of member. They can change member status from general pharmacist to an expert pharmacist or the expert pharmacist to the general pharmacist. The administrator also add a new case in the program, update the existing case in the database and delete a case. The last user is expert pharmacists. The expert pharmacists come from general pharmacists. The expert pharmacist cannot register by themselves. This user must change by administrator. The expert pharmacists can use the program similar with the administrator but the expert pharmacists cannot manage make the member management.

From this User scenario above, it can divide into use case diagram. The diagram is illustrated in Figure 1.

D:\All for desktop\Senior project\RequirementSpecfication\Use case diagram\Use case diagram.tif

Figure 1: The use case diagram

The Figure 1 is the use case diagram for all of the project, but for the progress one. The program which consists only 3 feature. The list of a feature is shown below

* Feature 2 : Rule base system
* Feature 5 : Pharmaceutical Dosage Form Production Ontology(PDPO)
* Feature 7 : Mobile connector

For make the requirement report for support the list of feature above. The use case diagram is redesign to a new use case at the Figure 2. The Figure 2 is illustrated below.

D:\All for desktop\Senior project\RequirementSpecfication\Use case diagram\Use case diagram-Progress report one.tif

# Chapter 3 | Requirement Specification

## 3.1 Functional Requirement

### 3.1.1 User Requirement Specification (URS)

From the use case diagram at the figure 2, there are 2 feature in the Ontology base expert system for generic drug production of pharmaceutical dosage form. The feature can divide into the User Requirement Specification. The User Requirement Specification (URS) is illustrated in Table below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No** | **Feature Name** | **URS No.** | **URS Name** | **Actor** |
| 1 | Calculate the drug reformulation by using the inference engine. | URS-01 | The user calculates a drug reformulation by using an inference engine. | General Pharmacists, Expert Pharmacists, Administrator |
| 2 | Manage the drug excipient | URS-02 | The user adds a new excipient into the database. | Expert Pharmacists, Administrator |
| URS-03 | The user updates an existing excipient into the database. |
| URS-04 | The user deletes an existing excipient into the database. |

### 

### 3.1.2 User Requirement Description

#### Feature 1: Calculate the drug reformulation by using the inference engine.

##### URS-01: The user calculates a drug reformulation by using an inference engine.

###### Input and output

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **No** | **Part** | **Name** | **Description** | **Example** | **Remarks** | **Output** |
| 1 | Active Pharmaceutical ingredient (API) | Name | Name of the drug should be the characters | “Paracetamol” | The word should be the character. | The system show the name on the screen. |
| Amount of strength | Amount of the strength should be the decimal value. | 500.00 | The value should be the decimal value. | The system show the amount of strength on the screen. |
| Solubility | Solubility of the drug | “Sparing soluble” | The word should be the character. | The system show the solubility on the screen. |
| Flow ability | Flow ability of the drug | “Poor” | The word should be the character. | The system show the flow ability on the screen. |
| Compatibility | Compatibility of the drug | “Good” | The word should be the character. | The system show the compatibility on the screen. |
| Temperature Stability | Temperature stability of the drug | “Stable” | The word should be the character. | The system show the Temperature Stability on the screen. |
| Moisture Stability | Moisture Stability of the drug | “Stable” | The word should be the character. | The system show the Moisture Stability on the screen. |
| 2 | DF properties | Total weight | The Total weight of the drug | 630.00 | The value should be the decimal value. | The system show the total weight on the screen. |
| Disintegration Time | Disintegration Time of the drug | 28 | The value should be the Integer value. | The system show the Disintegration Time on the screen. |
| Hardness | Hardness of the drug | 8.30 | The value should be the decimal value. | The system show Hardness on the screen. |
| Dissolution Profile | Dissolution Profile of the drug | 81.31 | The value should be the decimal value. | The system show the Dissolution Profile on the screen. |
| 3 | Excipients | Excipients’ name | The excipient that using for produce the generic drug. | “Microcrystalline cellulose” | The word should be the character. | The system show the Excipients’ name on the screen. |

###### Description

|  |  |  |  |
| --- | --- | --- | --- |
| **User Requirement Specification ID:** | URS-06 | | |
| **User Requirement Specification Name:** | The user calculates a drug reformulation by using an inference engine. | | |
| **Create By :** | Panupak Wichaidit | **Last update by :** | Panupak Wichaidit |
| **Date Created :** | April 2, 2014 | **Last Revision Date :** | April 2, 2014 |
| **Actor:** | General Pharmacists, Expert Pharmacists, Administrator | | |
| **Description:** | URS-06 is used, when the user wants to calculate a drug reformulation as a generic version by using an inference engine. | | |
| **Trigger:** | The user selects “Calculate” to calculate drug reformulation as a generic version. | | |
| **Pre-condition:** | * The user must installs the program into the tablet computer. * The user must log in to the system. | | |
| **Post-condition:** | * The system saves the user information into a database. | | |
| **Normal Flow:** | 1. The user opens the calculate drug reformulation page 2. The user inputs the Pharmaceutical value such as active Pharmaceutical ingredient (API), DF Properties and excipient. 3. The user select the evaluation symbol for calculate drug reformulation. 4. The system show the menu of inference engine. The menu is consist of rule base system, case base reasoning system and hybrid system. 5. The user select some of inference engine from the menu of inference engine for making calculation. 6. The system shows the result that include manufacturing and appropriate excipient. | | |
| **Alternative Flow:** | N/A | | |
| **Exception:** | * In step 2 of the normal flow, if the user input an Amount of strength at API part in a wrong format.  1. The system shows the error message about Amount of strength format is wrong. 2. The user go back to do the step 2 of the normal flow again.  * In step 2 of the normal flow, if the user input a Total weight at DF properties part in a wrong format.  1. The system shows the error message about Total weight format is wrong. 2. The user go back to do the step 2 of the normal flow again.  * In step 2 of the normal flow, if the user input a Disintegration Time at DF Properties in a wrong format.  1. The system shows the error message about Disintegration Time format is wrong. 2. The user go back to do the step 2 of the normal flow again.  * In step 2 of the normal flow, if user input a Hardness at DF Properties in a wrong format.  1. The system shows the error message about Hardness format is wrong. 2. The user go back to do the step 2 of the normal flow again.  * In step 2 of the normal flow, if user input Dissolution Profile at DF Properties in a wrong format.  1. The system shows the error message about Dissolution Profile format is wrong. 2. The user go back to the step 2 of the normal flow again.  * In all of step of the normal flow, if the system disconnects from an internet  1. The system shows the error message about internet disconnection. | | |
| **Include:** | URS-15 | | |

#### Feature 2: Manage the drug excipient.

##### URS-02: The user add a new excipient into the database.

###### Input and output

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No** | **Input Name** | **Description** | **Example** | **Remarks** | **Output** |
| 1 | Excipient’s name | Excipient’s name that | N/A | The word should be the character. | The system show the excipient’s name on the screen. |
| 2 | Quantity | The quantity of the excipients | N/A | The value should be the integer value. | The system show the quantity on the screen. |
| 3 | Other data | N/A | N/A | The word should be the numeric number. | The system show the telephone number on the screen. |

###### Description

|  |  |  |  |
| --- | --- | --- | --- |
| **User Requirement Specification ID:** | URS-09 | | |
| **User Requirement Specification Name:** | The user add a new excipient into the database. | | |
| **Create By :** | Panupak Wichaidit | **Last update by :** | Panupak Wichaidit |
| **Date Created :** | April 7, 2014 | **Last Revision Date :** | April 7, 2014 |
| **Actor:** | Expert Pharmacists, Administrator | | |
| **Description:** | URS-09 is used, when the user want to add a new excipient to the database. | | |
| **Trigger:** | The user select “Add the new excipient” for adding the new excipient to the database. | | |
| **Pre-condition:** | * The user must install the program into the tablet computer. * The user must log in to the system. | | |
| **Post-condition:** | * The system save the new excipient to the database. | | |
| **Normal Flow:** | 1. The user open adding the new excipient page. 2. The user input the excipient name, quantity and other data. 3. The user select “save” for adding the new excipient. 4. The system shows the new excipient adding successful page. | | |
| **Alternative Flow:** | * In the step 3 of the normal flow, if the user select “cancel” instead of selecting “save”.  1. The system shows the main page of the program. | | |
| **Exception:** | * In step 2 of the normal flow, if the user input the excipient name that same as other excipient name in the database.  1. The system shows the error message about the excipient name is already used. 2. The user go back to do the step 2 of the normal flow again.  * In step 2 of the normal flow, if the user input the quantity in a wrong format.  1. The system shows the error message about the quantity format is wrong. 2. The user go back to do the step 2 of the normal flow again.  * In step 2 of the normal flow, if the user input other data in a wrong format.  1. The system shows the error message about the other data is wrong. 2. The user go back to do the step 2 of the normal flow again.  * In all of step of the normal flow, if the system disconnects from an internet.  1. The system shows the error message about internet disconnection. | | |
| **Include:** | URS-02 | | |

##### URS-03: The user update an existing excipient in the database.

###### Input and output

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No** | **Input Name** | **Description** | **Example** | **Remarks** | **Output** |
| 1 | Excipient’s name | Excipient’s name that | N/A | The word should be the character. | The system show the excipient’s name on the screen. |
| 2 | Quantity | The quantity of the excipients | N/A | The value should be the integer value. | The system show the Quantity the screen. |
| 3 | Other data | N/A | N/A | The word should be the numeric number. | The system show the telephone number on the screen. |

###### Description

|  |  |  |  |
| --- | --- | --- | --- |
| **User Requirement Specification ID:** | URS-10 | | |
| **User Requirement Specification Name:** | The user update an existing excipient in the database. | | |
| **Create By :** | Panupak Wichaidit | **Last update by :** | Panupak Wichaidit |
| **Date Created :** | April 7, 2014 | **Last Revision Date :** | April 7, 2014 |
| **Actor:** | Expert Pharmacists, Administrator | | |
| **Description:** | URS-10 is used, when the user want to update the existing excipient in the database. | | |
| **Trigger:** | The user select “Update the existing excipient” for updating the existing excipient in the database. | | |
| **Pre-condition:** | * The user must install the program into the tablet computer. * The user must log in to the system. | | |
| **Post-condition:** | * The systems save the excipient updating to the database. | | |
| **Normal Flow:** | 1. The user open updating the existing excipient in the database. 2. The user select the excipient from a list. 3. The user input a new data such as the excipient name, quantity and other information. 4. The user select “confirm to update” for update the existing excipient in the database. 5. The system shows the existing excipient updating successful page. | | |
| **Alternative Flow:** | * In step 2 of the normal flow, if the user use search bar for searching the existing excipient by the excipient name instead of selecting the existing excipient in a list.  1. The user input the excipient name in a search bar. 2. The user select “searching” for searching the existing drug formulation in the database. 3. The system shows the excipient. 4. The step of this use case is resume at a step 3 of the normal flow.  * In the step 3 of the normal flow, if the user select “cancel” instead of selecting “save”.  1. The system shows the main page of the program. | | |
| **Exception:** | * In step 3 of the normal flow, if the user input the excipient name that same as other excipient name in the database.  1. The system shows the error message about the excipient name is already used. 2. The user go back to do the step 2 of the normal flow again.  * In step 3 of the normal flow, if the user input the quantity in a wrong format.  1. The system shows the error message about the quantity format is wrong. 2. The user go back to do the step 2 of the normal flow again.  * In step 3 of the normal flow, if the user input other data in a wrong format.  1. The system shows the error message about the quantity format is wrong. 2. The user go back to do the step 2 of the normal flow again.  * In all of step of the normal flow, if the system disconnects from an internet.  1. The system shows the error message about internet disconnection. | | |
| **Include:** | URS-02 | | |

##### URS-04: The user delete an existing excipient into the database.

###### Input and output

* **Input:** The administrator select the existing excipients from the list of the excipient’s name for deleting the excipient from the database.
* **Output:** The system delete the excipients from the database.

###### Description

|  |  |  |  |
| --- | --- | --- | --- |
| **User Requirement Specification ID:** | URS-11 | | |
| **User Requirement Specification Name:** | The user delete an existing excipient into the database. | | |
| **Create By :** | Panupak Wichaidit | **Last update by :** | Panupak Wichaidit |
| **Date Created :** | April 7, 2014 | **Last Revision Date :** | April 7, 2014 |
| **Actor:** | Expert Pharmacists, Administrator | | |
| **Description:** | URS-11 is used, when the user want to delete the existing excipient from the database. | | |
| **Trigger:** | The user select “delete the existing excipient” for deleting the existing excipient from the database. | | |
| **Pre-condition:** | * The user must install the program into the tablet computer. * The user must log in to the system. | | |
| **Post-condition:** | * The system deletes the excipient from the database. | | |
| **Normal Flow:** | 1. The user open deleting the existing excipient page. 2. The user select existing excipient from the list. 3. The user select “confirm to delete” for deleting the existing excipient from the database. 4. The system shows deleting the existing excipient successful page. | | |
| **Alternative Flow:** | * In step 2 of the normal flow, if the user use search bar for searching the existing excipient by the excipient name instead of selecting the existing excipient in a list.  1. The user input the excipient name in a search bar. 2. The user select “searching” for searching the existing drug formulation in the database. 3. The system show the excipient. 4. The step of this use case is resume at a step 3 of the normal flow.  * In the step 3 of the normal flow, if the user select “cancel” instead of selecting “confirm to delete”.  1. The system shows the main page of the program. | | |
| **Exception:** | * In all of step of the normal flow, if the system disconnects from an internet.  1. The system shows the error message about internet disconnection. | | |
| **Include:** | URS-02 | | |

### 3.1.3 System Requirement Specification (SRS)

From the normal flow, alternative flow and exception of the User Requirement Description, it can divide into System requirement specification (SRS).

#### URS-01: The user calculate a drug reformulation by using an inference engine.

|  |  |
| --- | --- |
| **No** | **System requirement specification (SRS)** |
| SRS-01 | The system provides the Graphic user interface (GUI) which receive active Pharmaceutical ingredient (API), DF Properties and excipient. |
| SRS-02 | The system can check the amount of strength format at Pharmaceutical ingredient (API).The amount of strength format must be a decimal value. |
| SRS-03 | The system can check the total weight at DF property. The total weight must be a decimal value. |
| SRS-04 | The system can check the disintegration time. The disintegration time must be an integer value. |
| SRS-05 | The system can check the hardness at DF property. The hardness must be a decimal value. |
| SRS-06 | The system can check the Dissolution Profile at DF property. The Dissolution Profile must be a decimal value. |
| SRS-07 | The system provides the inference engine page .the page is include case base reasoning system, rule base system and hybrid system. |
| SRS-08 | The system shows the result page that include manufacturing and appropriate excipient. |
| SRS-09 | The system shall display the error message “The amount of strength must be the decimal value”. |
| SRS-10 | The system shall display the error message “The total weight must be the decimal value”. |
| SRS-11 | The system shall display the error message “The disintegration time must be the integer value”. |
| SRS-12 | The system shall display the error message “The hardness must be the decimal value”. |
| SRS-13 | The system shall display the error message “The dissolution profile must be the decimal value”. |
| SRS-14 | The system shall display the error message “The system is disconnect from the internet”. |

#### URS-02: The user add a new excipient into the database.

|  |  |
| --- | --- |
| **No** | **System requirement specification (SRS)** |
| SRS-15 | The system provides the Graphic user interface (GUI) which receive excipient name, quantity and other data. |
| SRS-16 | The system can check the excipient name format. The excipient name format should be the character. |
| SRS-58 | The system can check the quantity. The quantity format should be the decimal value. |
| SRS-69 | The system shall show the successful add a new excipient page. |
| SRS-60 | The system shall display the error message “The excipient name should be the characters”. |
| SRS-61 | The system shall display the error message “The quantity should be the decimal value”. |
| SRS-62 | The system shall display the error message “The other data format is wrong”. |
| SRS-19 | The system shall display the error message “The system is disconnect from the internet”. |

#### URS-03: The user update an existing excipient into the database.

|  |  |
| --- | --- |
| **No** | **System requirement specification (SRS)** |
| SRS-56 | The system provides the Graphic user interface (GUI) which receive excipient name, quantity and other data. |
| SRS-63 | The system shows the list of the existing excipient in the database. |
| SRS-64 | The system provides the search bar for searching the list of excipient. The search bar use the name of excipient for searching. |
| SRS-57 | The system can check the excipient name format. The excipient name format should be the character. |
| SRS-58 | The system can check the quantity. The quantity format should be the decimal value. |
| SRS-65 | The system shall show the successful the existing excipient updating page. |
| SRS-60 | The system shall display the error message “The excipient name should be the characters”. |
| SRS-61 | The system shall display the error message “The quantity should be the decimal value”. |
| SRS-19 | The system shall display the error message “The system is disconnect from the internet”. |

#### URS-04: The user delete an existing excipient into the database.

|  |  |
| --- | --- |
| **No** | **System requirement specification (SRS)** |
| SRS-63 | The system shows the list of the existing excipient in the database. |
| SRS-64 | The system provides the search bar for searching the list of excipient. The search bar use the name of excipient for searching. |
| SRS-66 | The system shall show the successful delete the existing excipient page. |
| SRS-19 | The system shall display the error message “The system is disconnect from the internet”. |

## 3.2 Non - Functional Requirement