



UNIVERSITÀ DEGLI STUDI DI PARMA



BIOPHARMANET TEC

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ANNEX I **Agreement Company-UniPr**

Project: *New formulations and platforms for oral controlled release of drugs*

Title: *Project Plan*

Revision: *00*

Date: *day.month.year*

Sponsor: *Company, address, City, Country*

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TABLE OF CONTENTS

1. Introduction
2. Justification and Scope of the Project
 Expected outcomes
3. Scenario Definition
4. Reference Documents
5. Phases of the Project
6. Human resources involved
7. Time-points for critical evaluation of the activities
8. Timetable of the activities

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1. Introduction

Describe in a synthetic manner the background of the research project

2. Justification and scope of the project

Illustrate the reason for the research and clearly define the scope of the project. List the expected outcomes.

3. Scenario Definition

Illustrate the topic of the research project.

Define the target.

Establish the duration of the project

4. Reference Documents

List the relevant documents

5. Phases of the project

Provide a detailed description of the project as well as of its articulation in different phases.

Example

The project can be divided in two phases each one lasting 10 (ten) months. Each phase will be carried out through the following tasks:

Task 1 Definition of the experimental protocols;

Task 2, Analytical development for the API;

Task 3, Pharmaceutical development;

Task 4, Stability test;

Task 5, Proof of the platform concept;

Each task will be structured in different work-packages (WP).

Task 1

WP1.1 Definition of the protocols for Analytical development, Pharmaceutical development and Stability Test.

This is a dynamic Task in the sense that the protocols may be adjusted during the course of the project.

Task 2

As Analytical method the one reported in the official monograph of the USP 34 will be adopted..

- WP2.1 System suitability for the HPLC method reported in USP 34;

- WP2.2 Preparation of the working standard;



- WP2.3 Set-up of the dissolution test in biorelevant dissolution media.

Task 3

- WP3.1 Definition of the optimal in vitro dissolution profile;
- WP3.2.1 Definition of the target product profile.

6. Human resources involved

<i>Function</i>	<i>Name</i>	<i>Role in BPN-TEC</i>

7. Time points for critical evaluation of the activities

Example

- 1 report month 5 Teleconference discussion
- 2 report month 5 Mid-term meeting
- 3 report month 10 Teleconference discussion

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8. Timetable of the activities (Example)

WP	Month																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1.1																				
2.1																				
2.2																				
2.3																				
Kick-off Meeting																				
3.1																				
3.2.1																				
3.2.2																				
3.3																				
3.4																				
Mid-term Meeting																				
4.1																				
4.2																				
5.1																				
5.2																				
5.3																				
5.4																				
Final Meeting																				