

## GL PharmTech (GLPT) Co.

### Title (Name of Technology)

Compositions and Methods of Preparation Comprising Amoxicillin and  
Potassium Clavulanate or Salts Thereof

## Executive Summary

We, GL PharmTech (GLPT) Corporation, are the leading drug delivery and formulation company in Korea. We are dedicated to the development of technically-advanced and economically-attractive, or new-value-added pharmaceutical products, mainly through our proprietary formulation and drug delivery system. We specialize in oral drug delivery-providing oral controlled release and solubility-enhancing with the aim of making pharmaceutical products more effective and beneficial to patient and our customers.

The GLPT actively seeks for global partners to use our technologies for a competitive generic or upgraded version of branded drug in their countries including USA and Europe.

The GLPT having a Technology License intends to enter into a technology transfer or licensing transaction with regard to drug delivery and formulation. Terms of the transaction are not set, and interested parties may further discuss the details if they wish to enter into an agreement.

We have developed the tablet for suspension containing Amoxicillin and Potassium Clavulanate, equivalent to GSK's Augmentin® Suspension. This product is much superior to the reference product in terms of stability during storage and don't require storage in refrigerator which could avoid the reduction of drug's potency during delivery and storage on a practitioner's shelf.

② Industry Sector: 1. Academic/research (pharmaceutical), 3. Biotechnology (human therapeutic), 5. Drug delivery, 8. Non-profit org./Government (organizations), 9. Pharmaceutical (generic), 11. service (product development)

③ Therapeutic Target: 11. Hospital and Surgery (injection), 13. Infectious disease (5. Treatment - antibiotics, vaccine)

④ Development phase: early stage

⑤ Type of business relationship sought (including licensing availability): development collaboration, or non-exclusive or exclusive licensing agreement

## Key Technology Highlights

### □ Remarkably stability of main component

The dispersible tablet of this invention has excellent stability without previous formulation or storage.

### □ Suitable administration

It is easily done to administrate exact dosage of the dispersible tablet of this invention.

### □ Easiness of Formulation

The dispersible tablet of this invention was easily formulated and its administration is feasible.

### □ Simple portable tablet

The dispersible tablet of this invention is provided as a form of excellent portable tablet compared to a conventional dry syrup.

## Company Information Summary

### Company Description:

- CEO: YU-JIN CHOI
- Established: August, 2002
- Capital: US\$ 950,000
- Market Size: US\$ 3.6 M

### Business Field:

- CR (Contracted Research) Projects
- Patented Generic Formulation
- Improved version of drug
- Global product, not Domestic

### Company History

2002.08	Company established
2003. 05.	Received Society Prize of Korea Business Incubator
2004. 08.	Received R&D Fund from DC Chemical, Co., LTD.
2005.12.	Received Silver Prize from 2005 Patent Technology Commercialization Successes
2006. 06.	Certificated as Inno-Biz enterprises
2007. 05.	Received R&D Fund from the Korea Ministry of Commerce, Industry, and Energy
2007. 06.	Received R&D Fund from the Korea Ministry of Commerce, Industry, and Energy
2007. 07	Strategic alliance with Richwood Trading Co. (South Korea)
2008. 07	Korean 1st "Certificate of plant-free pharmaceutical production"

## Technology Overview

### ● Technology Platform

The core technology of GLPT is to provide promising dispersible tablet. The dispersible tablet of this invention has some advantages: easy formulation procedures and high solubility in water.

**Background and unmet needs:** Amoxicillin is a representative of  $\beta$ -lactam antibiotic substances and has efficacies on bacterial infection. Potassium clavulanate has a role of expanding anti-bacterial spectrum of amoxicillin as a function to inhibit  $\beta$ -lactamase. Mixture of amoxicillin/potassium clavulanate has been already developed and commercially utilized as a representative product, Augmentin®.

**Discovery and Achievements:** Mixture of amoxicillin/potassium clavulanate could be commercially purchased, which contains forms of tablet, dry syrup and injection. Among them, dry syrup was used in a form of suspension solution dissolved in a constant amount of water. However, dry syrup is prone to deterioration according to resuspended or storage conditions.

To overcome this problem, the GLPT has made intensive studies to develop an dispersible tablet for improving administration, formulation and solubility. As results, the GLPT has discovered the simple portable dispersible tablet of this invention with great stability, exact administration, easy formulation and high solubility in water.

**TABLE 1. Composition of dispersible tablet of this invention**

Classification	Components
Disintegrant	A and B
Filler	Microcrystalline cellulose and silicon dioxide
Glydent	Magnesium stearate
Sweetner	Acesulfame potassium
Pertume	Strawberry flavor cotton

The dispersible tablet of this invention was composed of disintegrant, filler, glydent, sweetner and pertume. The dispersible tablet of this invention was fabricated to be resuspended by disintegration in small amount of water within 1 min.

**TABLE 2. Specification**

Item	Standard	Reference
Appearance	White or pale yellow circular tablet	
Identification	Positive	
Disintegration Time	Within 3 min	15-25°C in pure water
Water content	> 9.0%	Karl Fisher method
Assay	90-120%	

**TABLE 3. Stability Test under Long-term Storage Conditions and Accelerated Conditions**

Period	Storage Conditions	Appearance	Confirm Test	Disintegration Time (sec)	Water content	Content (%)	
						Amoxicillin	Potassium clavulanate
Standard		White~pale yellow	Positive	Within 3 min	> 9.0%	90-120%	90-120%
Initial	-	fit	positive	39	6.88	103.16	105.57
1 month	25°C/RH60%	fit	positive	36	7.02	103.75	105.30
	40°C/RH75%	fit	positive	40	6.68	102.39	99.98
2 months	25°C/RH60%	fit	positive	44	6.67	104.74	104.79
	40°C/RH75%	fit	positive	36	6.45	105.77	99.11

The dispersible tablet of this invention represented most excellent stability in all items under long-term conditions (25°C/RH60%) and accelerated conditions (40°C/RH60%).