

Food & Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Drug Master File Staff
5901-B Ammendale Road
Beltsville, MD 20705-1266



Date: August 22, 2017
Drug Master File No. 031907
DMF Holder: KP Tech, Ltd.
Subject: Packaging Films
DMF Type: Type III
Submission Information: Original / Quality / New

Dear DMF Staff:

SUBMISSION FORMATS

Paper & Electronic Submission Content

The entire submission DMF 031907-0001 is delivered herewith in electronic Common Technical Document (eCTD) format in compliance with FDA Module 1 version 2.3 and other FDA specifications currently in effect.

Table 1: Description of Electronic Submission

Media #	Content	Format
Submitted via FDA Electronic Submission Gateway (ESG)	Modules 1 and 3	electronic Common Technical Document (eCTD), validated using GlobalSubmit Validate™ 2014 8.2.2

VIRUS FREE STATUS

DMF 031907-0001 is verified to be virus free.

Anti-Virus Software Used

Symantec Endpoint Protection and Symantec Network Access Control.

Version Number

Version 12.1.7004.6500 which is updated daily.

Company

Symantec Corporation.

HOLDER POINTS OF CONTACT

Table 2: Points of Contact

Regulatory Affairs Contact	eCTD Contact	DMF Agent
Mr. Jacob Woosoon Baik KP tech, Ltd. Phone: +82 31.321.4400 avantgarde@kp-tech.co.kr	Ms. Antoinette Azevedo eSubmissionsSolutions.com Mobile +1-619-787-1514 AAzevedo@e-SubmissionsSolutions.com	Mr. Frank Bieganousky Montesino Consulting, LLC Mobile +1-973-903-9138 Frank.bieganousky@montesino.com

STATEMENT OF COMMITMENT:

This is to certify that the information contained herein is current, and that the manufacturing processes and specifications for the products identified in this Drug Master File will be met and complied with. All significant changes will be communicated to affected customers and will be reported in amendments to this Drug Master File. Annual updates to this Drug Master File will also be submitted to the Food & Drug Administration.

We request that all information in this file be treated as confidential to the extent possible in accordance with 21 CFR 314.430 and 21 CFR 20.61, and that no information from this file be provided to any unauthorized persons without our written consent.

Please contact us if there are any questions whatsoever.

Sincerely,

Jacob Woosoon Baik 

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