

Our Ref:

Letter_API_(PKK)_V1

Head of Lab Services Section
Centre of Quality Control
National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia
Lot 36, Jalan Universiti
46730 Petaling Jaya, Selangor

SUBMISSION OF API INFORMATION FOR PRODUCT REGISTRATION APPLICATION

Product Name :
Call Number :
Active Pharmaceutical Ingredient :
API Manufacturer :
Product Registration Holder :
Product Category : **NCE**
: **Prescription (Full Evaluation)**
Submission Option : **DMF**
: **ACTD**
(Please tick ✓)

With reference to the above product, we have made payment on _____ and would like to submit a CD copy with required documents as below:

- S.4.1 Specification of API from API Manufacturer & Product Manufacturer
 - S.4.2 Analytical Procedures
 - S.4.3 Validation of Analytical Procedures
 - CoA of API from API manufacturer (2 batches)
 - CoA of API from Product manufacturer (2 batches)
- (Please tick ✓)

For future correspondence, kindly contact person-in-charge for this application as stated at signature below.

Remarks (if any):

(Signature)

Name:

Designation:

Company Name:

Contact Number:

Email address:

Date: