DMF 044458 **DMF ACKNOWLEDGEMENT**

KK FOILS
ATTENTION: MR. SHRAWAN KUMAR, PROPRIETOR
PLOT NO. - 114G, DAVNI INDUSTRIAL AREA, HPSIDC (DAVNI)
PO- MANPURA, NALAGARH, TEHSIL- BADDI
DIST- SOLAN -174101, HIMACHAL PRADESH, INDIA

Dear Mr. Shrawan Kumar,

The Food and Drug Administration acknowledges receipt of the following Drug Master File (DMF) submission:

DMF NUMBER ASSIGNED:	044458
DATE OF SUBMISSION:	JULY 4, 2026
DMF TYPE:	III
SUBJECT (TITLE):	PRINTED ALUMINUM FOILS (BLISTER FOIL, STRIP FOIL, ALU-ALU CFB FOIL) FOR PHARM INDUSTRY
HOLDER:	KK FOILS
SUBMITTED BY:	KK FOILS
AGENT:	PERFECT PHARMACEUTICAL CONSULTANTS PVT. LTD.

All subsequent correspondence to this DMF should be identified with the information as provided above.

Your DMF will be reviewed only in connection to a New Drug Application, Abbreviated New Drug Application, Investigational New Drug Application, Biological License Application, New Animal Drug Application, Abbreviated New Animal Drug Application, Investigational New Animal Drug Application, or DMF it is intended to support when a Letter of Authorization (LOA) is submitted to the DMF and a copy of the LOA is submitted in the application e.g., NDA, that references the DMF.

You are expected to:

- Adhere to the statement of commitment you have provided.
- Provide the following submissions to the DMF:
  - Letters of Authorization (LOAs) granting permission to a third party (authorized party) or self to reference the DMF and for FDA to review the DMF. Listing an authorized party in the Annual Report is not sufficient to authorize that party to reference the DMF. Submission of a copy of the LOA to the authorized party

without submitting the original LOA to the DMF (with DMF number) is also not sufficient to authorize that party to reference the DMF.

- Any change, addition or deletion of information
- Annual Reports to the DMF containing:
    - Date(s) of the amendment(s) reporting changes since the last Annual Report or the original DMF filing date, whichever is most recent or a statement that no amendments have been submitted since the last Annual Report or the original DMF filing date, whichever is most recent.
    - A complete list of all parties currently authorized to incorporate information in the DMF by reference; identifying by name, reference number, volume, date, and page number the information that each person is authorized to incorporate and the date of the LOA or a statement that there are no Authorized Parties.
    - A list of all parties whose authorization has been withdrawn, if applicable.
    - Holder signed DMF Statement of Commitment stating that the DMF is current and the holder will comply with the statements made in it.

For specific information on DMF, including submission types, letter template examples, and links to other resources, please refer to the DMF webpage.[1]

The holder of the DMF is responsible for compliance with 21 CFR 314.420 as interpreted on the Guideline for Drug Master Files webpage.[2]

Electronic submissions that are 10GB or smaller in size must be submitted through the Electronic Submission Gateway (ESG). Submissions that are over 10GB may be submitted on physical media (such as compact disc) to the following address:

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

For additional information on electronic submission, see the FDA eCTD webpage and the guidance for industry *Providing Regulatory Submissions in Electronic Format —Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD*

[1] https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs
[2] https://www.fda.gov/drugs/drug-master-files-dmfs/guideline-drug-master-files-dmf

Specifications.[3,4]

For any questions related to DMF submissions, please contact dmfquestion@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Don Henry
Director, Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

CC:
PERFECT PHARMACEUTICAL CONSULTANTS PVT. LTD.
ATTENTION: SUMIT GUPTA, DIRECTOR
PRESTIGE CLASSIC BLD., D WING, OFF. G4 & 5
CHINCHWAD STATION, PUNE-411019, INDIA

[3] https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd
[4] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications-0

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

CLAUDE THEOPHIN
07/31/2026 09:38:58 AM