DMF 042245 **DMF ACKNOWLEDGEMENT**

SUNPURE EXTRACTS PVT. LTD.
ATTN:
E-25, INDUSTRIAL AREA
SIKANDRABAD (U.P.) 203205, INDIA

Dear Sir,

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

DMF NUMBER ASSIGNED:	042245
DATE OF SUBMISSION:	JULY 2, 2025
DMF TYPE:	II
SUBJECT (TITLE):	PONGAMOL EXTRACT 95%
HOLDER:	SUNPURE EXTRACTS PVT. LTD.
SUBMITTED BY:	SUNPURE EXTRACTS 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.