



DMF 033156

DMF ACKNOWLEDGEMENT

SUNPURE EXTRACTS PVT., LTD.

Attention:

E-25, INDUSTRIAL AREA

SIKANDRABAD - 203205, UTTAR PRADESH, INDIA

Dear Sir,

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

<u>DMF NUMBER ASSIGNED:</u>	033156
<u>DATE OF SUBMISSION:</u>	SEPTEMBER 11, 2018
<u>DMF TYPE:</u>	II
<u>SUBJECT (TITLE):</u>	CENTELLA ASIATICA DRY EXTRACT 45%
<u>HOLDER:</u>	SUNPURE EXTRACTS PVT., LTD.
<u>SUBMITTED BY:</u>	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 responsible for compliance with 21 CFR314.420. See "The Guideline for Drug Master Files" <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073164.htm>

You are required to submit all changes in information regarding the DMF (21 CFR 314.420(c)). In particular the FDA must be notified of any changes in the holder name or ownership and/or the agent and/or the name of the contact person.

The types of information to be submitted may be found at the DMF Web Site: www.fda.gov/cder/dmf. See "**Submission of Amendments, Annual Reports, and Letters of Authorization.**"