DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

DMF 033932

DMF ACKNOWLEDGEMENT

NEELKANTH POLYMER INDUSTRIES
Attn: MR. NARAN CHOUDHARY, DIRECTOR
PLOT NO. 65/66, SECTOR, TALVALI NAKA
THANE-BELAPUR ROAD, GHANSOLI
NAVI MUMBAI-400 701, MAHARASHTRA, INDIA

Dear Mr. Naran Choudhary,

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

DMF NUMBER ASSIGNED:	033932
DATE OF SUBMISSION:	JUNE 19, 2019
DMF TYPE:	III
SUBJECT (TITLE):	PLASTIC BOTTLES, PLASTIC CAPS, DROPPER ASSEMBLY, MEASURING CAPS, CRC CAPS, INJECTION BARRELS AND INJECTION PISTONS FOR PHARMACEUTICAL PACKAGING
HOLDER:	NEELKANTH POLYMER INDUSTRIES
SUBMITTED BY:	NEELKANTH POLYMER INDUSTRIES
AGENT:	PERFECT PHARMACEUTICAL CONSULTANTS PVT. LTD.

All subsequent correspondence to this DMF should be identified with the information 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" https://www.fda.gov/drugs/drug-master-files-dmfs/guideline-drug-master-files-dmf

You are required to submit any addition, change, or deletion of information in a drug master file (21 CFR 314.420(c)). An Annual Report should be submitted every 12 months to keep the DMF in active status.

The types of information to be submitted may be found at the DMF Web Site: : https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs

See "Submission of Amendments, Annual Reports, and Letters of Authorization.

Your submission was successfully processed into the CDER Electronic Document Room, and is available to the assigned review division.

Application Type/Number:	MF033932
eCTD Sequence Number:	0001
CoreID:	ci1614602306171.46303@fdsuv08652_te2

Your official receipt date is calculated in accordance with the following final Guidance for Industry: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-receipt-date

Contact Information:

For technical assistance only: eSUB@fda.hhs.gov

For all other questions regarding your submission, contact your review division.

Thank you,

Electronic Document Room
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Your submission was successfully processed into the CDER Electronic Document Room, and is available to the assigned review division.

Application Type/Number:	MF033932
eCTD Sequence Number:	0002
CoreID:	ci1614603028858.210120@fdsuv08640_te2

Your official receipt date is calculated in accordance with the following final Guidance for Industry: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-receipt-date

Contact Information:

For technical assistance only: eSUB@fda.hhs.gov

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Thank you,

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Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Your submission was successfully processed into the CDER Electronic Document Room, and is available to the assigned review division.

Application Type/Number:	MF033932
eCTD Sequence Number:	0003
CoreID:	ci1665653753640.2558854@fdslv86004_te1

Your official receipt date is calculated in accordance with the following final Guidance for Industry: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-receipt-date

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