STANDARD OPERATING PROCEDURE	
Department: Regulatory Affairs	**SOP No.:**
Title: Test & Examination Licence for New Drug Product from State Drug Control Authority	**Effective Date:**
Supersede Revision No.: Nil	**Next Review Date:**
Revision No.: 00	**Page No.:** 1 of 4

1.0 OBJECTIVE:

To lay down a procedure for obtaining Manufacture Drugs for purpose of Examination, Test or Analysis from State Drug Control Authority (DCA).

2.0 SCOPE:

This SOP is applicable to Regulatory Affairs Department.

3.0 RESPONSIBILITY:

3.1 Junior Manager and above –Regulatory Affairs for Preparation and review of application
3.2 Deputy Manager and above – NPD for Identification and approval of New Drug
3.3 Sr. Manager and above – IPD for Raising request and Providing information
3.4 Deputy Manager and above – Corporate Affairs for Submission and obtaining the licence

4.0 DEFINITION(s):

Not applicable

5.0 PROCEDURE:

5.1 After identification and approval of a New Drug Product by NPD and IPD. The responsible person in NPD/IPD shall raise the request in Regulatory MIS Database.
5.2 RA shall Accept/Reject the request and upon Acceptance the request will be forwarded along with the checklist to the concerned departments for Test licence information.
5.3 Upon receipt of documents from concerned departments, RA will evaluate the same and if any changes required the same would be send back for corrections.
5.4 Upon receipt of the final documents application shall prepared by RA
5.5 Application shall be sent to Corporate Affairs department by RA
5.6 Corporate Affairs department shall submit the application to DCA and obtain Manufacture Drugs for purpose of Examination, Test or Analysis license with necessary follow up with DCA
5.7 Upon receipt of test and examination license, original copy shall be forwarded to Regulatory Affairs department by Corporate Affairs and photocopy shall be retained for records.
5.8 RA will inform to IPD/NPD on Receipt of Test licence of the product.
5.9 Test license is valid for one year from date of issue.
5.10 Flow chart for obtaining Manufacture Drugs for purpose of Examination, Test or Analysis license from DCA is enclosed for reference.

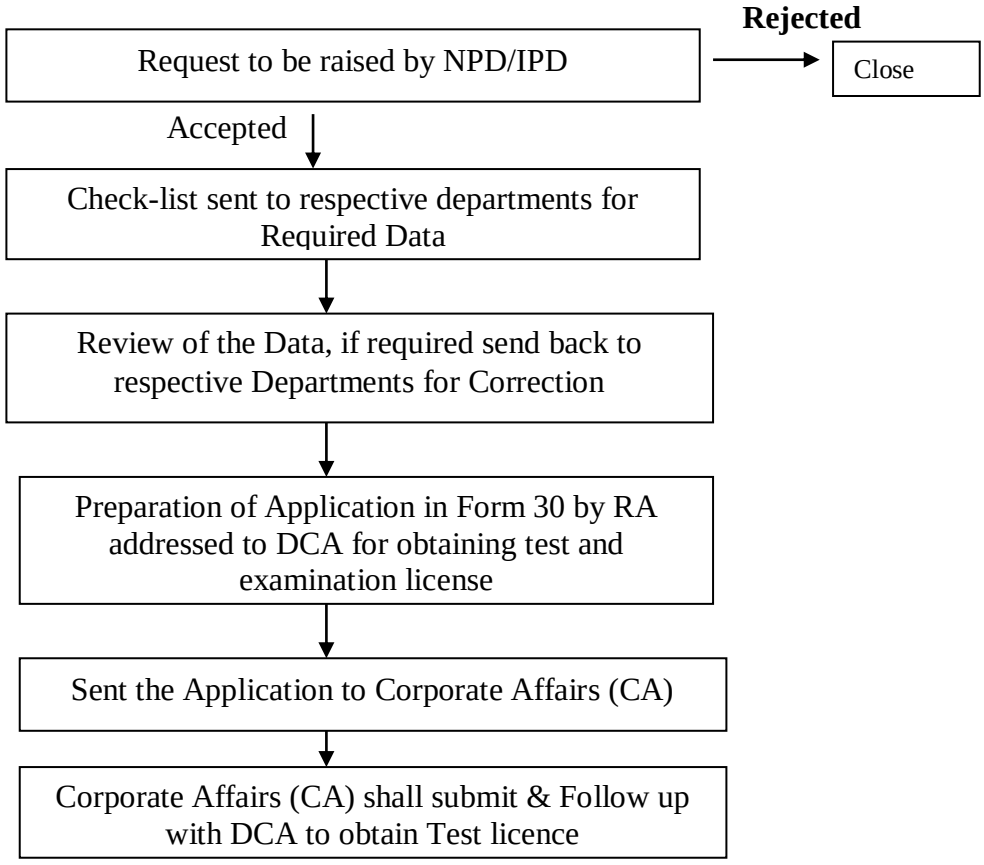
6.0 REFERENCES(s):

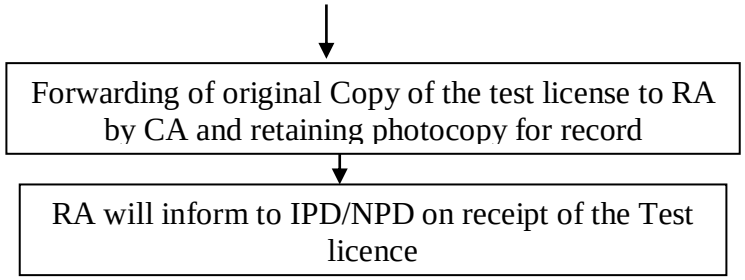
Not applicable

7.0 ABBREVIATIONS:

Abbreviation	Full description
SOP	Standard Operating Procedure
No.	Number
BF-ROW-RA	Branded Formulations – Rest of the World – Regulatory Affairs
RA	Regulatory Affairs
CA	Corporate Affairs
DCA	Drugs Control Administration
NOC	No Objection Certificate
NPD	New Product Development
IPD	Integrated Product Development
MIS	Manufacturing Information System

8.0 FLOW CHART(s):





9.0 ANNEXURE (s):

Annexure No.	Details/Title of Annexure	Format No. (Current version)

FORM – 30

(See Rule 90)

Application for licence to manufacture drugs for purpose of Examination, Test or Analysis

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I, XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX of ……., Plot Nos.: XXXXXXXXXXXXXXXXXXXX by occupation XXXXXXXXXXXXXXX XXXXXX for ……., Formulations Division hereby apply for a licence to manufacture the drugs specified in Annexure – I for the purpose of Examination, Test or Analysis at XXXXXXXXXXXXXXXXXXXX District XXXXXXX, and I undertake to comply with the conditions applicable to the licence.

Name of drugs:

As per Annexure – I

For ……

Signature
XXXXXXXXXXXXXXX

Date: