STANDARD OPERATING PROCEDURE

Department: Regulatory Affairs	**SOP No.:**
Title: Test Report of New Drug Substance from Central Drugs Laboratory (CDL)	**Effective Date:**
Supersede Revision No.: Nil	**Next Review Date:**
Revision No.: 00	**Page No.:** 1 of 5

1.0 OBJECTIVE:

To lay down a procedure for obtaining Test Report of New Drug Substance from Central Drugs Laboratory (CDL).

2.0 SCOPE:

This SOP is applicable to BF-ROW-RA of …….

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 Co-ordination in providing samples

3.3 Junior Manager and above – Corporate Affairs for Submission and obtaining the licence

4.0 DEFINITION(s):

Not applicable

5.0 PROCEDURE:

If new drug substance is sourced from outside of ……. API manufacturing unit or imported, the following procedure shall be followed:

5.1 Corporate Affairs shall provide information for the testing of Drug substance at CDL.

5.2 RA shall collect the information as per the requirement of Schedule Y from FR&D and CMS

5.3 Upon receipt of information from FR&D and CMS, RA shall review the data and if any changes required the same would be send back for corrections.

5.4 On receipt of the final error free documents, RA shall prepare the application in Form 44 (Enclosed in Annexure – I) as per Schedule Y requirement.

5.5 RA shall review and send the signed application to Corporate Affairs department.

5.6 Corporate Affairs department shall submit the application to DCG(I) and obtain NOC for testing of Drug substances at CDL.

5.7 Upon receipt of the license, Corporate Affairs department shall forward original copy to Regulatory Affairs department and photocopy shall be retained for their records.

5.8 NPD department shall co-ordinate in obtaining the sample to be tested with all the required details to RA.

5.9 RA shall prepare the sample with a label containing all the details (Name of the drug substance, Batch no., Mfg. Date, Exp. Date and sample quantity) and send the sample to Corporate Affairs department along with specifications and method of analysis.

5.10 Corporate Affairs department shall submit the sample to CDL for testing and shall obtain the test report from CDL after necessary follow up.

5.11 Original copy of test report shall be forwarded to Regulatory Affairs department and photocopy shall be retained for their records.

5.12 Flow chart for obtaining the test report from CDL is enclosed for reference.

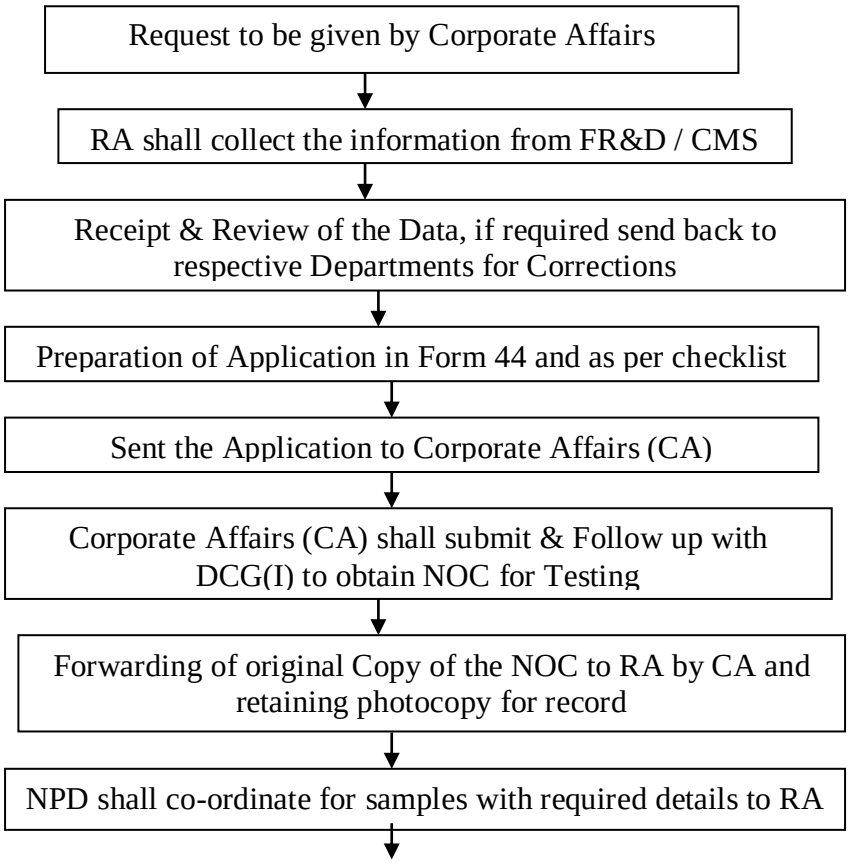
6.0 REFERENCES(s):

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
DCG(I)	Drugs Controller General of India
NOC	No Objection Certificate
NPD	New Product Development
CMS	Corporate Medical Services
CDL	Central Drugs Laboratory
CA	Corporate Affairs
API	Active Pharmaceutical Ingredient
FR&D	Formulations Research & Development

8.0 FLOW CHART(s):



RA to forward the samples along with the methods to CA

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CA shall submit the sample to CDL and follow up to obtain the report from CDL

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Forwarding of original Copy of the Test report to RA by CA and retaining photocopy for record

9.0 ANNEXURE (s):

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

FORM 44

(See rules 122-A, 122-B, 122-D and 122-DA)

Application for grant of permission to import or manufacture a New Drug or to undertake clinical trial

I, -------, ------- of M/s …….., hereby apply for grant of permission for import of and/or clinical trial or for approval to manufacture a new drug or fixed dose combination or subsequent permission for already approved new drug. The necessary information/data is given below:

1. Particulars of New Drug:

1.	Name of the drug	
2.	Dosage Form	
3.	Composition of the formula	
4.	Test Specification	
	a) Active ingredients	
	b) Inactive ingredients	
5.	Pharmacological classification of the drug	
6.	Indications for which proposed to be used	
7.	Manufacturer of the raw material (bulk drug substance)	
8.	Patent status of the drug	

2. Data submitted along with the application (as per Schedule 'Y' with indexing and page nos.):

A. Permission to market a new drug		
1.	Chemical and Pharmaceutical information	
2.	Animal Pharmacology	
3.	Animal Toxicology	
4.	Human/Clinical Pharmacology (Phase I)	
5.	Exploratory Clinical Trials (Phase II)	
6.	Confirmatory Clinical Trials (Phase III) (including published review articles)	
7.	Bio-availability, dissolution and stability study data	
8.	Regulatory status in other countries	
9.	Marketing information:	
	a) Proposed product monograph	
	b) Drafts of labels and cartons	
10.	Application for test licence	

B. Subsequent approval / permission for manufacture of already approved new drug		
a) Formulation		
1.	Bio-availability / bio-equivalence protocol	
2.	Name of the investigator / center	
3.	Source of raw material (bulk drug substance) and stability study data	
b) Raw material (bulk drug substance)		
1.	Manufacturing method	
2.	Quality control and / or analytical specifications	
3.	Animal toxicity data	
c) Approval / Permission for fixed dose combination		
1.	Therapeutic Justification (authentic literature in pre-reviewed journals / text books)	
2.	Data on Pharmacokinetics / Pharmacodynamics combination	
3.	Any other data generated by the applicant on the safety and efficacy of the combination.	
d) Subsequent approval or approval for new indication – new dosage form		
1.	Number and date of Approval / permission already granted	
2.	Therapeutic justification for new claim / modified dosage form	
3.	Data generated on safety, efficacy and quality parameters	

A total fee of Rupees ……../- (in words) Fifteen thousand Rupees only has been credited to the Government under the Head of Account …… (Photocopy of receipt is enclosed)

Dated……

Signature