



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

| | |
|--|------------------------|
| Department: Quality Control | SOP No.: |
| Title: Preparation of Standard Test Procedure | Effective Date: |
| Supersedes: Nil | Review Date: |
| Issue Date: | Page No.: |

1.0 OBJECTIVE:

To lay down a procedure for the Preparation, Approval, Authorization, Control, and Revision of Standard Test Procedures (STP) for Raw Material (RM), Finish Product (FP), Packagin material (PM) and Water .

2.0 SCOPE:

This SOP shall be applicable to Quality Control Department.

3.0 RESPONSIBILITY - Execution - Executive QC .
Checking - Assistant Manager QC

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE:

5.1 Preparation of STP for Finished Products & Packing Material :

5.1.1 After receipt of controlled copy of the STP from CQA/PRC .QC department shall prepare the STP

5.1.2 The STP shall be prepared on the approved format on A-4 size paper. (Refer Annexure-I for Finished Product and Annexure II for Packaging material).

5.1.3 The type of font for the contents in STP shall be 'Times New Roman' & font size shall be '11.'

5.1.4 All the STP's shall be written in clear, unambiguous language, easy to understand and follow.

5.1.5 Sequentially describe the test procedures of each test specified in the specifications.

5.2 STP s of the Raw Material shall be prepared as per respective Pharmacopoeia or standard test procedures received from CQA/ PRC / QA

5.3 Raw Material STP shall be prepared as mentioned on 5.1.2 to 5.1.5 on Annexure – III.

5.4 STP of various type of water shall be prepared on Annexure – IV, as per respective specifications

5.5 The Numbering System of the STPs shall be as under:

SXXXXX

Where,

S = Standard Test Procedure

XXXXX = is the unique specification No. of that material / product.

For Example : STP No. of potable water will be SWA001

5.6 After initiation, approval, and authorization of STP, the Master copy shall be submitted to QA Department for control and issuance.



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5.7 All the STP's shall be reviewed with in two years from the effective date and whenever there is any change in specifications or in testing procedure amended by the pharmacopoeia or relevant source.

5.8 Any change in STP shall be done through change control procedure.

5.9 After revision, Master copy of STP shall be submitted to QA for control and issuance.

6.0 SAFETY & PRECAUTIONS:
Not Applicable.

7.0 REVISION HISTORY:

| Revision No. | Reason for Revision | Superseded from & Date |
|--------------|---------------------|------------------------|
| | | |

8.0 DISTRIBUTION:

| Copy No. | Issuance Record | | | | Withdrawal Record | | Destruction Record | |
|----------|-----------------|--------------|------------------------------|----------------------------|-------------------|------------|--------------------|------------|
| | Date | Dept. issued | Name / Signature of receiver | Issued By Name / Signature | By | Sign/ Date | By | Sign/ Date |
| | | | | | | | | |

9.0 REFERENCES:

Documentation Control, SOP

Change Control Procedure, SOP

10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

QC : Quality Control

No. : Number

STP : Standard Test Procedure

RM : Raw Material

FP : Finished Product



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PM : Packaging Material

QA : Quality Assurance

CQA : Corporate Quality Assurance

Annexure I : STP format of RM

Annexure-II : STP format of FP

Annexure-III : STP format of PM

Annexure-IV : STP format of Water



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ANNEXURE-I

RAW MATERIAL STANDARD TEST PROCEDURE

| | | | |
|----------------------|----------------|--------|--|
| Name of Raw Material | | | |
| Item Code | | | |
| Reference | Page No. | 1 of Y | |
| STP No. | Effective Date | | |
| Supersede | Review Date | | |
| Storage Condition | Shelf Life | | |

APPROVAL DETAILS:

| | | Name | Signature | Date |
|-------------|-------------------|------|-----------|------|
| Prepared By | Quality Control | | | |
| Checked By | Quality Control | | | |
| | Quality Assurance | | | |
| Approved By | Quality Control | | | |
| | Quality Assurance | | | |

Revision History:

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Test Procedure:

Sequentially describe the test procedures in this section:



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ANNEXURE-II

FINISHED PRODUCTS STANDARD TEST PROCEDURE

| | | | |
|-----------------|--|----------------|--------|
| Name of Product | | | |
| Item Code | | Page No. | 1 of Y |
| Generic Name | | STP No. | |
| Label Claim | | Effective Date | |
| Reference | | Review Date | |
| Supersede | | Shelf Life | |

APPROVAL DETAILS:

| | | Name | Signature | Date |
|-------------|-------------------|------|-----------|------|
| Prepared By | Quality Control | | | |
| Checked By | Quality Control | | | |
| | Quality Assurance | | | |
| Approved By | Quality Control | | | |
| | Quality Assurance | | | |

Revision History:

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|--------------|---------------------|----------------|
| | | |

| | | | |
|-----------------|--|----------------|--------|
| Name of Product | | | |
| Item Code | | Page No. | Y of Y |
| Generic Name | | STP No. | |
| Label Claim | | Effective Date | |
| Reference | | Review Date | |
| Supersede | | Shelf Life | |

Test Procedure:

Sequentially describe the test procedures in this section:



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ANNEXURE-III

PACKING MATERIAL STANDARD TEST PROCEDURE

| | | | |
|--------------------------|----------------|--------|--|
| Name of Packing Material | | | |
| Item Code | | | |
| Reference | Page No. | 1 of Y | |
| STP No. | Effective Date | | |
| Supersede | Review Date | | |
| Storage Condition | Shelf Life | | |

APPROVAL DETAILS:

| | | Name | Signature | Date |
|-------------|-------------------|------|-----------|------|
| Prepared By | Quality Control | | | |
| Checked By | Quality Control | | | |
| | Quality Assurance | | | |
| Approved By | Quality Control | | | |
| | Quality Assurance | | | |

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Test Procedure:

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ANNEXURE-IV

WATER STANDARD TEST PROCEDURE

| | | | |
|---------------|--|----------------|--------|
| Name of Water | | | |
| Item Code | | | |
| Reference | | Page No. | 1 of Y |
| STP No. | | Effective Date | |
| Supersede | | Review Date | |

APPROVAL DETAILS:

| | | Name | Signature | Date |
|-------------|-------------------|------|-----------|------|
| Prepared By | Quality Control | | | |
| Checked By | Quality Control | | | |
| | Quality Assurance | | | |
| Approved By | Quality Control | | | |
| | Quality Assurance | | | |

Revision History:

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Test Procedure:

Sequentially describe the test procedures in this section: