STANDARD OPERATING PROCEDURE	
Department: Warehouse	**SOP No.:**
Title: Handling of Narcotic and Psychotropic Drugs	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down a procedure for Handling of Narcotic and Psychotropic Drugs.

2.0 SCOPE:

This SOP is applicable at …….

3.0 RESPONSIBILITY:

Head QA : Approval, Authorization, ensure Training and Implementation of this SOP.

Head QC : To Analyzed the sample and maintained the record.

Head Warehouse : Storage of Narcotic drugs in secured place and maintained record.

4.0 ACCOUNTABILITY:

Head QA : For the approval of this SOP & effective implementation of this SOP.

Plant Head : To adherence of this SOP.

5.0 ABBREVIATIONS:

API	Active Pharmaceutical Ingredient
BMR	Batch Manufacturing Record
HPLC	High Performance Liquid Chromatography
IPQA	In process Quality Assurance
No.	Number
NDPS	Narcotic Drugs and Pharmaceuticals Substance
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 DEFINITIONS:

6.1.1 API: Narcotic Drugs & Psychotropic Substances in the bulk drug for meant for manufacture into dosage forms/ formulations.

6.1.2 Narcotic Drugs: Narcotic drugs & Psychotropic substance in bulk drug & pharmaceutical product which are specified in schedule H, schedule H1 and Schedule X of the Drugs & Cosmetic Rules, 1945.

6.1.3 Documents: Any documentations (invoices, bills, memos, challans or Purchase orders) including accounts, books or records that shows purchase, storage, consumption, manufactured, sale or destruction of Narcotic Drugs.

6.1.4 Whenever such substances are received from the supplier, the consignment shall be properly checked and weighed & such material shall be stored in lock & key and labelled in presence of only authorized persons of QA/IPQA/QC/ stores & production for sampling, analysis, dispensing and manufacturing operation area of Narcotic and Psychotropic Drugs.

6.1.5 Special care shall be taken to check the seal of the consignment, If any problem observed in materials like found broken manufacturer seal then such case shall be immediately reported to Head –Warehouse , QA Head, Operation head , Nearest police station and Narcotics Department

6.1.6 If Materials was received in good conditions stores persons shall be prepared GRN in SAP, after GRN, Officer/Executive Warehouse shall maintain the record of materials in "Narcotics Register" of Annexure-I (Register of Consumption , Sale , Import or Export of Controlled substance).

6.1.7 Product Shelf Life: Term used to describe the specified shelf life/expiry date of the narcotic drugs.

6.1.8 Damaged Product: Damaged product is defined as Narcotic Drugs that is not in a condition to be supplied to a customer. This includes damage to shipping cartons or containers, broken, crushed or any temperature controlled Narcotic Drugs that has not been stored at specified conditions.

6.1.9 Expired inventory: Inventory of Narcotic Drugs received from manufacturing/ distribution locations/ customer, which are date, expired and segregated from good stock to prevent distribution.

6.1.10 Returned Product: Returned Product means any Narcotic Drugs that is returned to the facility of Stockiest & Distributors as the cartons or containers may be damaged, broken, crushed or otherwise unsolvable or as sales return or on recalls. Narcotics Drugs may also be returned as a result of customer complaints and quality deficiencies.

6.1.11 Samples: Samples after every stage of process i.e. mixing, blending, granulation, compression, tableting, coating, packing etc. were drawn and send for QC analysis. The test carried out were Loss on Drying, Assay, Test, Solubility test, HPLC, Identification, Sulphate Ash test, Uniformity of weight, Thickness/Hardness Test, core Tablets analysis etc.

6.2 MAINTENANCE OF RECORDS:

6.2.1 The site shall maintain statutory records as prescribed under NDPS Act,1985 and Drugs & Cosmetic Act, 1940, rules, notification and order issued there under and follow the minimum procedures recommended below relating to the following activities:

6.2.1.1 Procurement & storage of raw materials.

6.2.1.2 Production of finished goods.

6.2.1.3 Testing of samples& destruction of wastage/remnant samples

6.2.1.4 Storage and handling of finished goods**.**

6.2.1.5 Dispatch of Finished goods.

6.2.1.6 Transportation of finished goods.

6.2.2 The records so maintained are required to be preserved for a minimum period of five years.

6.2.3 The site shall hold license under Drugs & Cosmetic act, 1940 and rules made there under for manufacture of Pharma Drugs.

6.3 PROCUREMENT & STORAGE OF RAW MATERIALS :

6.3.1 The raw material/ packing material shall be procured from the approved vendor and as per the customer recommendation**.**

6.3.2 Purchase order shall be issued before procuring raw material/ packing material from the vendor.

6.3.3 No quantity of raw material/ packing material shall be procured in cash and all payments to the vendor shall be made only through banking channels.

6.3.4 No quantity of raw material/ packing material shall be received in the premises of the site without the suppliers invoice.

6.3.5 The quantity of Narcotic/Psychotropic Drugs received from suppliers shall be stored in secured premises under lock and key and the key to the premises shall be available only with Plant Head.

6.3.6 The secured place of storage shall be labelled in bold letters giving details of the Narcotic Drugs stored there.

6.3.7 The Narcotic Drugs are required to be stored in the secured place in such manner that physical checks and verification of the stock can be undertaken easily.

6.3.8 Physical stock of Narcotic Drugs stored in the secured place shall be carried out on fortnight basis and compared with the book stock and recorded as per **Annexure-I**. Discrepancy if any, observed during physical stock taking it shall be reported to the Plant Head.

6.3.9 Access to the secured storage area of Narcotic/ Psychotropic Drugs shall be restricted to only personnel specifically authorised by the Plant Head.

6.3.10 No quantity of Narcotic Drugs shall be issued for use in manufacturing of finished product without receipt of requisition slip.

6.3.11 The receipt, storage, withdrawal of samples and issue of raw materials/packing materials shall be well documented in the records.

6.4 PRODUCTION OF FINISHED GOODS:

6.4.1 The production department should maintained and keep a record as per **Annexure-II**, for each Pharma Drugs manufactured. The said record shall be duly authenticated by the incharge of production.

6.4.2 The quantity of raw material/packing material received for manufactured/packing of finished goods and its disposal shall be documented in Batch wise Manufacturing/packing record and its disposal in the form of destruction note signed by IPQA in reconciliation of Batch manufacturing/ packing record.

6.4.3 The nature of process undertaken in the manufacturing of finished goods, details of such process and result thereof shall be well documented in Batch wise Manufacturing records.

6.4.4 The quantity of wastage generated and samples drawn for testing and analysis at various stages (as per **Annexure-III**) of the manufacturing and finished goods shall be well documented in Batch wise Manufacturing Records.

6.4.5 If the samples of Narcotic Drugs either in Raw material stage or finished product stage require commercial lab analysis, then it shall done using Form 6 of the NDPS Rules, 1985.

6.5 TESTING OF SAMPLES & DESTRUCTION OF WASTAGES/REMNANT SAMPLES:

6.5.1 The date, quantity and description of samples drawn from raw materials, intermediates stage, finished product, packed goods etc. shall be well documented in the respective records maintained in the lab as well as production department.

6.5.2 The nature of test carried out, the time taken for such test, quantity of samples consumed, quantity of remnant sample, result of the test and other details concerning the test shall also be documented in the records maintained in the analysis laboratory.

6.5.3 Separate register showing details and particular of remnant samples and its disposal shall be maintained in the quality control laboratory as per **Annexure-IV** and as well as production.

6.5.4 No quantity of remnant samples or wastage of Narcotic Drugs shall be destroyed in the quality control laboratory itself without under the supervision of a committee consisting of QC incharge and two officers immediately subordinate to such incharge.

6.5.5 Record of such destruction including the name, quantity etc of the remnant sample, date and mode of destruction etc shall be prepared which shall be signed by members of the destruction committee in the respective format provide for the same.

6.5.6 Remnant samples or wastage sent to solid waste management agency for destruction shall be sent on a challan giving complete details of each sample or wastage and its quantity or it shall be incinerated in our boiler capturing the mode of destruction.

6.5.7 If the remnant sample or wastage of Narcotic/ Psychotropic Drugs is sent to solid waste management agency for destruction, it shall be dispatched only under the cover of a consignment note in form 6 of the NDPS rules, 1945.

6.5.8 A certificate from the solid waste management agency shall obtained after destruction from the solid waste management agency detailing therein complete details of each sample or wastage and its quantity so destroyed.

6.6 STORAGE AND HANDLING OF FINISHED GOODS:

6.6.1 The finished goods manufactured shall be supplied only against purchase order of the customer.

6.6.2 No quantity of finished goods shall be supplied without under the cover of invoice.

6.6.3 The quantity of Narcotic Drugs manufactured shall be stored in secured premises under lock and key and the key to the premises shall be available only with plant head of the finished goods stores.

6.6.4 The Narcotic Drugs are required to be stored in the secured place in such manner that physical checks and verification of the stock can be undertaken easily.

6.6.5 Physical stock of Narcotic Drugs stored in the secured place shall be carried out on fortnight basis and compared with the book stock and recorded. Discrepancy if any, observed during physical stock taking it shall be reported to the plant.

6.6.6 Access to the secured storage area of Narcotic/ Psychotropic Drugs shall be restricted to only personnel specifically authorised by the Plant Head.

6.6.7 Records shall be maintained relating to receipt, storage and dispatch and such records shall be audited internally at regular intervals.

6.7 DISPATCH OF FINISHED GOODS:

6.7.1 Dispatch of Pharma Drugs shall be made only on receipt of authorized dispatch advice or delivery order duly signed by the designated/authorized officer of marketing or logistics and permitted by the stores in charge.

6.7.2 Supply of Narcotic Drugs shall be made only against written purchase order from the customer.

6.7.3 Pharma drugs shall be dispatched only against invoice which shall include the following minimum information:

6.7.3.1 Date of transaction

6.7.3.2 Consignor and consignee name and address with telephone, facsimile numbers.

6.7.3.3 Description and quantity of the substance along with unit of measure.

6.7.3.4 No. of bundles/packages/containers.

6.7.3.5 Means of transportation.

6.8 TRANSPORTATION OF FINISHED PRODUCT:

6.8.1 Reliable and reputed transporters shall be used for transporting the finished Pharma Drugs.

6.8.2 Copy of the driving license and a photo identity of the driver of the vehicle shall be procured before dispatching the Finished Pharma Drugs and preserved along with the dispatch documents of the consignments.

6.8.3 The packages/ containers containing the Finished Pharma Drugs shall be sealed with identifiable and tamper proof seals and the details of seals used shall be recorded in the accompanying delivery documents.

6.8.4 Proper acknowledgement of the receipt of the Finished Pharma Products shall be obtained from the driver. Acknowledgment shall also be received from the consignee and preserved along with the dispatch documents of the consignments.

6.8.5 The delivery of the consignment of Finished Pharma Products shall be made only at the address of the consignee or their assigned place of delivery mentioned in the delivery documents and not to any other place.

6.8.6 Any loss of Narcotic Drugs during delivery or transportation shall be immediately reported to head of distribution of the customer and plant head as well as to the Police Authorities.

6.8.7 The above conditions must be followed, even when the site itself is carrying out the transportation in their own vehicles.

6.9 HANDLING OF NARCOTIC DRUGS (EXPIRED AND RETURNED):

6.9.1 In the basis of expiry tracked, the expired NDPS raw materials shall be rejected in the category date of expired rejection & shall be kept ready for destruction raising the Destruction note for the same.

6.9.2 These materials are placed in the destruction area and permanent marker ink sprayed & the container is sealed with proper labeling.

6.9.3 The sealed bags shall be sent to solid waste management agency for destruction on a challans complete detail of each NDPA products and its quantity in form 6.

6.9.4 A certificate from the solid waste management agency shall obtain after destruction from the solid waste management agency shall detailing there in complete details of each sample or wastage and its quantity destroyed.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Register of Consumption, Sale, Import or Export of Controlled substance	
Annexure-II	Consumption of Narcotic substances in Production	
Annexure-III	Consumption of Narcotic substances in Quality control (During Sampling)	
Annexure-IV	Consumption of Narcotic substances in Quality control (During Analysis)	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Warehouse
- Master Copy Quality Assurance

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9.0 REFERENCES:

- NDPS Act-1985
- Drugs & Cosmetic Act-1940 & Rules 1945

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By

PHARMA DEVILS

WAREHOUSE DEPARTMENT

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ANNEXURE-I
REGISTER OF CONSUMPTION, SALE, IMPORT OR EXPORT OF CONTROLLED SUBSTANCES

Month……....

Date	Quantity in hand at beginning of the day	Details of Quantity of the substance received / imported				Details of quantity	
		SI. No.	Quantity (in Kg)	From whom received (Registration number, name and address of the persons to be given)	Consignment Note/ bill of Entry No.	SI. No.	Quantity (in Kg)

Name of the controlled substance…….....

Of the substance distributed/sold/exported/imported/consumed		Consumed (batch No.)	Purpose for consumption	Handling Loss if any	Quantity in Hand at the close of day	Initial of the Authorized Person
To whom sold /sent (Name and Address of the person and location of the premises to be given)	Consignment Note issue Slip No./date					

PHARMA DEVILS

WAREHOUSE DEPARTMENT

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ANNEXURE-II
CONSUMPTION OF NARCOTIC SUBSTANCES IN PRODUCTION

Month & Year: **Name of the Narcotic substances:**

Date of receipt of Raw Material	Product Name	B. No.	B. Size	Quantity consumption	Stage	Handling loss if any	Quantity for destruction	Initial of the Authorized Person

PHARMA DEVILS

WAREHOUSE DEPARTMENT

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ANNEXURE-III
CONSUMPTION OF NARCOTIC SUBSTANCES IN QUALITY CONTROL (DURING SAMPLING)

Month & Year: **Name of the Narcotic substances:**

Date of sampling	Total quantity sampled	B. No.	Mfg. Date	Exp. Date	A.R No./C. No.	Handling loss if any	Quantity sampled	Initial of the person sampled

PHARMA DEVILS

WAREHOUSE DEPARTMENT

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ANNEXURE-IV

CONSUMPTION OF NARCOTIC SUBSTANCES IN QUALITY CONTROL (DURING ANALYSIS)

Month & Year: **Name of the Narcotic substances:**

Date	Product name	B. No.	Mfg Date	Exp. Date	Quantity sampled				Quantity consumed				Handling loss if any	Qty. for destruction	Initial of the Authorized person
					For Blend	For core	For coated	For finished product	For Blend	For core	For coated	For finished product			