DISTRIBUTION RECORDS

DISTRIBUTION

The division and movement of the pharmaceutical products from the premises of the manufacturer of such products, or another central point, to the end user thereof, or to an intermediate point by means of various transport methods, via various storage and/or health establishments.

There are some aspects in distribution to which the principles of good manufacturing practice (GMP) should be applied.

- Organization and management
- Personnel
- Premises, Warehousing and storage
- Vehicles and Equipment
- Containers and Container labeling:
- Dispatch

DISTRIBUTION RECORDS

Distribution records are written data related to distribution of drug products from the manufacturer to the distributors.

The complete data regarding all batches of drug products should be maintained.

OBJECTIVE

- To immediately recall, investigate or to take remedial measure against the defective product.
- Maintenance of records of finished product is essential to facilitate complete recall of batch if necessary.
- investigate or to take remedial measure against the defective product.

THE CONTENT OF DISTRIBUTION RECORDS

Product description

- Describe the product being transfer to a new owner (e.g. Drug name, manufacturer, lot number, strength, dosage form).

Transaction information

- Describe the sale, transfer, return, or other disposition of the product (e.g. quantity, invoice number, invoice date)

Distribution information

- Describe the party selling or transferring ownership the product (e.g. business name and signature of person).

Recipient information

- Describes the party receiving the product (e.g. business name and address, data received, name and signature of the person).

For compressed medical gas products

- Distribution records are not required to contain lot or control numbers.

WHO Guideline for Distribution Records:

- Written instructions and records should be available Procedure should be established and maintained.
- Documents should be designed, reviewed and distributed with care.
- The title, nature and purpose of each document should be clearly stated
- The content of document should be clear and unambiguous. Documents should be laid out in an orderly fashion and be easy to check.
- All documents should be completed, approved, signed (as required) and dated by an appropriate authorized person.
- There should be compliance with national legislative requirements with regard to the nature, content and retention of documentation, relating to the distribution of pharmaceutical products
- The distributor must establish and maintain procedures for the identification, collection, indexing, storage, maintenance, disposal of and access to all applicable documentation.
- All record must be readily retrievable, stored and retained using facilities. Documents should be reviewed regularly and kept up to date.
- Mechanisms should exist to allow for transfer of information.
- Records should be kept and be readily available upon request.

- In the case of temperature-sensitivity pharmaceutical products, records of investigations and actions should be retained for at least one year after the expiry date of the product.
- Where the records are generated and kept in electronic for, their back-ups should, be available to prevent any accidental data loss.
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Inventory card M/S (Name & address of company)

Name of product:

Receipt			**Issue**			
Date	Transfer note number	Quantity received	Quantity issued	Invoice number	Balance	Sign of issue person

DISTRIBUTION REGISTER FORMAT

Receipt					**Distribution**					
Date	**TNN**	**Qty received**	**BNo.**	**Qty issued**	**BNo.**	**Invoice no.**	**Date**	**Name & address of distributor**	**Balance**	**Sign of issued person**

Distribution records includes documentation such as invoices, bills of loading, customer receipts, internal warehousing storage & inventory records.