



PRODUCTION BLOCK

Next Wave (India)

*Rampur Ghat Road, Paonta Sahib,
Distt. Sirmour (H.P.)*





QC & QA BLOCK

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INTRODUCTION

- Established in 2005, Next Wave (India) is a venture formed through dreams of four well known pharma professionals with an only aim of helping the medical fraternity in healing the ailing & protecting the healthy people of our society.
- The plant is built amidst green & pollution free environment with multiple manufacturing facilities under one roof.
- The plant is built in an approx. area of 5,000 m², with total covered area of 60,000 sq. ft.
- At Next Wave (India), quality is of prime importance which is achieved through a well equipped laboratory built as per cGLP guidelines.
- The facility is built to provide uninterrupted process flow with validated processes and equipments.

Next Wave (India)



VISION

To spread our wings into International Market

To enter into:

- South East Asian Region
- CIS Countries
- Middle East & Mediterranean Region
- Latin America.



PRODUCTS

At Next Wave (India) following products can be manufactured:

- 2.7 billion units of **Tablets** per annum.
- 540 million units of **Capsules** per annum.
- 36 million units of **Liquid Orals** per annum.
- 36 million units of **Ointments** per annum.

All sections are of non-betalactam category

PRODUCTS

Manufacturer of Quality Sustained Release Products & following therapeutic categories

- Analgesic
- Cardio-vascular
- Antimicrobial
- Analgesic
- Anti-Inflammatory
- Antispasmodic
- Gastro-intestinal
- Anti-diabetic
- Enzymes
- Anti-asthmatic
- Anti-cold
- Topical Anti-infective
- Antipyretic
- Antihistamine
- Vitamin & Mineral Supplements

Next Wave (India) regularly takes approvals from DCGI of different products like:

- Bromocriptine Mesylate Mouth Dissolving Tablets IP
- Citicoline Syrup
- Lidocaine & Prilocaine Gel
- Levocetirizine Tablets
- Ofloxacin & Ornidazole Tablets
- Aceclofenac Tablets
- Aceclofenac & Paracetamol Tablets
- Methyl Cobalamine, Zinc Sulphate, Calcium Pantothenate, Pyridoxine, Folic Acid, Niacinamide & Chromium Tablets
- Methyl Cobalamine, Alphaliopic Acid, Thiamine, Pyridoxine & Folic Acid Tablets

QUALITY SYSTEM

Quality Policy

“We are committed to achieve the maximum customer satisfaction & excellence in providing the quality products globally by application of sound quality management systems”

This commitment is achieved through:

- Qualified & trained employees
- Adopting cGMP practices & complying all regulatory requirements
- Strong business ethics
- Passion for performance
- Integrated systems & processes
- Constant focus on improvements of systems

“Challenges are what make life interesting; overcoming them is what makes life meaningful.”

At Next Wave (India), we try to make our customer’s life meaningful.

QUALITY MANAGEMENT SYSTEM

We sustain our quality management system through applying certain policies like:

System Control

- Change Control
- Deviation Control
- HACCP
- Self Inspection
- OOS Control
- Stability

Qualification

- Vendor Audit
- Equipment/Instrument
- Personnel

Validation

- Process
- Method
- System
- Water
- Air (AHUs)

Others

- Trend Analysis
- Training (Internal/External)

EMPLOYEE STRENGTH

Skilled personnel involve - management, staff, and workers.

They are categorized into technical and non-technical viz.,

- Technical – Pharmacy / Science literate;
- Non-technical – Arts and Commerce literate.

Department	Number
Quality Assurance	10
Quality Control	14
Production	15
Warehouse	4
Engineering & Instrumentation	8
Personnel & Administration	7
Total	58

PREMISES & EQUIPMENTS – Production

Production division of Next Wave (India) is ornamented with latest and advanced equipments like:

Tablet Department

- ❖ RMG
- ❖ FBP
- ❖ FBD
- ❖ Cage Blender
- ❖ Compression Machines - 35/27/20 station (5 nos.)
- ❖ Auto Coater (2 nos.)
- ❖ Inspection Machines (2 nos.)
- ❖ Alu-Alu with Camera System/Blister/Strip Machines

Capsule Department

- ❖ Octagonal Blender
- ❖ Semi-automatic Filling Machine
- ❖ Inspection & Polishing Machine

Liquid Oral Department

- ❖ Automatic Manufacturing Plant
- ❖ Automatic Filling Line

Ointment Department

- ❖ Automatic Manufacturing Plant
- ❖ Semi-automatic Filling & Sealing Machine

PREMISES & EQUIPMENTS – Quality Control

Next Wave (India) has a well developed Quality Control Lab built as per cGLP guidelines. Which is further divided into Chemical, Microbiology and Packing Material Testing Labs.

Chemical Lab

- ❖ HPLC (5 nos.)
- ❖ FTIR
- ❖ Auto Titrator
- ❖ UV Spectrophotometer
- ❖ Dissolution Apparatus (3 nos.)
- ❖ Milli Q Water Purification System
- ❖ Brookfield Viscometer
- ❖ Walk-in type stability chamber (2 nos.)
- ❖ Stability Chamber (2 nos.)

Microbiology Lab

- ❖ PLC controlled Double Door Autoclave
- ❖ Vertical Autoclave
- ❖ B.O.D Incubator
- ❖ Bio Safety Cabinet
- ❖ Antibiotic Zone Reader
- ❖ Dynamic & Static Pass box
- ❖ Colony counter

Quality is never an accident; it is always the result of intelligent effort.

*Quoted by John Ruskin,
Implemented by Next Wave
(India)*

Packing Material Testing Lab

- ❖ Bursting Strength Machine
- ❖ Vertical Autoclave

PREMISES & EQUIPMENTS – Engineering

The complete manufacturing unit is well supported by the established Engineering System. It is comprised of:

- ❖ Generator Set (4 nos.)
- ❖ Boiler
- ❖ Screw-Type Air Compressor (2 nos.)
- ❖ R.O. Plant
- ❖ PW Plant
- ❖ Water Loop Circulation System

PREMISES & EQUIPMENTS – HVAC System

- ✓ Total **48 dedicated AHUs** double skin type as well as dehumidifiers wherever required are used in conditioning the process and non process areas to the desired level of temperature and humidity.
- ✓ Special care is being taken to prevent cross contamination of different product exposed areas and categories. In general process area, room conditions are maintained at 25 ± 2 °C and 50 ± 5 % RH maximum or as required.

PREMISES & EQUIPMENTS – Water System

The different types of water used in Next Wave (India) include:

- **Raw Water** : For Cleaning, Sanitation, Housekeeping, Boiler, Cooling Tower.
- **Drinking Water** : For Human Consumption
- **Purified Water** : For Final Rinse, Process requirements in production areas.

Source of Water:

The source of water for plant is underground sources. Bore well has been made for the same.

Flow of Water System:

Bore well water → Raw Water storage tank → Sand filter → Carbon filter → R.O. System

→ Cation Bed → Anion Bed → Degasser → Mixed Bed → Storage Tank → Loop

system(10μfilter » 2500 lph UV Light » 5μfilter » 10000 lph UV Light » 2μfilter) → User point

Next Wave (India)



GMP & VENDOR CERTIFICATION

Next Wave (India) facility is approved/certified by:

- ✓ WHO – GMP
- ✓ GLP certified Laboratory

- ✓ Mankind Pharma
- ✓ Lifestar Pharma
- ✓ Magnet Labs
- ✓ Alkem Laboratories Limited
- ✓ Strides Acrolab Limited



World Health Organization

World Health Organization



ARCOLAB LIMITED

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“A dream you dream alone is only a dream. A dream you dream together is reality.”



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