

"A goal without a plan is just a wish"



**Very Good Rated by DRAP**

"A state -of- the art pharmaceutical manufacturing unit"

# Manufacturing Profile

## MISSION STATEMENT

- ⇒ Our aspiration is to make Alza a leading Pharmaceutical Unit of Pakistan, which will cater patients, customers & the communities to live a better life through quality products.
- ⇒ Alza will use its professional marketing & pharmaceuticals expertise to bring customer ideas to life.





**ALZA is a Spanish word  
which means “To Rise”.**



**Alza Pharmaceuticals** - A state-of-the-art Pharmaceutical Manufacturing Unit, located at Jhelum Road Rawalpindi, is equipped with highly sophisticated and advanced facilities. It manufactures medicines of therapeutic classes like, Ophthalmology & Dermatology.

**Alza Pharmaceuticals** new manufacturing facility with 26899 sq. ft. covered area has been completed in 2015. The FDA/WHO approved cGMP guidelines are strictly followed in every single operation of plant.

**Alza Pharmaceuticals** is a subsidiary of Al-Shifa Trust Eye Hospital which is a tertiary care teaching hospital having world renowned faculty of Physicians & Surgeons in the field of Ophthalmology. Hospital has a clinical research center & ethical research committee which publishes research journal of Ophthalmology after every 6 months. Many research papers have been published by research scholars and post graduate students.

The annual in-house consumption of Eye Drops is about 35 to 40 million rupees. To save upon the expenses, the Board of Trustees decided to establish a Pharmaceutical Manufacturing unit for eye products to fulfill the requirements of the hospital and to provide high quality products to in-door and out-door patients.

The manufacturing was started in 1999 by the name of “Al-Shifa Pharmaceuticals”, under the supervision of highly professional and technical staff in accordance with the standards set by Ministry of Health Pakistan. Initially the unit was established in an ad hoc building that was producing products to fulfill the in-house requirements.

In 2009, expansion was planned but it was decided not to upgrade the existing manufacturing facilities rather set up a new unit in a dedicated building.

A new layout plan was approved by DRAP having manufacturing facilities for different dosage forms. Currently it has been decided to start manufacturing of Ophthalmological and Dermatological products for in-house as well as out side use.

**Alza Pharmaceuticals** plant is equipped with high class HVAC systems. Most of the equipment are digitally programmed for highest precision & accuracy. Its sterile production area is set with the complete line-up including washing, sterilization, autoclaving, manufacturing, filling, nozzling, capping & sealing from well renowned pharmaceutical equipment manufacturers.

Sterile water (USP) is a main vehicle for manufacturing most of the ophth & derma products. The water treatment system at **Alza Pharmaceuticals** is of highest class and meets all regulatory parameters.



## HVAC (Heat, Ventilation and Air- Conditioning System)

### HVAC system performs four basic functions:

- ▶ Maintains space temperature - Temperature can affect product quality directly as many products are heat sensitive. It can also affect product indirectly by fostering the growth of microbial contaminants on workers.
- ▶ Controls airborne particles, dust and microorganism through air filtration using high efficiency particulate air (HEPA) filters.
- ▶ Maintains room pressure- Rooms must be kept under a "Positive or Negative" pressure, meaning that air flow between processing room & adjacent area through doors or other openings to reduce airborne contamination. This is achieved by balancing pressure-differential between rooms & adjacent spaces.
- ▶ Maintains space moisture (Relative Humidity) – Humidity is controlled by cooling air to dew point temperatures or by using dehumidifiers. Humidity can affect the efficacy and stability of drugs.

**Each of the above parameters is controlled and evaluated in light of its potential to impact product quality.**

### Alza Pharmaceuticals has

Dedicated Technical floor for HVAC and Water Treatment Plant with 12 feet Height.

Dedicated AHU for each section and corridor (4 Sections and 9 AHU).

Building Management System (BMS) is installed for on line monitoring of HVAC system.



The sterile production facilities must be free of airborne particles that should not exceed 100 in number per cubic feet area for class 100 clean room (FS-209E). This is essential for sterile production. The clean room is maintained by HEPA filter & laminar air flow.

## HEPA (High Efficiency Particulate Air) filters

HEPA (high efficiency particulate air) filter is installed at terminal points so that only HEPA filtered air can enter the clean area. HEPA filters can prevent at least 99.97% of airborne particles.

## Laminar air flow

It is generally defined as airflow in which the entire body of air within a confined area moves in essentially unidirectional velocity along parallel flow lines. The filtered air may be directed vertically or horizontally across the work area. This laminar flow of clean air protects materials in the work area from particulate and cross contamination.

## Room construction

All walls, floors & ceilings are constructed as per cGMP guidelines giving a smooth & easily cleanable surface free of cracks or crevices. The floors are coated with Self-leveling Epoxy (SLE) to provide a hard impact & chemical resistant surface. All corners between the floor, walls & ceiling are finished with PVC coving to prevent the accumulation of debris & moistures.



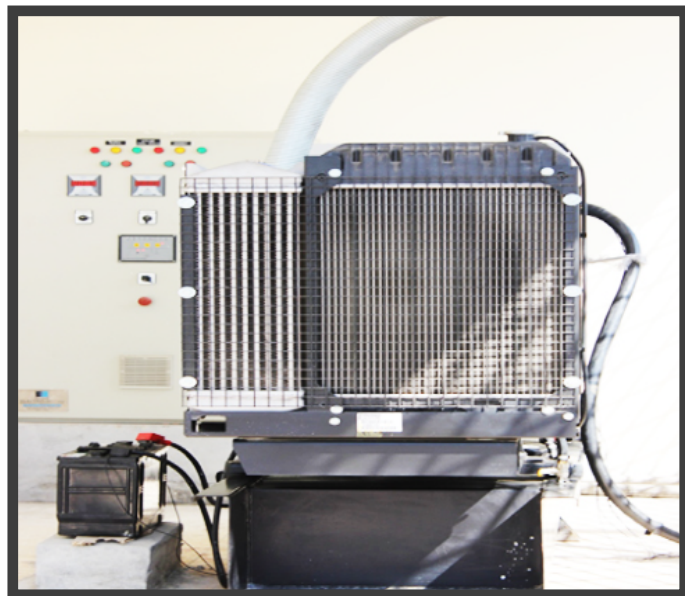
### Water Treatment Plant

Water plays a very important role in the manufacturing of eye drops. Alza Pharmaceuticals has installed a double pass R.O., distillation unit& closed loop system thus eliminating any risk of water contamination at any stage.



### Automatic Generator

An automatic generator is installed in this plant, which provides uninterrupted power supply to maintain smooth operations of HVAC and machineries of this



## Formulations manufactured presently at Alza Pharma plant

### Ophthalmic products

Sterile Solution, Suspension, Gel.

### Topical dosage forms

Semisolid: Creams, Ointment & Gel

Drops: Ear drop & Nasal drop.

### Production Capacity

With the inauguration of the latest plant the yearly production capacity of Alza pharma will come up to

Dosage Forms	Yearly Production Capacity
Eye Drops	20 million/shift
Tubes	7.6 million/shift

In Alza Pharmaceuticals, quality is the main objective which is also reflected in its slogan

**'It's all about Quality'.**

Strict quality control procedures are maintained at every step starting from sourcing of raw materials to dispatch of finished products. The FDA /WHO approved current Good Laboratory Practices (cGLP) are followed in every step of operation.



Written Standard Operating Procedures (SOPs) are maintained for every process, which are being closely monitored to ensure that all concerned personnel are complying with these procedures.

Alza pharma's Quality Control (QC) lab is well equipped with the most modern & sophisticated equipments like High Performance Liquid Chromatography (HPLC), Spectrophotometer (UV), Total Organic Carbon Analyzer (TOC Analyzer), Particle Counter and many other latest computer aided instruments & accessories to ensure the highest quality products.

The total Quality Assurance activities are accomplished by two departments – Quality Compliance & Quality Control, which are comprised of competent Pharmacists, Chemists & Microbiologist.







## Contac Us

we are always ready to assist you

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