

# STARWAYS PHARMACEUTICALS (PVT) LTD

AN OVERVIEW

Factory: Nowshera Economic Zone Risalpur,

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Company Name: STARWAYS PHARMACEUTICALS (PVT) LTD

Location: Nowshera Economic Zone Risalpur,

Nowshera, KPK, Pakistan.

DML No: 000999





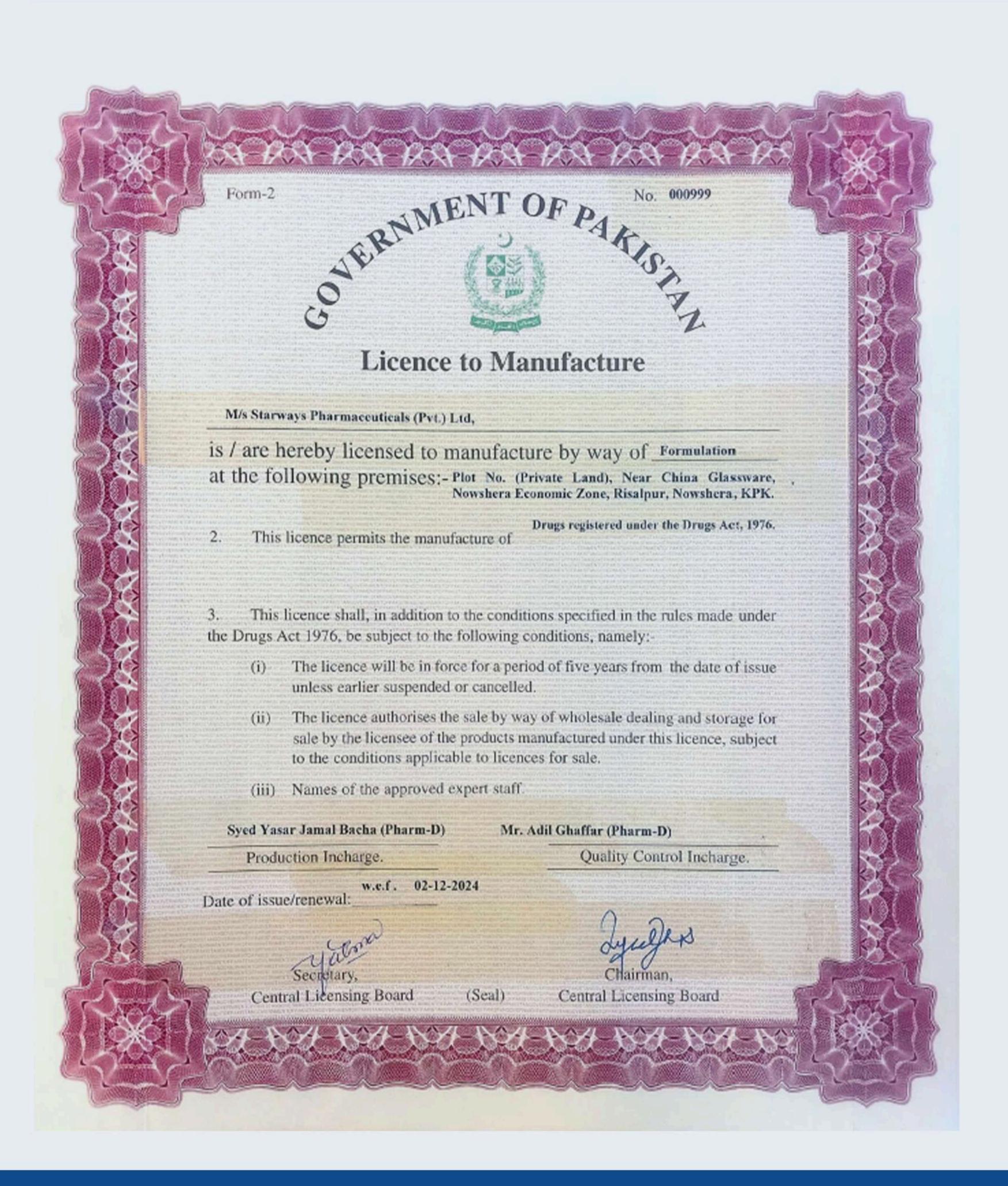
At Starways Pharma, we share a culture of equal growth opportunity, Welcomed innovation, creativity and exploration.

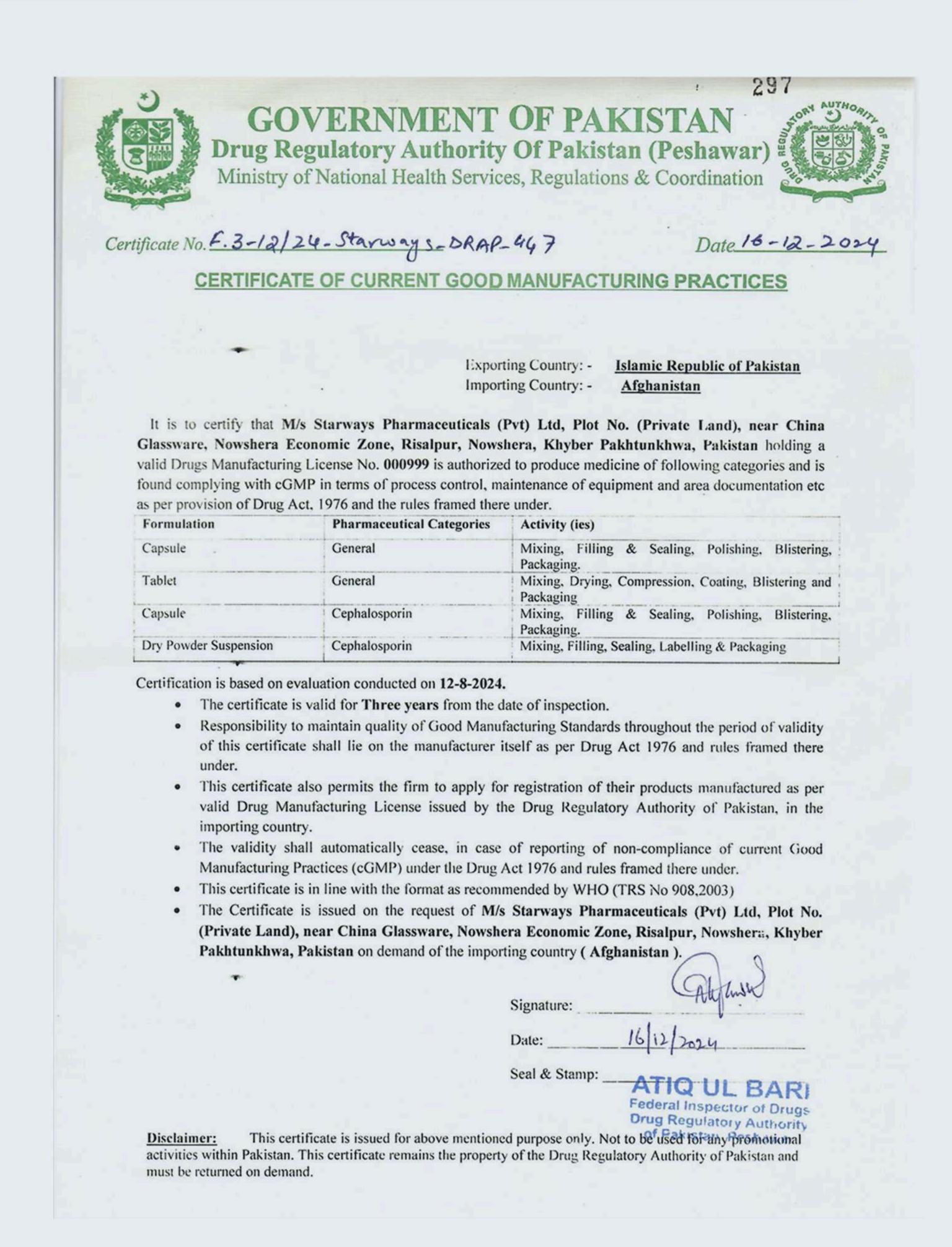
This distinctive culture has lead us to our most prefered, human friendly managment system....... The Managment by Objectives.



## CERTIFICATES AND APPROVALS







Drug Manufacturing License Issued by Drug Regulatory Authority of Pakistan

CGMP Certificate Issued by Drug Regulatory Authority of Pakistan

## CERTIFICATES AND APPROVALS







Certificate of INCORPORATION

Tax Payer Registeration Certificate

## **Approved Sections for Production of Human Drugs**



#### Section

Category (ies)

Capsule (General)

Tablet (General)

Sachet (General)

Dry Poweder Suspension (General)

Capsule (Cephalosporin)

Dry Powder Suspension (Cephalosporin)

## Activity (ies)

Mixing, Filling, Polishing,

Blistering, Packaging

Mixing, Drying, Granulating

Compressing, Coating, Blistering,

Packaging

Mixing, Filling, Sealing,

Packaging

Mixing, Filling, Sealing,

Labelling & Packaging

Mixing, Filling, Poslishing,

Blistering, Packaging

Mixing, Filling, Sealing,

Labelling & Packaging







## A Sneak Peak Into the Facility



## Total covered Area: 23710 sq ft

Quality Control Lab:	1760 sq ft
General Tablet Section:	1137 sq ft
General Capsule Section:	1469 sq ft
Sachet FIlling:	70 sq ft
Blister Room:	312 sq ft
Dry Powder Suspension General:	275 sq ft
Packing Hall:	960 sq ft
Vial & Bottle Store:	850 sq ft
Decoating:	227 sq ft
Dry Powder Vail Filling And Ceiling Section:	2971 sq ft
Capsule Section:	803 sq ft
Vail Packing Hall:	1023 sq ft
Dry Powder Section:	545 sq ft
Raw Material Store:	1125 sq ft
Packing Material Store:	965 sq ft
Finished Goods Store:	679 sq ft
Female Change Room:	260 sq ft
Male Change Room:	266 sq ft

#### TOTAL AREA OF PLOT 205' X 219' = 44895.000 SfT COVERED AREA

1.	CEO OFFICE	- 447.391 Sft
2.	RECEPTION	- 299.406 Sft
3.	ACCOUNT OFFICE SECTION	- 400.74 Sft
4.	CONFERENCE ROOM	- 317.742 Sft
5.	EXECUTIVE CHANGE ROOM	- 115.94 Sft
6.	FEMALE CHANGE ROOM	- 377.391 Sft
7.	MALE CHANGE ROOM	- 427.876 Sft
8.	QUALITY CONTROL LAB	- 1760.52 Sft
9.	GENERAL TABLET SECTION	- 1136.81 Sft
10.	GENERAL / CAPSULE SECTION	- 1469.250 Sft
10a.	SACHET FILLING	- 70.00 Sft
11.	BLISTER ROOM	- 312.034 Sft
11a.	DRY POWDER SUSPENSION	GENERAL 275.000 Sft
12.	PACKING HALL	- 959.640 Sft
13.	VIAL & BOTTLE STORE	- 848.521 Sft
14.	DECOATING	- 227.094 Sft
15.	DRY POWDER VAIL FILLING A	
	CEILING SECTION	- 2971.913 Sft
16.	CAPSULE SECTION	- 803.241 Sft
17.	VAIL PACKING HALL	- 1023.295 Sft
18.	BLISTER ROOM	- 244.45 Sft
19.	DRY POWDER SECTION	- 545.949 Sft
20.	RAW MATERIALS STORE	- 1125.163 Sft
21.	PACKING MATERIAL STORE	- 965.492 Sft
22.	FINISH GOODS STORE	- 679.637 Sft
23.	MALE CHANGE ROOM	- 266.986 Sft
24.	FEMALE CHANGE ROOM	- 260.52 Sft
25.	RAW MATERIAL STORE	- 719.712 Sft
26.	PAKING MATERIAL STORE	- 459.657 Sft
27.	FINISH GOODS STORE	- 340.626 Sft
28.	PASSAGE	- 3477.000 Sft
29.	VARANDAH	- 381.375 Sft
TOT	AL COVERED AREA	- 23710.290 Sft

S.No	Product Name	API	Reg. No	Pack Size			
	Tablets General						
1	Majezik 100mg Tablet	Flurbiprofen	127067	3 x 10's			
2	Montelukast 5mg Tablet	Montelukast Sodium	127068	1 x 14's			
3	Montelukast 10mg Tablet	Montelukast Sodium	127069	1 x 14's			
4	SWP Cipro 250mg Tablet	Ciprofloxacin Hcl	127081	1 x 10's			
5	SWP Cipro 500mg Tablet	Ciprofloxacin Hcl	127082	1 x 10's			
6	ST-Met 50/500mg Tablet	Sitagliptin Phosphate + Metformin Hcl	127809	2 x 7's			
7	ST-Met 50/1000mg Tablet	Sitagliptin Phosphate + Metformin Hcl	127810	2 x 7's			
8	Azmyc 500 mg Tablets	Azithromycin Dihydrate	127813	1 x 6's			
9	Azmyc 250 mg Tablets	Azithromycin Dihydrate	127814	1 x 6's			
10	SW-Flox 250mg Tablets	Levofloxacin Hemihydrate	127815	1 x 10's			
11	SW-Flox 500mg Tablets	Levofloxacin Hemihydrate	127816	1 x 10's			
12	Starlenz 600mg tablet	Linzolid	128117	2 x 6's			
13	SW Pram 10mg Tablets	Escitalopram Oxalate	128132	1 x 14's			

Capsules General						
14	Ompezo 40mg Caspule	Omeprazole Enteric Coated Pellets	126824	2 x 7's		
15	Ompezo 20mg caspule	Omeprazole Enteric Coated Pellets	126825	2 x 7's		
16	Esoway 20mg capsule	Esomeprazole Enteric Coated Pelletes	127811	2 x 7's		
17	Esoway 40mg Capsule	Esomeprazole Enteric Coated Pelletes	127812	2 x 7's		
18	Tamurex 0.4mg Capsules	Tamsulosin HCL Pellets	128133	2 x 10's		
Capsules Ceph						
19	Cefixm 400mg Capsule	Cefixime Trihydrate (Compacted)	127819	1 x 5's		
20	SW Ceph 250mg Capsule	Cephradine Monohydrate (Compacted)	128126	2 x 6's		
21	SW Ceph 500mg Capsule	Cephradine Monohydrate (Compacted)	128127	2 x 6's		
22	SW Clor 500mg Capsules	Cefaclor Monohydrate	128130	2 x 6's		
23	SW Clor 250mg Capsules	Cefaclor Monohydrate	128131	2 x 6's		
Dry Suspension Ceph						
24	Cefixm 200mg/5ml DS	Cefixime Trihydrate (Micronised)	127817	30 ml		
25	Cefixm 100mg/5ml DS	Cefixime Trihydrate (Micronised)	127818	30 ml		
26	SW Clor 125mg/5ml DS	Cefaclor Monohydrate	128128	60ml		
27	SW Clor 250mg/5ml DS	Cefaclor Monohydrate	128129	60ml		



#### Esomeprazole





- 40 mg
- Duodenal ulcer
- Gastric ulcer
- Reflux oesophagitis
- Symptomatic gastric oesophageal reflux disease
- NSAID associated gastric and duodenal ulcer or erosions
- · Helicobacter pylori eradication in peptic ulcer disease
- Zollinger-Ellison syndrome











Azithromycin (USP)

Ciprofloxacin



- 500 mg Urinary Tract Infections (UTIs)
- Gastrointestinal (GI) infections
- Respiratory Tract Infections (including Pseudomonal infections in cystic fibrosis)
- Skin and Skin Structure Infections
- Chronic Bacterial Prostatitis
- Bone and Joint Infections (e.g., Osteomyelitis)
- · Sexually Transmitted Infections (e.g., Gonorrhoea)
- Surgical Prophylaxis (select cases)
- Most other bacterial infections responsive to ciprofloxacin





Helicobacter pylori eradication in peptic ulcer

250 mg

Zollinger-Ellison syndrome



Cervicitis

20 mg

40 mg

Duodenal ulcer

Reflux oesophagitis

Gastric ulcer

disease

disease

or erosions

- Lower respiratory tract infections
- Multiple myeloma
- Otitis media
- Reversal of excessive bradycardia
- Skin and soft tissue infections
- Soft tissue and skin infections
- Status epilepticus (unlicensed use)
- Upper respiratory tract infections
- Urethritis









250mg

14 Tablets

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# SM-HOX

(Levofloxacin Tablets USP)



250 mg

- Reatment of acute pyelonephritis
- Management of bronchitis and respiratory tract infections
- Treatment of complicated urinary tract infections (UTIs)
- Management of epididymitis
- Used in nephrogenic and partial pituitary diabetes insipidus
- Treatment of pneumonia and otitis externa
- Relief of oedema and otitis media
- Short-term treatment of severe congestive heart failure
- Treatment of skin and soft tissue infections

# Montelukast

Montelukast Sodium(USP)

- 5 mg
- 10 mg



- Effective in musculoskeletal disorders
- Indicated for trauma such as sprains and strains
- Provides analgesic relief in mild to moderate pain
- Also used for dental pain, post-operative pain, dysmenorrhea, and migraine



50mg + 1000 mg

50 mg + 500mg

- (Sitagliptin+Metformin HCL) Tablets BP
- Initial therapy in type 2 diabetes mellitus to improve glycemic control when diet and exercise are inadequate

   Adjunct to diet and exercise in nationts inadequately centralled
- Adjunct to diet and exercise in patients inadequately controlled on Metformin HCL or Sitagliptin alone or already on the combination
- Triple combination with a sulphonylurea in patients inadequately controlled on Metformin HCL and a sulphonylurea
- Triple combination with a PPAR T agonist (thiazolidinedione) in patients inadequately controlled on Metformin HCL and a PPAR T agonist
- Adjunct to diet and exercise to improve glycemic control in combination with insulin



100 mg

Flurbiprofen (USP)



Adomte kukast

- Used for rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis
- Effective in musculoskeletal disorders
- Indicated for trauma such as sprains and strains
- · Provides analgesic relief in mild to moderate pain
- Also used for dental pain, post-operative pain, dysmenorrhea, and migraine



#### Escitalopram

#### 10 mg

- Indicated for major depressive disorder
- Used in adults and adolescents
- Treats acute depressive episodes
- Maintains long-term depression control
- Helps manage depressed mood
- Reduces loss of interest
- Addresses appetite or weight changes
- Improves sleep disturbances
- Eases psychomotor agitation or slowing
- Reduces fatigue and low energy
- Helps with guilt or worthlessness
- Aids concentration and thinking
- Addresses suicidal thoughts or attempts



STARWAYS
Pharmaceuticals



## 12murex

#### 0.4 mg

Tamsulosin HCL

- Selective and competitive binding to postsynaptic a1-adrenoceptors, especially a1A and a1D subtypes.
- Causes relaxation of prostatic and urethral smooth muscle.
- Results in increased urinary flow rate.
- Reduces symptoms of benign prostatic hyperplasia (BPH).
- Improves irritative symptoms linked to bladder instability.



250 mg

Cephradine



- Bone and joint infections
- Genitourinary tract infections
- Lower respiratory tract infections
- (including pharyngitis, Upper respiratory tract infections tonsillitis)
- Pneumonia and general respiratory tract infections
- Prostatitis
- Skin and soft tissue infections
- Surgical prophylaxis
- Adjunctive therapy for bacterial infections as an alternative choice



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#### Linezolid



- · VRE infections (Enterococcus faecium), with or without bacteremia
- Nosocomial pneumonia (S. aureus MSSA/MRSA, S. pneumoniae including MDRSP)
- Complicated skin infections (S. aureus MSSA/MRSA, S. pyogenes, S. agalactiae)
- Uncomplicated skin infections (S. aureus MSSA only, S. pyogenes)
- Community-acquired pneumonia (S. pneumoniae incl. MDRSP, S. aureus MSSA only)





(Cefixime USP)









#### Cefixime 100mg/5ml Suspension

- Mild antibiotic for children
- Used for throat, ear, and respiratory infections
- Pleasant-tasting formula for easy dosing

#### STARWAYS

### Cefixime 200mg/5ml Suspension

- For moderate bacterial infections in children
- Suitable for upper respiratory and urinary infections

Provides stronger dosage when needed

#### Cefixime 400mg Tablets

- Broad-spectrum antibiotic for adults
- Treats sinusitis, tonsillitis, UTIs, and bronchitis
- Once-daily dosing for convenience



# SW GLOR











125 mg/5ml

250 mg/5ml

250 mg

500 mg

- Indicated for arrhythmias post-myocardial infarction
- Effective against bronchitis
- Active in genitourinary infections

- Prescribed for otitis media
- Helps manage pharyngitis

• Used in pneumonia cases

- Useful in respiratory infections
- Suitable for skin infections
- Works for soft tissue infections
- Commonly given for tonsillitis















Well-Equipped Qulity Control Lab



## Material And Product Control





- Specifications & Test Methods
- Validation of Analytical Equipment and Analytical Methods
- Supplier Approval & Control

## Control Process

Production rate



#### OUTPUT **PROCESS INPUT** Tablets Compression **Quality Attributes Potential CPPs** Quality Attributes Appearance Pre-compression force Blend uniformity Tablet weight Compression force Granule Surface Area Weight uniformity Press Speed Ribbon Density Content Die fill depth Compactability **Content Uniformity** Feeder Speed API psd Hardness Ejection Force Friability Height of drop Dissolution Rate Press geometry Disintegration time Pitch Circle Diameter Thickness Roller diameter **Process Performance Tooling Geometry** Yield Punch head dimensions

Punch tip dimensions

- Material and Product Labelling
- Sampling and Testing
- Stability Testing
- Storage and Handling of Materials and Products
- Rejects and Disposals
- Periodic Product Review
- Retained Samples of Materials and Products
- Reprocessing, Reworking and Repacking

## Incident Management

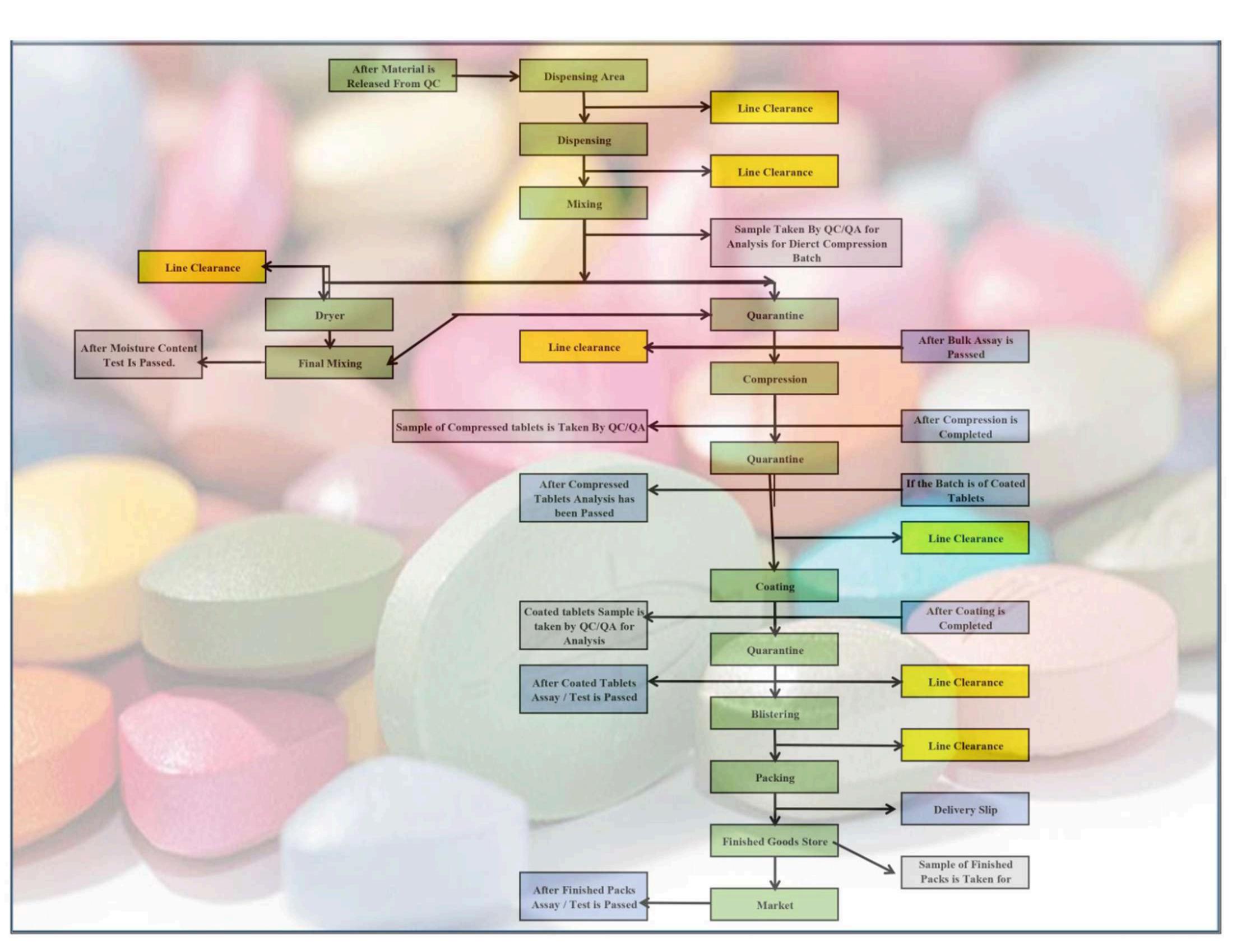




- Self Inspection
- Corrective and Preventive Action
- Quality Performance Indicators

## Process Assurance





- Batch processing Record
- Process Validation
- In-Process Controls
- Deviation and Exception Handling
- Yield Calculation and Reconciliation

## Continuous Improvement





Product Recalls



Customer Complaints



# THANK YOU