Sohan Healthcare Pvt. Ltd. Presentation

SOHAN

Healthcare Pvt.Ltd

VISION

To be Global leader in Pharmaceutical manufacturing by process innovation and unparalleled efficiencies.

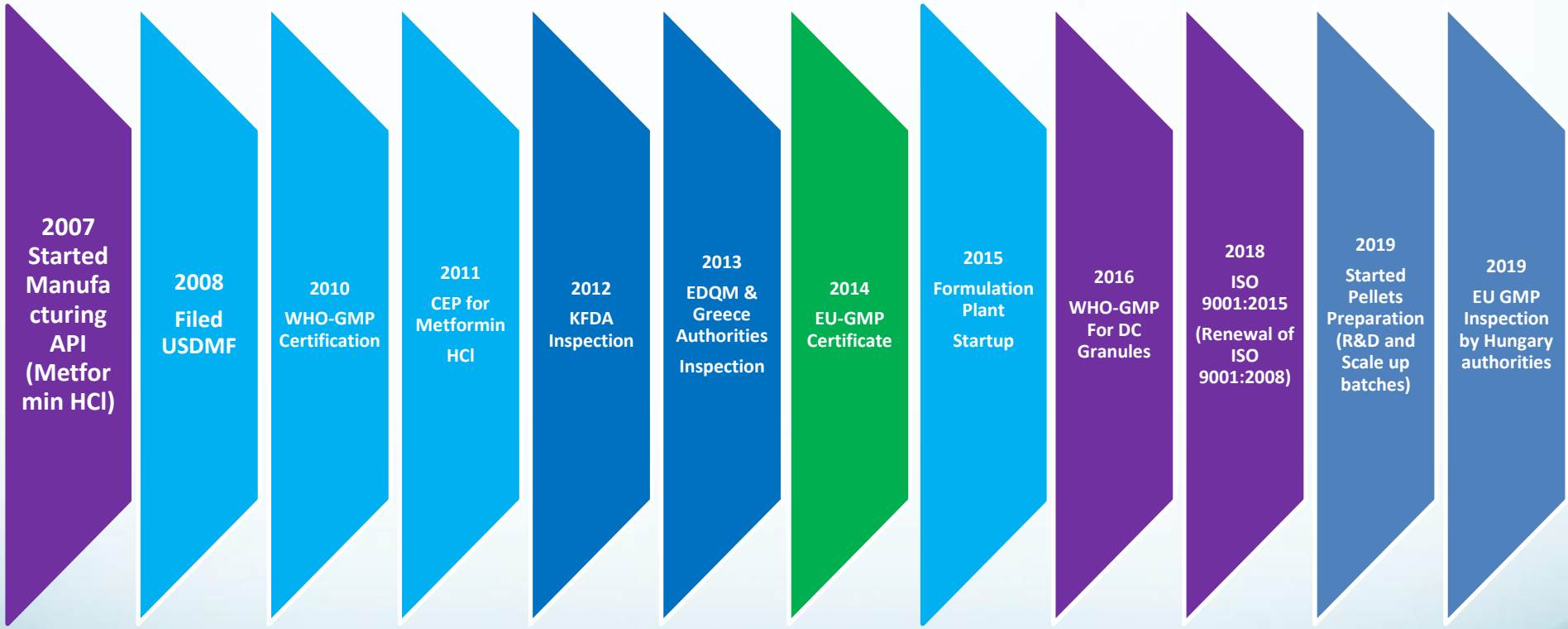
About Us

•Sohan Healthcare is an ISO certified pharmaceutical manufacturing company with Active Pharmaceutical Ingredient (API) & Pharmaceutical formulation intermediate.

•Founded by Mr Sohan Chakkarwar – Managing Director in the year 2006 at Kurkhumbh an upcoming dynamic manufacturing suburb, which is located 70 KMS from the vibrant city of Pune in Maharashtra, India.

•Our current turn over of the company ~ 14.25 Million US$

KEY MILESTONES



Infrastructure Overview

•API manufacturing facility is dedicated for Metformin with total area of 95000 sq ft.

•Currently Manufacturing Metformin HCl API with capacity of 800 MT / Month.

•We are also coming up with multi purpose API facility of area of around 75000 sq ft. adjoining to current area.

•API Development and Kilo Lab of 4000 Sq ft area.

•FDF Development Lab of 3500 Sq ft and expandable to another 3000 sq ft.

•Pharmaceutical formulation intermediate is in the area of 45000 sq ft and expandable to additional 45000 sq ft.

PFIs (Pharmaceutical Finished Intermediates)

•Manufacture DC Granules and Pellets

•Batch Size of 550 Kg’s DC Granules & 150 – 400 Kg’s for Pellets.

•Current capacity is of 1500 MT / Annum.

•We have already installed equipments for additional Capacity of 1500 MT/ Annum.

•GMP:
-Facility is created as per c GMP guidelines which can be approved by any regulatory authorities.
-Recently audited and approved by European Health Authority.

REGULATORY STATUS

Sr. No.	Description	Name of the API/ inspection date	Ref. No.	Validity
1	ISO 9001:2015	Metformin HCl	---	19 Oct 2019
2.	COS	Metformin HCl Inspection was on 9th , 10th and 11th Dec. 2013	R1-CEP 2009-233 Rev 02 dated 14th January 2016	December 2020
3.	KFDA	Metformin HCl Inspection was on 30th and 31st Jan.2012	20120601-37-C-294-16 dated 01.06.2012	----
4.	EU GMP	13-17th May 2019	EU GMP Certificate No. 2014-233	----
5.	WHO (For API)	10th & 11th Aug 2017	NEW-WHO-GMP/CERT/PD/60349/2017/11/21325	05 NOV 2019
6.	WHO (For DC Granules)	28th, 29th May 2018 and 17th September 2018	NEW-WHO-GMP/CERT/PD/72513/2018/11/25589	05 NOV 2021

LIST OF EQUIPMENTS FOR PELLETS MANUFACTURING

Sr.No	R&D AREA	PILOT SCALE AREA	GRANULATION AREA-1	GRANULATION AREA-2
01	Sifter (20" size)	Sifter (20" size)	Sifter (36" Size)	Sifter (36" Size)
02	Fluid Bed processor 12L (Glatt) Capacity: 0.45 kg to 2.4 Kg	Fluid Bed Processor 60kg Capacity: 18 kg to 48 kg	Fluid Bed Dryer Capacity : 150 kg to 300 L Make:Tapassya	Fluid Bed Equipment 1300C (ACG) Capacity: 120 kg to 320 kg
03	Hot plate	Saizoner Mixer granulator (SMG) 150L	Saizoner Mixer granulator (SMG) 1200 L	Solution preparation Vessel 300L
04	Stirrer	Paste kettle 25L	Paste kettle 250 L Cone Mill	Steam jacketed vessel 300L
05	Comill	Multimill	Solution preparation Vessel 100 L	Conta Blender 1000L and 2500L
06	Octagonal Blender 15 L	Octagonal Blender 200L	Delumper cum milling system	
07	Saizoner Mixer granulator (SMG) 25L and 10L	Tablet compression machine [16 station]	Octagonal Blender 2000 L Metal Detector (CEIA)	
08		Coating Pan 12" / 24"	Powder Transfer System 1500 kg /Hr	
Proposed Equipment List	Extruder			Extruder, Spheroniser
	Spheroniser			Comill, Saizoner, PTS
	Tray dryer			Coating pan
	Proposed equipments used in both areas			Tray dryer


SAIZOMER MIXER
GRANULATOR
1200 LIT.
SMG-201


2000 Ltr.
GONAL BLENDER
OGB-201
METAL DETECTOR MDR-201


RAPID MIXER GRANULATOR
R.M.G
25 LTR
CHAMUNDA
We care...


OCTAGONAL BLENDER
CHAMUNDA
OCTAGONAL
BLENDER
200 LTR


FBP
CHAMUNDA
FLUID BED
PROCESSOR
60 KG


CHAMUNDA
R.M.G
150 LTR


COMPRESSION
MACHINE


FLUID BED PROCESSOR
FBP-303
FBP-303/A


GFBLab

LIST OF EQUIPMENTS OF QUALITY CONTROL

Instrument	Nos.	Make
HPLC	9	Waters
FT-IR spectrophotometer	1	Agilent
UV Vis Spectrophotometer	1	Agilent
GC with Head Space	2	Agilent
Karl Fisher Titrator	2	Veego
Melting Point Apparatus	1	Veego
Bulk density Apparatus	1	Veego
Potentiometer	3	Metrohm (1),Spectra Lab (2)
pH Meter	1	Lab India
Analytical Balance	5	Sartorius (4), Sansui (1)
Hot Air Oven	2	Cintex
Muffle Furnace	1	Cintex
Stability Chamber	7	Cintex
Sieve Shaker	1	Electrolab

LIST OF EQUIPMENTS OF MICROBIOLOGY

MICRO	
Microbiology Name of Instruments	**Qty.**
Refrigerator	1
Autoclave	2
BOD Incubator	2
Bacteriological Incubator	2
Laminar Air Flow Unit	1
Microscope	1
Colony Counter	1


RA-02


Sohan Healthcare Pvt. Ltd.
Microscope Cleaning

Formulation R&D Features

• R&D plays a major role in company's strategy for creating new products and adding features to old ones.

•We have a R&D capability of High value & niche molecules.

•Total build up area is 3000 sq ft and further can be expanded to 6000 sq ft.

•Dedicated 2 rooms for 6 Kg’s line & 60 kg’s line.

•We have Glatt machine for regular and MUPS pellets.

•Approvable by any health authority with featured GLP labs.

•Separate Raw material & finished storage rooms.

•Separate AHU for all individual rooms.

•Unidirectional flow maintained.

Type of Pellets (R&D and Commercial support)

•**DRUG COATING:** In this process drug is layered onto seed materials in powder, solution or suspension forms leads to heterogeneous pellets.

•**IMMEDIATE RELEASE(IR):** are formulated to release the active drug immediately after oral administration. In the formulation of conventional drug products, no deliberate effort is made to modify the drug release rate.

•**BARRIER COATING:** A core material is coated with the drug substance using pan coater following a barrier coating process in which drug loaded pellets were coated with HPMC E5 called Barrier Coating.

•**SUSTAIN RELEASE COATING(SR):** SR maintains "controlled release“ as drug release over a sustained period but not at a constant rate.

•**ENTERIC COATING(EC):** An enteric coating is a polymer barrier applied on oral medication that prevents its dissolution or disintegration in the gastric environment Pellets and granules (usually filled into capsule shells) are the most common enteric-coated dosage forms.

Pelletization techniques:

A .Drug layering on nonpareil seeds or Sugar Spheres.

B. Extrusion/ Spheronization

C. MUPS

BRIEF SUMMARY OF QUALITY MANAGEMENT SYSTEM

- Quality Management systems are established and practiced as per cGMP requirements. Organization chart, responsibilities of Quality Assurance, Quality Control, Production, Maintenance, Stores, R&D and Personnel & Admin are defined.
- Standard operating procedures are in place for all activities that are carried out in the facility. These procedures are reviewed periodically and updated to be in line with current GMP.
- Internal audits are carried out as per defined schedule and reports are generated. These reports are forwarded to the respective departments for addressing the non-compliances and closing out the same with in a definite time frame.
- There is a factory-wide calibration program to ensure that all measuring devices are in a state of calibration.
- Suppliers of critical materials are evaluated and qualified. Stability studies are carried out in accordance with ICH guidelines.
- Annual product quality reviews are carried out.
- Conducting training on analytical techniques, GMP,GLP and Standard Operating Procedures.
- Conducting stability studies
- Performing Microbiological testing for water samples, products and environmental monitoring.
- Deviation and Change Control programs are in place to ensure that all deviations are addressed and all proposed changes are vetted by QA before getting implemented.
- Head-QA or his designee should release the finished product for sale after reviewing the batch manufacturing records, analytical reports and ensures that the product is manufactured as per the approved/authorized manufacturing process and complies as per the specification.

Metformin XR 500 mg, 750 mg and 1000 mg Tablets Dossier Checklist;

Test Product name	Metformin SR 500 mg	Metformin SR 750 mg	Metformin SR 1000 mg
Reference Product	Glucophage XR 500 mg	Glucophage XR 750 mg	Glucophage XR 1000 mg
Form	Tablet	Tablet	Tablet
Strength	500 mg	750 mg	1000 mg
Shape/Size of Tablet	Round shaped Biconvex tablets debossed with 500 on one side and plain on other side	Capsules shaped Biconvex tablets debossed with 750 on one side and plain on other side	Modified Capsule shaped Biconvex tablets debossed with 1000 on one side and plain on other side
Color	White to Off White	White to Off White	White to Off White
Therapy	Anti-Diabetic	Anti-Diabetic	Anti-Diabetic
Generic API	Metformin HCl	Metformin HCl	Metformin HCl
Existing Source	Sohan	Sohan	Sohan
Stability of Tablets in Blister	40/75 and 25/60	40/75 and 25/60	40/75 and 25/60
Batch Size (Minimum)	250,000	166,000	125,000
Batch Size (Maximum)	750,000	500,000	450,000
Pack type	Blister Pack	Blister Pack	Blister Pack
Innovator reference	Glucophage XR 500 mg	Glucophage XR 750 mg	Glucophage XR 1000 mg
Manufacturer of RLD	Merck	Merck	Merck
Bioequivalence / Type	Fast/ Fed	Fast/ Fed	Fast/Fed
BE center/ Approvals	Vergo Labs / MHRA & NPA	Vergo Labs / MHRA & NPA	Vergo Labs / MHRA & NPA
No of subjects/ Volunteers	Fasting - 28	Fasting - 28	Fasting - 28
	Fed - 28	Fed - 28	Fed - 28
Manufacturing site	India		
GMP certificates	EU GMP certified		

Metformin XR Tablets: Advantages Over our competitors

1. We have successfully developed all three strengths of Metformin XR 500 mg, 750 mg and 1000 mg.
2. All the strengths are dose proportionate.
3. We have successfully completed BE Studies for all the three strengths, with Fed and Fast. Moreover all the three strengths comply to steady state requirement as per UK & EU regulation.
4. The reference product " Glucophage XR" Marketed by Merck is picked up from UK and it is manufactured in two sites in France, the same reference product is available in UK, EU and RoW markets.
5. Our product is ready for offer with stability for EU and RoW zones.
6. Product will be manufactured in EU approved facility.
7. We are forward integrated with Metformin API, with monthly production capacity of 800 MT.
8. Our API and FDF both are free from NDMA or NDEA Impurities.

Product List

ACTIVE PHARMACEUTICAL INGREDIENTS

Commercial

METFORMIN HCl EP/BP/USP/JP/IP (Offered with CEP)

Development Completed

FOLIC ACID EP/BP/USP/JP/IP: Validation batches to be initiated.

GLICLAZIDE EP/BP/JP: Validation completed, stability completed up to 4 months.

ALOGLIPTIN IN – HOUSE: To be validated

SEMI FINISHED FORMULATIONS

DC GRANULES

Commercial

METFORMIN DC GRANULES (IR & XR)

Development Completed

IBUPROFEN 90% W/W GRANULES

SILDENAFIL CITRATE 7.5% TASTE MASK GRANULES

TADALAFIL 7.5% TASTE MASK GRANULES

Product List

PELLETS

Development Completed

ORLISTAT IR 50% W/W

SODIUM VALPROATE PROLONGED RELEASE COATED GRANULES

FENOFIBRATE 66% GRANULES

TAMSULOSIN HCL SR 0.14%, 0.16%, 0.20%, 0.25% W/W

OMEPRAZOLE PELLETS 8.5% W/W

MEBEVERINE HCL SR 75% W/W

DUTASTERIDE IR 0.25% W/W

MESALAZINE SR 53%

DICLOFENAC SODIUM EC 45%

DICLOFENAC SODIUM SR 40%

THEOPHYLLINE EC 60 %

THEOPHYLLINE IR 89.29 %

u/d

ESOMEPRAZOLE 22%

TAMSULOSIN HCL SR 0.2% W/W + DUTASTERIDE IR 0.25% W/W

LANSOPRAZOLE 8.5% W/W

PANTOPRAZOLE EC 17% W/W + DOMPERIDONE SR 30% W/W

Thank You

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