

Introduction



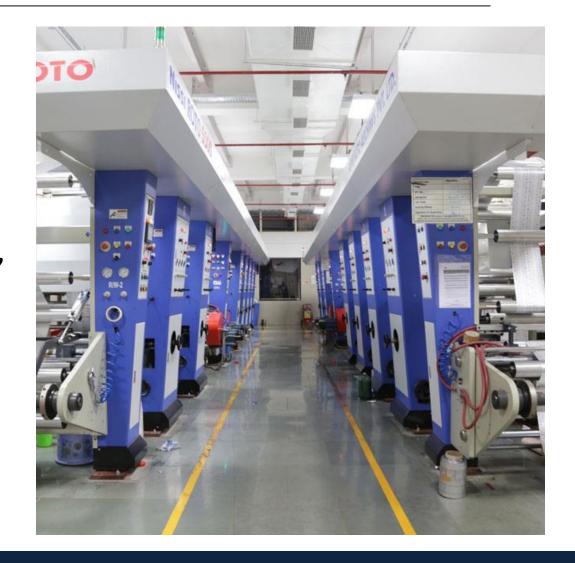
Medgoal Packaging Foils is an

International Standard packaging manufacturer of premium quality Aluminium Foil for pharmaceutical industries since last 10 years.

Our prime production facility is spread over **11,000 sq.ft.** build up area located in **Vasai, Maharashtra, INDIA**.

We are a sister concern of industry's leading Manidhari Foils Pvt. Ltd.

With a focused vision & mission, we are committed to quality, on-time delivery & customer satisfaction.



Vision



We have a focused vision on quality, affordability and variety as a pharmaceutical packaging manufacturer, aiming to meet our customer's requirements.

We provide equal opportunities to our staff members, ensuring their growth and contribution in building value based company.



Mission



We design, manufacture and process pharmaceutical packaging materials with industry standards, in a sterilised environment and with complete safety.

Our every process follows Quality Control and Quality Standards of the packaging foil. This is why we say 'Think Packaging, Think Medgoal'.



Values



We lead, engage and inspire our employees to pursue our vision, encouraging their growth that support our business objectives.

We relentlessly focus on driving business forward by adapting standard processes and ensure clear communication between our clients and all key stakeholders.



Quality Policy



We have a well documented quality policy and are committed to continuous improvement to achieve perfection.

We have now achieved a reputed position in pharmaceutical packaging manufacturing industry.

We feel proud to say, we are the 'Best Choice' for all our satisfied clients.



Research & Development



Continuing with the legacy of **Manidhari Foils Pvt. Ltd,** our focused R&D approach helps us to achieve:

- Overt & Covert Anti counterfeit designs,
- Green inks like water based heat seal lacquer
- Water based low VOC inks.

We use most safest Siegwerk Inks & Dag Inks who are leading suppliers of printing inks for packaging applications across the world.

We are now committed to induce Green technology and fulfil our social responsibility.



Quality Laboratory



Our Quality Laboratory is largely equipped with following:

1. Weighing balance 8. Leak test apparatus

2. Heat sealer 9. Water bath

3. Laboratory oven 10. COF tester

4. Scuff tester 11. Bond/Seal strength tester

5. Oven 12. Dying pan

6. Tester 13. Bursting strength apparatus

7. Pin hole tested 14. Gas chromatograph

All these ensures the Quality check at every step of our manufacturing process.



Quality Certification



Our key success is to always comply with the International Quality Standards.





AN ISO 9001:2015 CERTIFIED COMPANY

Pohoomal Building, Gala.no.6, Building.No.3, 1st Floor, Survey.no.68.

Noar Meenakshi Industrial Estate, Nalkpada, Vasai (E),Dist : Palghar Maharashtra
www.medgoalpackagingfoils.com : Email : medgoalpackagingfoils@gmail.com

Date: 01/10/2017

TO WHOMSOEVER IT MAY CONCERN

This is to certify that the Aluminium folls (plain/printed) produced by us for Pharmaceutical application are of FOOD GRADF, non toxic and can be safely used for packing of Tablet/Capsules products & does not contain any harmful material of animal origin susceptible to TSE minimizing the risk of Transmitting Animal Spongiform Enceptialopathy agents via medical products are related general monograph no. 1483 and to Bovine Spongiform encephalopathy (BSE).

For Medical Packaging Foils



Quality Certification



Our business proficiency is helping us achieve more goals as we continue to grow...



Certificate of Registration

This is to certify that the

Quality Management System for Medical Devices

MEDGOAL PACKAGING FOILS

UNIT NO. 6, 7 & 8, 1ST FLOOR, POHOOMAL BUILDING NO. 3, SURVEY NO. 68, OPP. DIE PLAST COMPANY, NAIKPADA, VASAI EAST- 401208, DIST. PALGHAR, MAHARASHTRA, INDIA

> has been independently assessed and is compliant with the requirements of:

ISO 15378:2017

Good Manufacturing Practices Guide For Primary Material

PRINTING FOILS FOR PHARMACEUTICALIFMCG PACKAGING AND MANUFACTURING OF COATED ALUMINIUM BLISTER FOILS, POLY LAMINATED STRIP PHARMACEUTICALS FOILS, GLASSINE PAPER POLY LAMINATED & GLASSINE PAPER VMCH COATED

Certificate Number: UQ-2020021712

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of initial registration 17th February 2020

Date of this Certificate 17th February 2020

Certificate Expiry 16th February 2021 Recertification Duenutject to the company 16th February 2023







Food and Drug Administration Silver Spring, MD 20993

DMF ACKNOWLEDGEMENT

MEDGOAL PACKAGING FOILS

Attention: MR. SUSHIL JAIN, PROPRIETOR POHOOMAL BLDG, GALA NO.6, 1ST FLOOR, SURVEY NO. 68

BUILDING NO.3, NEAR MEENAKSHI INDUSTRIAL ESTATE NAIKPADA VASAI EAST-401208, DIST. PALGHAR, MAHARASHTRA, INDIA

Dear Mr. Sushil Jain,

DMF 034767

The Food and Drug Administration acknowledges receipt of the following Drug Master File (DMF)

DMF NUMBER ASSIGNED: DATE OF SUBMISSION: MAY 21, 2020

DMF TYPE:

SUBJECT (TITLE): PRINTING BLISTER ALUMINIUM FOIL, STRIP PHARMACEUTICALS FOIL, GLASSINE PAPER POLY

LAMINATED & GLASSINE PAPER VMCH COATED FOR

PHARMACEUTICAL/FMCG PACKAGING

HOLDER: MEDGOAL PACKAGING FOILS SUBMITTED BY: MEDGOAL PACKAGING FOILS

AGENT: PERFECT PHARMACEUTICAL CONSULTANTS PVT. LTD.

All subsequent correspondence to this DMF should be identified with the information as provided above.

Your DMF will be reviewed only in connection to a New Drug Application, Abbreviated New Drug Application, Investigational New Drug Application, Biological License Application, New Animal Drug Application, Abbreviated New Animal Drug Application, Investigational New Animal Drug Application, or DMF it is intended to support when a Letter of Authorization (LOA) is submitted to the DMF and a copy of the LOA is submitted in the application e.g., NDA, that references the DMF.

For information on various DMF submissions, example of letter templates and DMF Guidance for Industry, check the DMF website at https://www.fda.gov/drugs/forms-submission-requirements/drugmaster-files-dmfs





Medgoal Packaging Foils has an annual capacity of 1200 MTPA of finished products.

Our Core Material i.e. Aluminium is corrosion resistant, non-toxic, easy to cast, 100% recyclable, sustainable metal and has a high conductivity.

Our hard Aluminium Foil is suitable for blister packing of Pharmaceutical products such as Tablet, Capsules, etc.,. It has following general specifications:

Standard Foil Guage	Tolerance (+/- 8%)
0.020 mm	+/- 0.0016 mm
0.025 mm	+/- 0.002 mm





Colourless Vinyl Resin (option for tinted resin available) conforming to the applicable Government regulations regarding direct contact with medicines and drugs. The resin is suitable for heat sealing to PVC/PVDC coated PVC.

Coating Thickness options:

(a) 4-6 GSM with a tolerance of +/- 0.5 GSM (b) 6-8 GSM with a tolerance of +/- 0.5 GSM Standard, if not specified, heat sealing coating GSM is 4 with a tolerance of +/- 0.5.

Seal strength with PVC/PVDC: 8 N/25 mm min.





Printing and Lacquer coating:

Printed as per text, layout and shade approved by customer. For non-printed specification, clear lacquer to be coated as a protective coating and good printability.

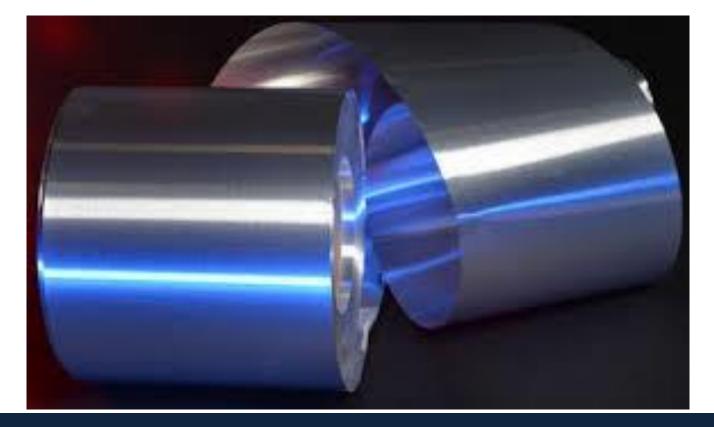
Printing inks and lacquer coatings are capable to withstand 180 deg. C for 1 sec. dwell time.





Configuration: Printed and Unprinted Blister Foils are available in the reel forms.

Unprinted blister foils are also available as Jumbo roll.





Winding direction	Generally printed or clear lacquer side is out with heat seal coating inside.
Core	Material Options: (a) PVC Core (b) Card Board Core ID - 76 mm +/- 0.5 mm
	The length of the core is equal to the width of the web.
Splices	Butt type made with 25 mm pressure sensitive tape.
Reel outer diameter	250 +/- 10 mm for slit material, 400 +/- 10 mm for jumbos.
Reel wander	Within +/- 1 mm
Reel / WEB width	Plain - 45mm to 800 mm with a tolerance of +/- 0.5 mm
	Printed - 45mm to 600 mm with a tolerance of +/- 0.5 mm
Joints per reel	Maximum 2 // Average less than 1
Pin Holes	0.025, 0.030 micron foils are free from pin holes
	0.020 micron 40% foil is free from pin holes, rest less than 10 PSM
Identification	Each reel shall be identified with a sticker pasted inside the core with reel numbers.
	Specification, Net Weight, Operator Name, Reel Number & Date of Manufacture.
Packaging	Blister foils are packed in cardboard carton. Relevant Markings are provided on each outer package
Recommended operating conditions	Sealing Temp - 170 to 180 Degree C
	Sealing Pressure - 2.8 to 5.6 kg/sq. cm, 40 to 80 ibs/sq.inch
	Dwell time - 0.025 to 0.5 sec.



COVERING AREA of 1kg Finished	Gauge & Temper Foil	Covering area in sq. M/kg. with 4 GSM nominal Heat Sealing Coating					
	0.020 (Hard)	17.18					
MATERIAL (Nominal)	0.025 (Hard)	13.94					
	0.030 (Hard)	11.72					
	FOIL GAUGE	Thickness (mm)			GSM		
Thickness Tolerances of foil		Min. (-8%)	Nominal	Max.(+8%)	Min. (-8%)	Nominal	Max.(+8%)
							F0 F
	0.020 MM	0.018	0.02	0.022	49.9	54.2	58.5
	0.020 MM 0.025 MM	0.018 0.023	0.02	0.022	49.9 62.33	54.2 67.75	73.17
		9390-880003	20 808084334	OLIV ENGINEE	5-74924 (2000-00)	NEW STREET, WAS S.	500 BANKER (1995)



We also manufacture a range of soft Aluminium Foils suitable for strip packaging of Pharmaceutical products such as Tablet, Capsules, etc, It has following general specifications:

STANDARD POLYMER GAUGE	NOMINAL	TOLERANCES (+/- 15%)
OPTIONS	GSM	GSM
150	34.39	+/- 5.16
180	41.27	+/- 6.19
200	45.85	+/- 6.88



PRINTING & LACQUER COATING	Printed as per text, layout and approved by the customer. For non-printed specification, clear lacquer to be coated as a protective coating & good printability. Printing links & lacquer coatings are capable to with stand 180 degree C for 1 sec. dwell time.						
CONFIGURATION	Printed & Unprinted pharma foils are available in the reel forms.						
	Unprinted pharma foils are also available as jumbo roll.						
WINDING DIRECTION	Generally, printed or clear lacquer side is out in the finished reel						
CORE	Material Options : (a) PVC Core (b) Card Board Core ID - 76 mm +/- 0.5 mm						
	The length of the core is equal to the width of the web.						
SPLICES	Butt type made with 25 mm pressure sensitive tape.						
REEL OUTER DIAMETER	250 +/- 10 mm for slit material, 400 +/- 10 mm for jumbos.						
REEL WANDER	Within +/- 1 mm						
REEL / WEB WIDTH	Plain - 45mm to 800 mm with a tolerance of +/- 0.5 mm						
	Printed - 45mm to 600 mm with a tolerance of +/- 0.5 mm						
JOINTS PER REEL	Maximum 2 // Average less than 1						
PIN HOLES	Nil						



IDENTIFICATION	Each reel shall be indentified with a sticker pasted inside the core with reel numbers.				
	Specification, Net Weight, Operator Name, Reel Number & Date of Manufacture.				
PACKING	Blister foils are packed in cardboard carton. Relevant Markings are provided on each outer package				
RECOMMENDED OPERATING CONDITIONS	Sealing Temp - 130 to 150 Degree C				
	Sealing Pressure - 2.8 to 5.6 kg/sq. cm, 40 to 80 ibs/sq.inch				
	Dwell time - 0.025 to 0.5 sec.				



COVERING AREA of 1kg Finished	Gauge & Temper Foil	Covering area in sq. mts/kg. with 150 Gauge Polyethylene lamination		
	0.025 (Soft)	9.78		
MATERIAL (NOMINAL)	0.030 (Soft)	8.64		
	0.040 (Soft)	7		



	FOIL GAUGE	THICKNESS (mm)			GSM			
TABLE SHOWING THICKNESS		Min. (-8%)	Nominal	Max.(+8%)	Min. (-8%)	Nominal	Max.(+8%)	
TOLERANCES OF FOIL	0.025 MM	0.023	0.025	0.027	62.33	67.75	73.17	
	0.030 MM	0.028	0.03	0.032	74.8	81.3	87.8	
	0.040 MM	0.037	0.04	0.043	99.73	108.4	117.07	
	FOIL CALICE	TH	ICKNESS (ı	mm)	GSM			
THICKNESS TOLERANCE OF	FOIL GAUGE	Min. (-15%)	Nominal	Max.(+15%)	Min. (-15%)	Nominal	Max.(+15%)	
POLYETHYLENE	150	0.0319	0.038	0.043	29.23	34.39	39.55	
POLYETHYLENE	180	0.0383	0.045	0.052	35.08	41.27	47.46	
	200	0.0425	0.05	0.058	38.97	45.85	52.73	



	FOIL GAUGE	THICKNESS (mm)			GSM		
TABLE SHOWING THICKNESS		Min. (-8%)	Nominal	Max.(+8%)	Min. (-8%)	Nominal	Max.(+8%)
TOLERANCES OF FOIL	0.025 MM	0.023	0.025	0.027	62.33	67.75	73.17
	0.030 MM	0.028	0.03	0.032	74.8	81.3	87.8
	0.040 MM	0.037	0.04	0.043	99.73	108.4	117.07
THICKNESS TOLERANCE OF	FOIL GAUGE	THICKNESS (mm)			GSM		
	FOIL GAUGE	Min. (-15%)	Nominal	Max.(+15%)	Min. (-15%)	Nominal	Max.(+15%)
POLYETHYLENE	150	0.0319	0.038	0.043	29.23	34.39	39.55
POLITETHTLENE	180	0.0383	0.045	0.052	35.08	41.27	47.46
	200	0.0425	0.05	0.058	38.97	45.85	52.73
TEST CERTIFICATE	This is to certify that the actual observed values of different parameters will accompany the supplies.						

Our Product- Glassin Poly / VMCH



We manufacture this from of a high grade resin.

This resin is used in the Pharmaceutical industry for packing tablets, Injection Ampoules.

It is also used in the food industry to sachets for packing sugar.

We can manufacturer printed Glassine VMCH (42 GSM Glossy Paper) coated paper as per the colour requirement of the customers.



Our Valued Clients



We supply a Coated/Poly laminated and printed Blister Aluminium Foils & Strip Pack Pharma Foils/Glassin Poly-VMCH to our major Pharmaceutical clients.

We thank all our clients to trust our innovative approach and our products.

Our Indian and international clients help us achieve our business goals.

Glenmark				Flamingo
Pharmaceuticals	Cipla Ltd.	Zydus	Zim Laboratories	Pharmaceuticals
Ltd.			Ltd.	Ltd.











We Conclude



We have achieved a reputed position in the industry by following international standards.

We could achieve this because of:

- Professionally skilled and experienced manpower
- Value based and ethical business practice
- Strong and wide spread marketing network
- Industry leading prices
- Quick and effective delivery



Thank You!

