Erawat

HARD CAPSULES
HPMC/VEG & GELATINE
www.erawat.com

Erawat Pharma Limited

HARD CAPSULES

HPMC/VEG & GELATINE

Manufacturers of **"Empty Hard Gelatin Capsules"** since 1997

OUR CAPACITIES

At present Erawat Pharma has production capacity of
5.5 Billion Capsules / Annum for GELATIN
300 Million Capsules / Annum for HPMC

We also possess a very unique strength here, as being the manufacturer of the machines ourselves in the engineering group unit and having our own R&D, we can anytime increase our capacities to any extent in a very short span of time.

WHO ARE WE AND WHAT'S OUR EXPERIENCE

Erawat Pharma Limited., an Erawat Group Company, ranks among the top Capsule manufacturers in the Country. We have active DMF Registration, GMP ISO & Halal Certifications.

Founded in 1997, we have a very rich experience of 20 years in manufacturing of hard capsules; and a 30 years of total group experience in the capsules manufacturing technologies. Because of our high technical competence and very strong R & D support, besides having achieved excellence in the manufacturing of Gelatin Capsules, we have also developed capability of manufacturing HPMC Capsules or the Vegetarian Capsules.

As is known well, manufacturing of HPMC Capsules is a very special capability, which only a very few Companies worldwide have been able to achieve and Erawat Pharma is one of them. With our strong R & D capability & with our very high emphasis on process controls and through our strong engineering back up, we have been able to successfully develop Capsules best suited for running on the high speed Capsule filling machines. With our excellence in quality and consistency in deliveries, we can easily boast of supplying Capsules to most of the top ranking Companies within India and to a wide range of customers Internationally, including European & US Customers

OUR GUIDING PHILOSOPHY AND QUALITY POLICY

Erawat Pharma strongly believes in “Building an Ever – Growing Relationship” with our associates, whether a customer or a supplier or any other stake holder in any form. When it comes to serving our customers, we make it sure to step beyond quality and serve the customers’ requirements with CONSISTENCY.

Our Group's Quality Policy clearly states that:
We are committed to meet the customer and regulatory requirement, in order to ensure total customer satisfaction. We believe in achieving this by collecting and critically working on customer's feedback, continuous improvement in product quality, continuous improvement in productivity and following GMP with active implementation of documented systems and procedures.

WHY YOU SHOULD BUY FROM US

With constant research and development on the product and continuous and deep interaction with the customers, Erawat Pharma group understands what exactly will benefit them in terms of money as well as in terms of ease of carrying out their procurement and production activities.

Accordingly we modify and upgrade our own systems, service levels and product quality. We are very agile in understanding new or specific requirements of our customers and develop products accordingly for them.

Apart from the above, following edges are of customer's benefit & interest :

Minimal rejections on filing machine, resulting in higher yield and lesser wastage of expensive formulation.

Readily available technical team from Erawat Group's Engineering and R&D unit to rectify mechanical and setting related problems **on customer's filling machines, if required.**

Machine performance such as to give minimum downtime on filing machine, thus increasing machine and operator output.

Dedicated fleet of air – conditioned containers to door deliver capsules up to customer's plant in India.

Wide and varied range of capsules to cater to most of the requirements of customers.

As we manufactures the machines ourselves, we have a facility of highly automated plant and sophisticated support staff. This gives an extra edge over competition, in supplying better capsules with higher consistency and continuity. Customers can rely on us more than any other supplier.

US DMF certified since 2004

Short and customizable lead – time

Halal Certified

ISO certified

GMP certified

Confirms to WHO-GMP, USP, BP

Following Is The Wide And Varied Range Of Products That We Offer

Hard Capsules

Gelatin

- Size – 00
- Size – 0el
- Size – 0
- Size – 1
- Size – 2
- Size – 3
- Size – 4
- Size – 5

Varieties

- Sticky Free
- Preservative Free
- SLS Free
- TSE/BSE Free
- Metallic
- Pearl
- Liquid Filling

HPMC/Veg

- Size – 00
- Size – 0el
- Size – 0
- Size – 2
- Size – 3

Special printing option of "Metallic colour printing" on regular shades also available which is specifically useful for Brand Security, fighting counterfeit drugs and for attractive visual appeal.

MANUFACTURING SETUP

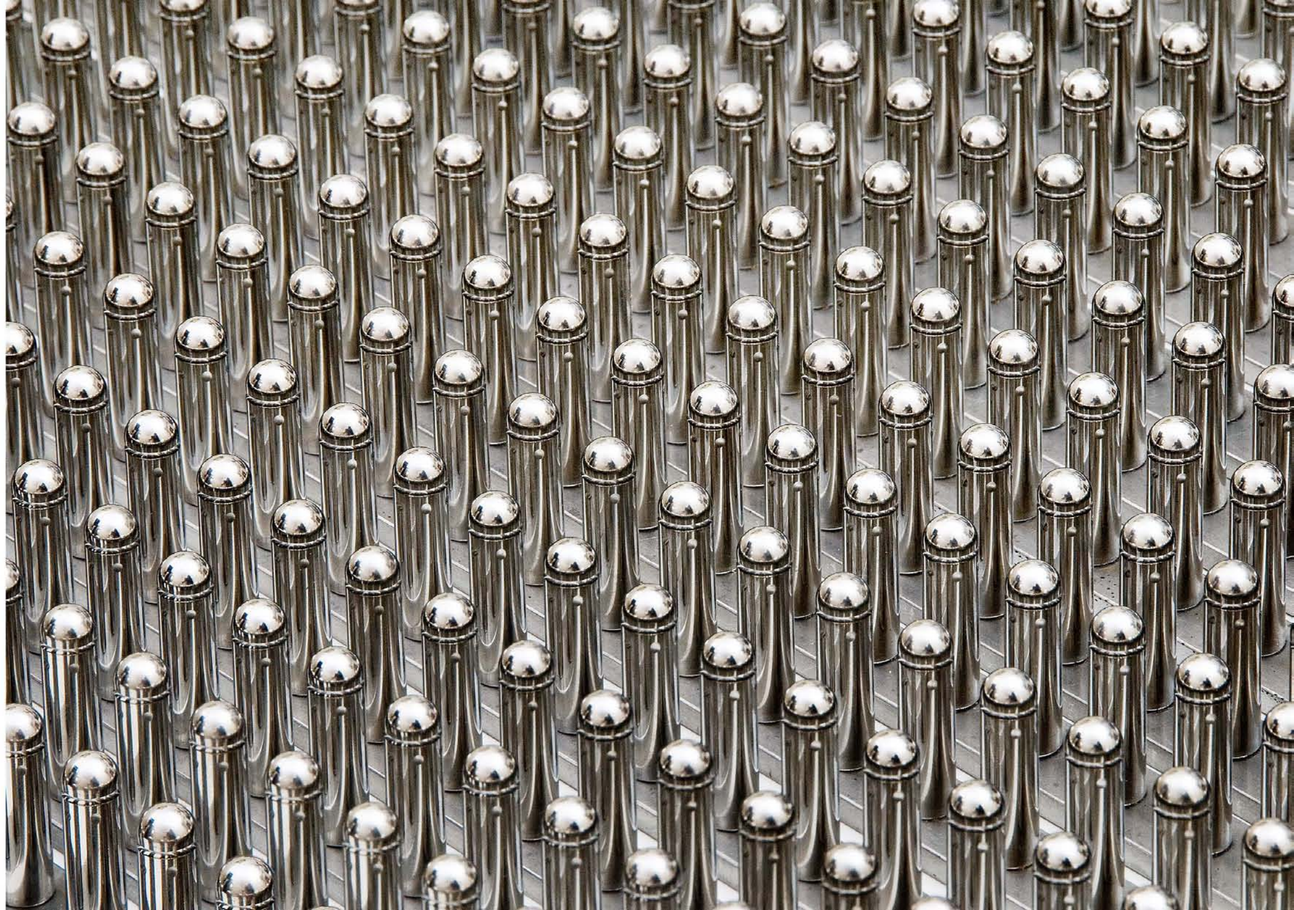
MACHINERY

Our Highspeed capsule manufacturing plants and the printing machines are manufactured at highly Sophisticated Engineering facility of the group, Erawat Engineering Pvt. Ltd. Some of the distinct features of our capsule manufacturing plant are:-

- Usage of indigenous and superior technology.
- Possesses pneumatic drives, Programmable logic controls, dedicated drives.
- Linear Motion Bearing that makes the product superior and matching the International Standard. Due to this Engineering strength next door, we have an on going R&D and continuous improvements in our plants and process, which gives us a unique position in the market for providing quality and consistency.

CAPACITY

QUANTITY (PIECES)	SIZE
35 million per month	#00
35 million per month	#0el (Elongated)
105 million per month	#0
35 million per month	#1
150 million per month	#2
35 million per month	#3
35 million per month	#4
35 million per month	#5



QA AND QC

QA & QC are obviously the foundation pillars for making a quality product and Erawat Pharma Group certainly understands the same. While our QA department is always on toes to ensure that systems, procedures, quality and manufacturing norms, specifications etc are strictly adhered to, our products are further passed through quality checks on as many as 45 different parameters, to make sure that only the best is supplied to customers.

Men, Materials, Machinery and Methods are aligned to our core ideology and quality policy.

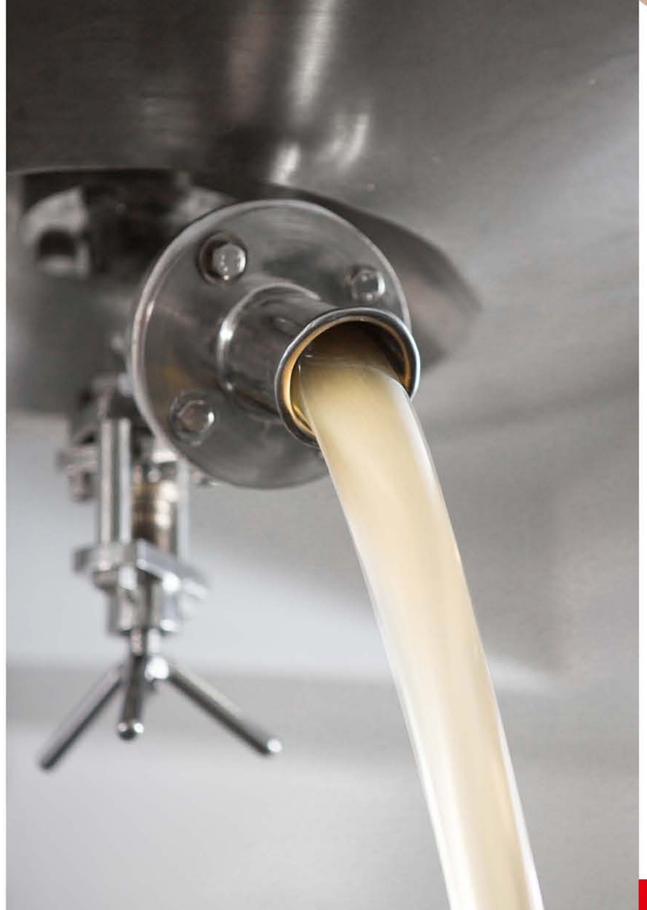
Even after so many checks and activities, actual performance of these capsules on filling machine at customers premises, is simulated on capsule filling testing machines at our end as well.

QUALITY OF RAW MATERIALS THAT WE USE AND THEIR SUPPLIERS

To ensure supply of quality product to the customers we use only the best available Raw Material in the market and do not compromises on RM quality even if it's available on cheaper cost.

Our major source of TSE/BSE free gelatin is from UK and India. For HPMC, RM is sourced from World's top 2 supplier. Colour pigments are sourced from world's top supplier of this product.

Customers can rest assured that all these RMs are up to our specifications and are properly certified by various agencies like US FDA, EDQM, and HALAL etc; as applicable to the product.



PRINTING & TESTING FOR EMPTY HARD GELATIN CAPSULES

We posses special capsule printing machines, manufactured at our own engineering facility Erawat Engineering Pvt. Ltd. The machine is capable of printing on capsules as per the customized requirements of our clients.

We provide printing in several varieties as follows :

LINEAR / CIRCULAR PRINTING

- **Double color oriented**
- **Single color oriented**
- **Regular Linear printing**

The metallic printing facility is also available with us which saves the capsules from any counterfeiting possibilities.

Gelatin :
We use pharmaceutical grade bone gelatin(as per IP). This is free from BSE and TSE and is strictly certified with HALAL and EDQM certificate.

We do not use hide & fish gelatin at all

HIGH SPEED FILLING MACHINE TEST

Filling Machine Performance

We are involved in manufacturing capsules that can be filled using any type of filling machine at various speeds. These capsules can be filled using automatic machines like Zanasi, GKF, PAM, Se jong, MG2 on speeds as high as 150,000 capsules/hr. and also on semi automatic machines and hand filling machines. These are in compliance with USP and B.P.

Standards

The capsules are tested on the parameters such as Dimensions, Brittleness, Uniformity of weight, Disintegration Time, Microbiological Limits, Loss on Drying, Storage and Labeling. These are manufactured in compliance with I.P. Specifications and USP & BP. 1996.

SPECIFICATIONS FOR EMPTY HARD GELATIN CAPSULES

The various quality variants are controlled as per specification prescribed in I.P. 1996.

However our Quality Control norms are even Stringent than those specified in I.P. 1996. We operate under narrower limits for various attributes, like Dimension, Weight etc. than those permitted in I.P. 1996.

TABLE 1

DIMENSIONS (in mm)

	OUTSIDE DIAMETER		LENGTH	
SIZE	BODY (mm)	CAP (mm)	BODY (mm)	CAP (mm)
00	8.16 - 8.28	8.49 - 8.61	19.70 - 20.70	11.30 - 12.30
0el	7.30 - 7.42	7.61 - 7.73	19.90 - 20.70	11.40 - 12.20
0	7.28 - 7.40	7.60 - 7.72	18.00 - 19.00	10.20 - 11.20
1	6.57 - 6.69	6.87 - 6.99	16.10 - 17.10	9.30 - 10.30
2	6.02 - 6.14	6.31 - 6.43	14.70 - 15.70	8.50 - 9.50
3	5.50 - 5.62	5.77 - 5.89	13.10 - 14.10	7.60 - 8.60
4	5.01 - 5.13	5.27 - 5.39	11.70 - 12.70	6.70 - 7.70
5	4.59 - 4.71	4.85 - 4.97	8.80 - 9.80	5.70 - 6.70

TABLE 2			
	CLOSED JOINED LENGTH OF EMPTY SHELLS	DOUBLE WALL THICKNESS	
SIZE	Closed Joined Length (mm)	BODY (mm)	CAP (mm)
00	23.00 - 23.80	0.180 - 0.240	0.190 - 0.250
0el	22.80 - 23.60	0.182 - 0.218	0.188 - 0.224
0	21.00 - 21.60	0.180 - 0.240	0.190 - 0.250
1	19.10 - 19.90	0.174 - 0.234	0.180 - 0.240
2	17.40 - 18.20	0.174 - 0.234	0.180 - 0.240
3	15.40 - 16.20	0.164 - 0.224	0.170 - 0.230
4	14.00 - 14.60	0.164 - 0.224	0.164 - 0.224
5	10.90 - 11.30	0.0164 - 0.224	0.164 - 0.224

TABLE 3		
WEIGHT OF CAPSULES (in milligram) & VOLUME (in CC)		
AVERAGE WEIGHT (Deviation ± 5%) & VOLUME (in CC)		
Size	Average weight (mg) (Avg. of 20 Capsules Taken Together)	Volume (CC)
00	119	0.95
0el	104	0.78
0	96	0.68
1	76	0.50
2	63	0.38
3	50	0.30
4	40	0.21
5	28	0.13

TABLE 4		
MICROBIOLOGICAL LIMITS		
	= Less than 1000 / gm	TOTAL COUNTS OF ORGANISM
	= NIL (Absent in 1 gm)	E COLI
	= NIL (Absent in 10 gm)	SALMONELLA
TESTS AS PRESCRIBED BY IP 2014		

TABLE 5		
MOISTURE CONTENT AND DISINTEGRATION TIME		
	= 12.5 to 16.0 %	MOISTURE CONTENT
	= Less than 15 minutes.	DISNTEGRATION TIME

Loss On Drying

Between 12.5 per cent and 16 per cent, determined on capsule shells weighing 1.0 g by drying in an oven at 105° C for 4 hours or to constant weight.

Storage

Capsules should be stored in dry and cool place and boxes should be well closed. The relative humidity is kept between 45 percent and 55 per cent. The temperature should be between 23°C to 27°C.

Filling Performance

We conduct Simulation Test of machine filling for every box of capsules. Our capsules run smoothly on all type of filling machines including Fully Automatic High Speed Filling Machines.

PACKAGING OF GELATIN CAPSULES

Primary Packaging

The finally formulated hard gelatin capsules ready for dispatch are initially put in LLD Polyethylene bag.

Secondary Packing

The empty gelatin capsules in polyethylene bag is then packed in sturdy double corrugated cartons, all the six sides lined with thermocol sheets for providing cushioning and thermal insulation.

Export Packing

For protecting capsules from fluctuating and severe conditions of humidity as well as temperature, the capsules are first packed in poly-bags, then these bags are put in "Aluminum Foil LLDP co-extruded bags". Further, the assortment of bags is put in corrugated box that is lined with Thermocol on all the six inner sides of the box. In addition to this, these jam-packed boxes are then laminated with poly film. Thereby we not only take care of the humidity and temperature but also take into thought the miss-handling that might take place while the transportation.

Labeling

After packaging, labeling is the other significant task to complete. Labeling being entirely a different department, the cartons are appropriately labeled representing basic information viz., quantity, size, color, destination, storage conditions, etc. Visual test are carried out in order to ensure that colors are harmonious and the script is legible.
Proper manufacturing of box numbers & sample capsules / capsules color image is glued on each box which helps in simple visual identification of provide.

Standard Packing

Quantity Per Box in pcs.
The following table gives our Standard Packing :

Quantities & box sizes might differ as per the total order quantity, mode of shipment & temp / humidity condition.

BOX SIZES	QTY. (in pcs.)	Size
590mm X 440mm X 740mm	75000	#00
590mm X 440mm X 740mm	95000	#0el (Elongated)
590mm X 440mm X 740mm	100000	#0
590mm X 440mm X 740mm	140000	#1
590mm X 440mm X 740mm	175000	#2
590mm X 440mm X 740mm	200000	#3
590mm X 440mm X 740mm	300000	#4
590mm X 440mm X 740mm	400000	#5

GELATIN

INTRODUCTION TO HPMC CAPSULE SHELLS

Empty cellulose capsule shells are nontoxic vegetarian capsule shells which are manufactured from Non animal origin material HPMC.

HPMC is widely used in food and pharmaceutical industry as an additive, and are included in monographs of many pharmacopoeia like IP,USP,Ph.Eur HPMC are approved by FDA and EMA as food additive for direct or indirect applications.. WHO-JECFA database has no limits on the amount of HPMC intake.

UNIQUE PROPERTIES OF HPMC CAPSULE SHELLS

Well Suited for Moisture Sensitive Formulations

The low moisture content of these capsules enhances its applications to

- Formulations that contain hygroscopic material including dry powder inhalers
- Formulations with active ingredients that are moisture sensitive

Excellent Machinebility and Mechanical and chemical Stability

An exclusive capsule design coupled with elastic polymer structure enables high machines efficiency –

- Extensive field testing on a wide array of capsule filling and blister packaging equipment confirm robust commercial performance
- HPMC Capsule shells are not affected by moisture and chemicals Even in low humidity environments they maintain their elasticity and ability to resist mechanical breakage
- No adjustment is necessary for customers who use gelatin capsules in their operations

Resistance to cross Linking

With a well characterized and stable polymer structure HPMC capsule offer reduced potential for cross linking

Globally Accepted formulation

The non-animal components of the HPMC capsule formulation are accepted for pharmaceutical use in all major global markets.

Relaxation from regulatory documentation

TSE certification is not required, reducing the resources required for regulatory filing and international shipping and customs documentation.

A simpler approach yields a new dimension in performance

The chemical simplicity of HPMC Capsules which contains just three primary components (HPMC, Carrageenan and water and colorants as desired) can yield important advantages.

HYPROMELLOSE CELLULOSE OR HPMC

Hypromellose (INN), short for Hydroxy Propyl Methyl Cellulose. HPMC is solely plant based and free of animal products. Hypromellose is a solid, and is a slightly off-white to beige powder in appearance and may be formed into granules. The compound forms colloids when dissolved in water. This non-toxic ingredient is combustible and can react vigorously with oxidizing agents.

Hypromellose in an aqueous solution, unlike methylcellulose, exhibits a thermal gelation property. That is, when the solution heats up to a critical temperature, the solution congeals into a non-flowable but semi-flexible mass. Typically, this critical (congealing) temperature is inversely related to both the solution concentration of HPMC and the concentration of the methoxy group within the HPMC molecule (which in turn depends on both the degree of substitution of the methoxy group and the molar substitution. That is, the higher the concentration of the methoxy group, the lower the critical temperature. The viscosity of the resulting mass, however, is directly related to the concentration of the methoxy group.

Names	
Other names	Hydroxypropyl methylcellulose; hydroxypropyl methyl cellulose; HPMC; E464
Identifiers	
CAS Number	9004-65-3
ATC code	S01KA02
ChemSpider	21241863
UNII	36SFW2JZ0W
Properties	
Chemical formula	variable
Molar mass	variable

KAPPA CARRAGEENAN

Kappa Carrageenan is a hydrocolloid extracted from some red seaweeds belonging to the Gigartina, Hypnea, Eucheuma, Chondrus and Iridaea species. It is used in a wide variety of applications in the food and pharmaceuticals industry as a thickening, gelling, stabilizing and suspending agent in water and milk systems. Carrageenan has a unique ability to form a wide variety of gel textures at room temperature: rigid or elastic, clear or turbid, tough or tender, heat stable or thermally reversible, low or high melting/gelling temperatures. It may also be used as a suspending, gelling, emulsifying, stabilizing and water retaining agent in other industrial applications.

PRODUCT & PRODUCT RANGE

We manufactured Empty Hard HPMC Capsules in following sizes .

01	Size "00"
02	Size "0"
03	Size "1"
04	Size "2"
05	Size "3"
06	Size "4"

QUALITY CONTROL

Acceptable Quality Level (Sample size 1250 nos. capsules)

Capsule Defect Category	Acceptable Quality Level (AQL %)
Critical	0.01
Major	0.40
Minor	1.0

Capsules are manufactured under controlled condition to ensure conformance to specifications.

Classification of capsule defects

Critical defect	A defect that affects the performance of a capsule For the final product For capsule filling
Major defect	A defect that may not affect the machine performance critically.
Minor defect	A defect that has no effect on the performance of a capsule as a package. It is a slight blemish that makes the capsule visually imperfect.

HPMC

DIMENSIONAL ANALYSIS

Dimension of capsules are controlled to ensure conformance to specifications.

CAPSULE SIZE	00	0	1	2	3	4
Body volume (ml)	0.95	0.68	0.50	0.37	0.30	0.21
Capsule Capacity(mg) for powder density						
0.6 g/cc	570	408	288	222	180	126
0.8 g/cc	760	544	384	296	240	168
1.0 g/cc	950	680	480	370	300	210
1.2 g/cc	1140	816	576	444	360	252
Avg. wt in mg	119	96	76	63	50	40
Tolerance in %	±10	±10	±10	±10	±10	±10
Tolerance (mm)	±0.5	±0.5	±0.5	±0.5	±0.5	±0.5
Body Nominal (mm)	20.2	18.5	16.6	15.2	13.6	12.2
Tolerance (mm)	±0.5	±0.5	±0.5	±0.5	±0.5	±0.5

Nominal Joined length (mm)	23.5	21.8	19.5	18.0	15.6	14.2
Tolerance (mm)	±0.4	±0.4	±0.4	±0.4	±0.4	±0.4
Cap Nominal (mm)	8.55	7.66	6.93	6.37	5.83	5.33
Tolerance (mm)	±0.06	±0.06	±0.06	±0.06	±0.06	±0.06
Body Nominal (mm)	8.22	7.34	6.63	6.08	5.56	5.07
Tolerance (mm)	±0.06	±0.06	±0.06	±0.06	±0.06	±0.06
Body Nominal (mm)	8.22	7.34	6.63	6.08	5.56	5.07
Tolerance (mm)	±0.06	±0.06	±0.06	±0.06	±0.06	±0.06
Cap Nominal (mm)	0.210	0.205	0.200	0.198	0.196	0.194
Tolerance (mm)	±0.018	±0.018	±0.018	±0.018	±0.018	±0.018
Body Nominal (mm)	0.206	0.195	0.193	0.191	0.188	0.182
Tolerance (mm)	±0.018	±0.018	±0.018	±0.018	±0.018	±0.018

HPMC

FINAL TEST ON PRODUCT

Dimension of capsules are controlled to ensure conformance to specifications.

TEST	SPECIFICATION	METHOD
Description	Cylindrical, Opaque, Telescopic Capsules	I.P
Identification	The smoke of burned capsule smells like burning woodchip or paper	I.P
Odour	No Foreign Odour	I.P.
Disintegration Time in 0.1N HCl at 37 + 1 C	Less Than 15 Minutes	I.P.
Loss on Drying	3.0-8.0 %	I.P. / USP
pH (1% aq solution)	5.0-7.0	IHT
Heavy Metals	< 0.001%	I.P.
Arsenic	<3 ppm	I.P.
Self Locking Feature	Shell and body lock together and are not readily separated.	IHT
Brittleness	Shell deforms under pressure but does not crack	IHT

MICROBIOLOGICAL TEST		
Total Bacterial Count	Less Than 1000 cfu / gm	I.P. / USP
Escherichia Coli	Absent in 10 gms	I.P. / USP
Salmonella	Absent in 10 gms	I.P. / USP
Staphylococcus Aureus	Absent in 10 gms	I.P. / USP
Pseudomonas	Absent in 10 gms	I.P. / USP
Clostridium Spec.	Absent in 10 gms	I.P. / USP
Yeast and Moulds	Below 100 cfu/ gm	I.P. / USP

PACAKING, TRANSPORTATION, STORAGE & FILLING

Packaging

- Capsules are packed in food grade antistatic plastic bags.
- These plastic bags are then packed into heavy duty corrugated boxes.
- The box is then sealed with BOPP tapped from top and bottom.
- Finally label is pasted on the box having information of size, colour, Batch no., Box No., Quantity and other relevant information.

TRANSPORTATION

- Capsule packed in boxes are transported in conditions through reefer container vehicles.
- Temperature is maintained between 10°C to 30°C and Rh is maintained between 40% to 65%.
- All the dedicated vehicles used for capsules transportation have temperature Data logger fitted in the vehicle, to ensure that the temperature during transit is within specification.

WAREHOUSING/ STORAGE

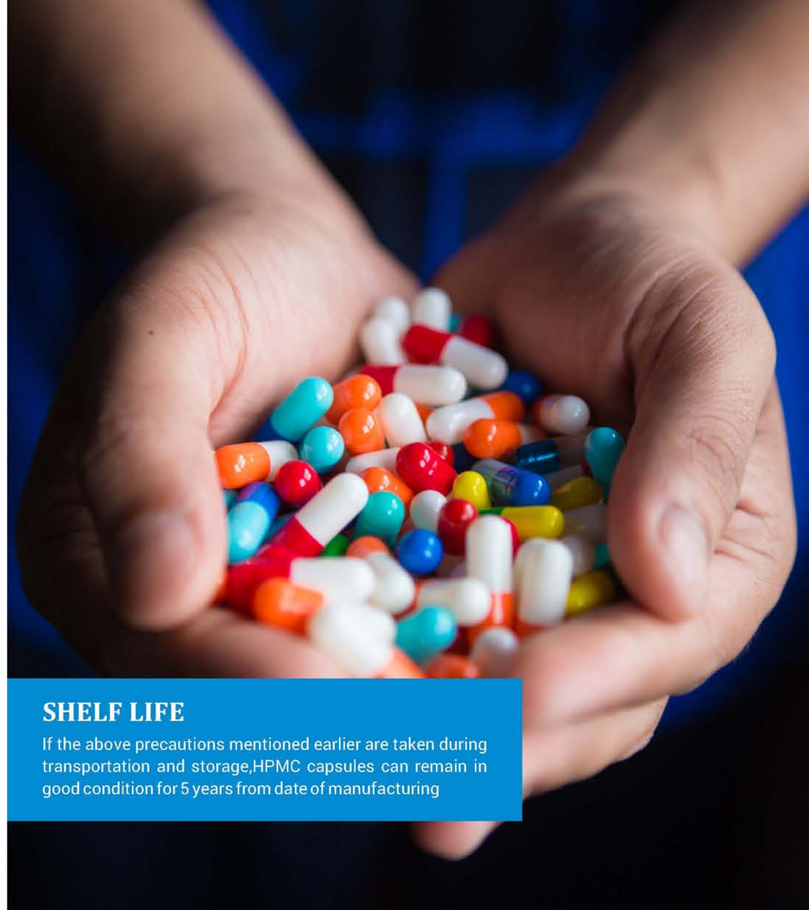
- When not in use, Capsules are to be stored in unopened packed condition.
- The Temperature and Rh during storage should be between 20°C to 35°C & 40%to 65%.

OTHER PRECAUTIONS

- Store capsules away from direct sunlight/ Hot water/ Air radiators, hot water pipes & steam pipes.
- Store capsules on pallets on the ground.
- Store capsules away from potential sources of water condensation e.g. under water pipes.
- Do not store empty capsules in freezers.

CAUTION

- If for any reason inner Poly bag is opened then the opened poly bag containing capsule should be closed in the best manner possible either by heat sealing or usage of good quality adhesive taps to reduce moisture loss/gain during storage.
- The storage condition beyond the recommended limits will result in damage to capsules Quality and its shell life performance on filling Machine.



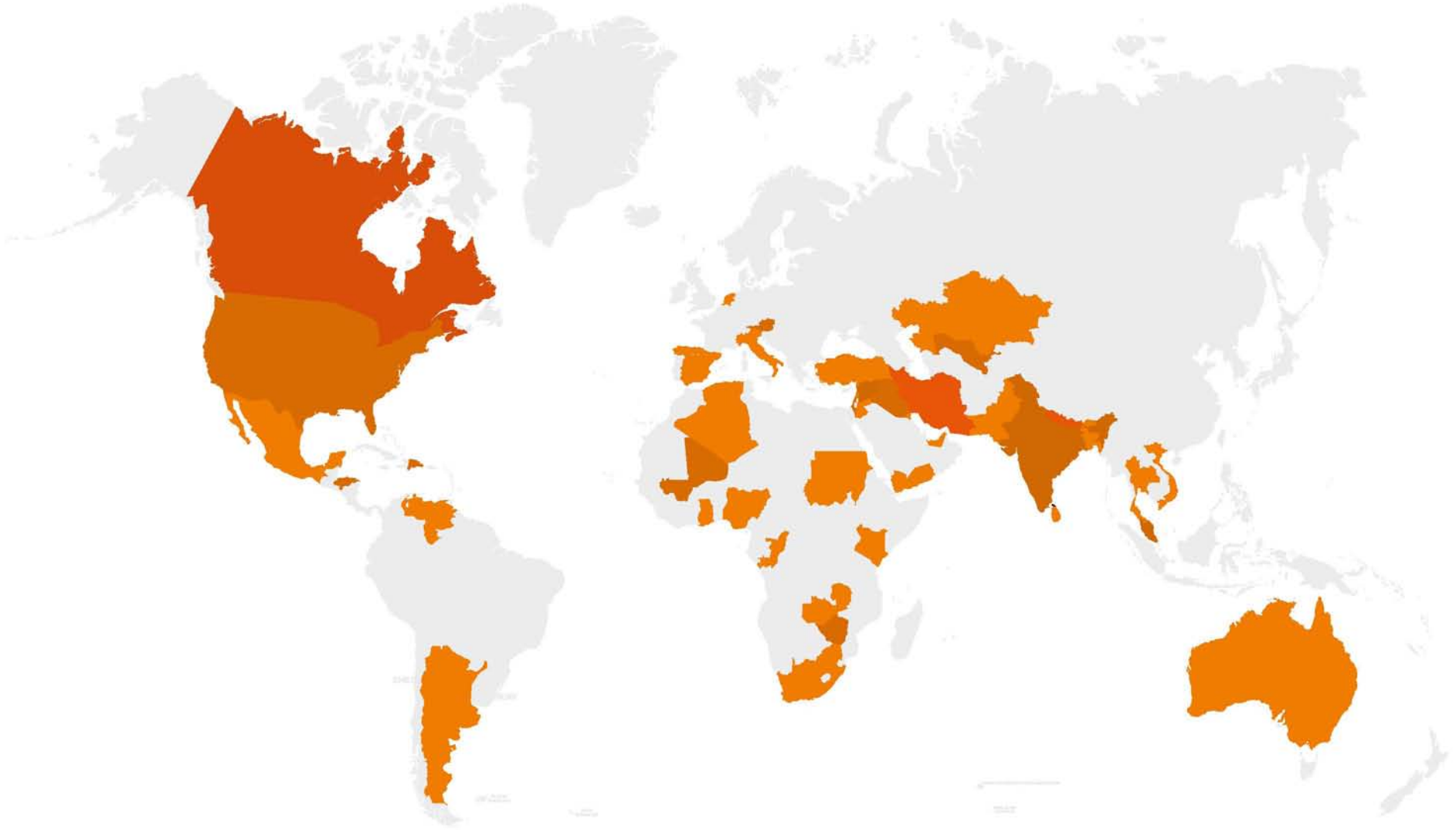
SHELF LIFE

If the above precautions mentioned earlier are taken during transportation and storage,HPMC capsules can remain in good condition for 5 years from date of manufacturing

LOCATION

ERAWAT PHARMA LIMITED is located at Pithumpur Industrial Area, near Indore, the Industrial Capital of Madhya Pradesh. This place is well connected to all parts of the country and the world.

Our unit is situated right beside ICD (Inland Container Depot) of Indian Container Corporation (CONCOR), which is a dry port within Pithumpur Industrial Estate. This facilitates custom clearance and export of products from here thus reducing the delivery time considerably. The Industrial Estate is having a culture & environment of quality due to presence of large industrial houses with latest technology from within and through collaboration with many developed countries.



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