

# TECHNICAL SPECIFICATION



**MEDI-CAPS LIMITED**





## INTRODUCTION

**Medi-Caps Limited** an ISO-9002 certified company is in successful fourteenth year of production of Hard Gelatin Capsule Shells IP. Since our inception in 1986 we have focused clearly on the production of finest gelatin capsules in various sizes # 00,0,1,2,3,4 which are widely used in packaging of drugs, vitamins, antibiotics & cosmetics.

The Company has an array of fourteen fully automatic capsule making machines of international grade. The machines are operated by skilled persons and are managed by technocrats having vast experience in capsule manufacturing industry. Presently capsules of size 00 to 4 are manufactured in the company. As the Company is having WHO GMP certification, the Standard Operating Procedures (SOP) are followed meticulously all over the factory to produce Quality product.

As a first step in quality assurance, the Company has a big bay of automatic sorting machines, which help isolate capsules having various kinds of visual defects.

All incoming raw material, in-process production and capsules are subjected to rigorous quality checks in a tightly controlled Q.A. Department to ensure delivery of capsules of best quality to our esteemed customers.

The company has a large bonded storeroom with controlled temperature and humidity conditions to ensure safe storage of manufactured capsules.

This document is purported to provide the customers of **Medi-Caps Ltd., (MCL)** with a source of technical information on two piece hard gelatin capsules manufactured at its factory at Pithampur. Distt. Dhar, Madhya Pradesh India.



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**WORKS :-** SECTOR 1, MHOW-NEEMUCH ROAD,  
PITHAMPUR, DISTT.DHAR, (M.P.) 454 775.  
INDIA  
PH. - +91-7292-507445, 507446.  
FAX - +91-7292-507387  
MAIL - info@medicaps.com

**OFFICE :-** 401,CHETAK CENTRE,  
12/2, R.N.T. MARG, INDORE (M.P.). 452 001,  
INDIA.  
PH. - +91-731-2518435, 2514062.  
FAX - +91-731-2528269.



**MEDI-CAPS LIMITED**



## **QUALITY POLICY & OBJECTIVES**

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### **Quality Policy**

Excellence at all levels of activities, leading to continuous improvement of product, process systems, cost effectiveness and productivity for total customer satisfaction.

Through :

1. Participative work culture.
  2. Adherence to product specifications.
  3. Optimized use of state of art technology.
  4. Continuous training for all, in technical and managerial skills
  5. Prompt and positive response to customer needs.
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### **Quality Objectives**

1. We shall manufacture products conforming to the specifications & quality as required by the customer following Good Manufacturing Practice (GMP)
2. We shall commit ourselves to meet the requirements of our customers through a sound quality system, & supply quality & cost effective products as per delivery schedules.
3. We shall satisfy the customer by providing the value of money he is paying for the quality product thus reduces customer complaints.
4. We shall have ongoing program of training for all our employees in order to update their competence.



## GENERAL INFORMATION

### SIZE

Capsules are manufactured in size 00, 0, 1, 2, 3, & 4 with various caps & body colours and different locking facilities.

### COLOURS

The Company has a practice to maintain stocks of capsules with colour shades of common industry requirements. Capsules are also manufactured with colour shades as per the choice of the customer. In that case, colour samples are prepared at our well-equipped preparation room and sent for approval to the customer. The manufacturing process starts only after the customer is satisfied with the colour shade developed at Medi Caps Limited.

### TYPES

Two types of capsules are manufactured and the type depend upon the locking facility. The two types are described below:-

A) **SINGLE LOCK CAPSULES:** There is a lock ring only on the cap and the closed joined length can vary within tolerable limits.

B) **SELF-LOCK (DOUBLE LOCK) CAPSULES:** There is a locking on the cap as well as the body. The closed joined length is fixed for these types of capsules. Obviously, different sizes have different Fixed Joined Length (FJL). Therefore the capsule filling machines are to be set as per FJL. If capsules are locked below the FJL, denting may occur and if locked length is above FJL, the capsule may not lock altogether.

### COMPOSITION

The various ingredients used for capsule manufacturing comply with appropriate regulatory requirements for use in food and drug products & some of them comprise mainly of the following:-

A) H.S. Grade Gelatin.

B) Purified water.

C) Food colours like Erythrosine, Carmoisine, Ponceu 4 R, Brilliant Blue, Indigo Carmine, Tartrazine and Sunset Yellow.

D) Yellow and Red Iron Oxide.

E) Titanium Dioxide.



## **PRINTING**

Capsules can be printed with Product identification information provided by the customer. The printing at MCL is done by Linear (straight) printing, circular (spiral) printing & rectified spin printing (circular printing with orientation) methods on state-of-the-art high speed printing machines. The customer has a choice to choose from the different printing colours. Printing inks used for printing are food grade.

## **QUALITY CONTROL & QUALITY ASSURANCE**

To have a high standard of sustained excellence in quality, quality control measures are applied at all levels of production, inspection and despatch. The objective of the quality control system is to ensure consistency, uniformity & conformance to specification through process control and monitoring.

## **RAW MATERIAL INSPECTION**

All materials and inputs required to produce capsules are tested as per proper applicable standards. Gelatin and D.M. water are tested for their pharmaceutical grade; other raw materials are tested as per respective specified tests in Indian pharmacopoeia.

## **IN PROCESS CONTROL**

All parameters like temperature, humidity and viscosity are continuously monitored & controlled to have weight and moisture contents of capsules within specified limits. All the machines are fitted with vibrator sorting attachments, which automatically remove loose and mini cap/body production. The samples are drawn periodically during the production so as monitor length, weight, wall thickness, dome thickness, shoulder thickness and moisture content of the capsules. In the machine room, the capsules are subjected to visual quality checks periodically for Critical, Major and Minor defects (Details about these defect are included later in the manual). On noticing any defects at any level of quality checks especially at the machine room, corrective action is taken immediately.

## **SORTING**

The capsules is visually inspected on translucent glass on sorting machines. This stage removes physical defects such as variation in colour, shade, bubbles, pinholes, bad cuts, loose caps and bodies, oversize in length, telescopic dents and any other faults. The good capsules from sorting department may be sent for printing depending on customer's requirement. The printed capsules are again sent for sorting to remove printing defects.



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### **FINAL TESTING**

The good capsules-printed or unprinted from sorting department are collected in drums and sent for checking for final quality control by supervisors. Statistical Quality Control tools are used during inspection and final testing. A sample is taken out to be tasted at laboratory for compliance with IP and customer specifications; each box is finally checked for visual defects before packing, so that customers get best quality capsules.

### **QUALITY AUDITS**

Based on various quality control records, a continuous study is made to prevent repetition of defects so that the improvement in the quality is a continuous process in our plant. We assure that only quality capsules are supplied having extremely high conformance to specifications and therefore having an internal high level of quality.

### **R & D DEPARTMENT**

To ensure nearly Zero defect quality with regular upgradation, we have in-house R & D Department which is continuously involved in research and studies of new technologies gearing up to meet the demands of our vast client base.



## EVALUATION CRITERIA FOR CAPSULE DEFECTS

### VISUAL QUALITY

By the term 'Visual Quality' we mean that there should not be any deviation in the specified visual quality attributes i.e. standard shape, visual defects, capsule defects etc., these defects are classified as :-

- A. Critical
- B. Major
- C. Minor

A). CRITICAL DEFECT:- Is a defect that affects the performance of a capsule as a package for the final product or contributes to a major filling problem.

B). MAJOR DEFECT :-Is a defect that may cause a problem on a capsule filling machine.

C). MINOR DEFECT : -Is 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.

### CATEGORISATION OF VISUAL DEFECTS

Critical Defects	Major Defects	Minor Defects
Pin Holes	Chipped Edges	Rough Edges
Mashed Capsules	Collet Pinches	Dents (Small)
Telescopic	Dents (Large)	Black Spots
Uncut Body	Double Cap	Bubbles
Split Capsules	Uncut Cap	Scratches
Ring inside Cap	Loose Body	Specks
	Loose Cap	Uneven Cut
	Loose Capsules	



**ACCEPTANCE LEVEL**

In order to determine acceptance level of a box based on visual quality, a sample of 1000 capsules is drawn from the box containing one Lac capsules. Then defective capsules are sorted on inspection sorting machine and are grouped in Critical, Major and Minor. The acceptance level of defects is as under:-

- Critical** - Not more than 0.05 %
- Major** - Not more than 0.50 %
- Minor** - Not more than 1.00 %

The total of Critical, Major and Minor should not be more than 1.5 % of the sample. If it is more than 1.5 % then it is sent for resorting till we get the defect level within this limit.

**PRINTING DEFECTS :-**

**DEFINITION OF PRINTING DEFECTS**

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**Critical Defects**

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**Major Defects**

A printing defect that prevents legend from being normally identified.

Printing of defect will fall into this category , provided that the legend is legible.

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**CATEGORISATION OF PRINTING DEFECTS**

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**Critical Defects**

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**Major Defects**

Missing Print  
Illegible Print  
Multiple Print  
Wrong Marking

Smudged Ink  
Incomplete Letters  
Incomplete Message  
Ink Spots  
Ink Lines  
Displaced Print  
Light Print  
Dark Print

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### **ACCEPTANCE LEVEL**

In order to determine acceptance level of a box based on visual quality, a sample of 1000 capsules is drawn from the box containing one Lac capsules. Then defective capsules are inspected on inspection sorting machine and are grouped into Critical and Major defects. The acceptance level of defects is as under :-

**Critical** - Not more than 0.05 %

**Major** - Not more than 1.0 %

The total of Critical and Major should not be more than 1 % of the sample. If it is more than 1% then it is sent for resorting till we get the defect level within 1%.

### **MOISTURE CONTENT**

The Moisture content is between 12.5 % and 16% W/W determined on capsule shells by drying in an oven at 105°C for 4 hours or to constant weight. It is checked before final packing. Capsules are to be stored under ideal atmospheric conditions. If exposed to dry atmosphere, they lose moisture and if exposed to high humidity they gain moisture. Moisture content below 12.5 % can lead to brittleness in capsules and above 16% will cause the capsules to deform.

### **SOLUBILITY (DISINTEGRATION TIME)**

Empty capsules disintegrate within 15 minute at 37° C +/- 2°.C (Test procedure as per IP 1996 Appendix 7.1 or equivalent)

### **MICROBIAL LIMITS**

Total bacterial count should not be more than 1000 per gm. of the capsules shells. 1.0 gm should be free from Escheichia coli and Salmonellae.(Test procedure IP 1996 Appendix 9.4 or equivalent).



### **BRITTLENESS TEST AND ACCEPTANCE CRITERION**

The sample capsule are inspected for defects spreading them on a vibrator sorting machine, inspection should be with naked eye on inspection time should range between 2 to 3 minutes for 1000 capsules.

### **BRITTLENESS ACCEPTANCE LEVEL**

<b>Sample Size</b>	<b>Acceptance Number</b>	<b>Rejection Number</b>
100	3	5



## EVALUATION CRITERIA OF DIMENTIONS

For testing dimensions of the capsules, it is recommended that measurement should be taken under controlled condition of temperature and humidity. Temperature between 20° C to 25° C and relative humidity between 40 % to 60 % are recommended.

## WEIGHT

A dipping process manufactures Weight Capsules. The weight of individual capsules varies about a target value. The table given below shows the desired target weight in milligrams for each capsule size :

## EMPTY CAPSULE WEIGHT

SIZE	Lot average Weight mg./capsule	Variation (+/- mg.)on average wt
00	126	
0	96	9.6 +/- 3 mg
1	76	7.6 +/- 2 mg
2	63	6.3 +/- 2 mg
3	50	5.0 +/- 2 mg
4	40	4.0 +/- 2 mg

The weights above are determined from the gross weight of a sample of 100 capsules at the standard moisture content 12.5 % to 16.0 %.

## NOTE :

Significant weight changes can occur if moisture content is allowed to change. Therefore the weights indicated in the above table should not be used as tare weights in capsules filling. An actual tare weight should be determined at regular intervals during filling in order to assure proper filled weights.



**LENGTH**

Length of capsules are checked during manufacturing process and during quality check at various stages to ensure that each batch confirms to the specification as mentioned below :-

<b>Size</b>	<b>Cap length (mm)</b>	<b>Body length (mm)</b>
00	11.3 - 12.3	19.6 - 20.6
0	10.82 - 11.54	18.36 - 19.08
1	9.65 - 10.37	16.36 - 17.08
2	8.81 - 9.53	14.98 - 15.70
3	7.87 - 8.59	13.12 - 13.84
4	7.11 - 7.83	11.98 - 12.70

**CAPACITY**

Hard gelatin capsule shells are normally used for the incorporation of medicament usually in the form of powders, pellets or granules, tablets, semi solid materials, paste and liquid. The quantity of material that can be filled into the capsule depends upon the nature of the material. the most useful capacity value is the available volume of capsule body.

**APPROXIMATE THEOROTICAL CAPACITY IN ml**

<b>Capsule Size</b>	<b>Volume(ml)</b>
00	0.97
0	0.67
1	0.48
2	0.37
3	0.27
4	0.20

**Note :**

For filling of powder, the approximate filling weight depends upon the density of the powder. The maximum capacity for liquid and paste formulation is 90 % of the body volume.



## OUTSIDE DIAMETER

The following are the specification for outside diameter.

### OUTSIDE DIAMETER

Size	Cap Dia.(mm)	Body Dia.(mm)
00	8.41 - 8.53	8.07 - 8.19
0	7.57 - 7.69	7.26 -7.38
1	6.85 - 6.97	6.56 -6.68
2	6.28 - 6.40	6.01 -6.13
3	5.75 - 5.87	5.50 -5.62
4	5.25 - 5.37	5.00 -5.12

#### Note :

The diametrical measurement are to be taken with the help of special go,nogo gauges and not by vernier caliper or micrometer.

The above mentioned dimensions are not recommended to be the basis for acceptance, rejection of a lot because due to their slightly tapered shape and also due to the flexibility of capsule shells, exact outside diameter of the cap and body are difficult to measure.



## DOUBLE WALL THICKNESS

The specifications for double wall thickness (DWT) are as follows :

Size	Cap (mm)			Body (mm)		
	Target	Min.	Max	Target	Min.	Max
00		0.190	0.226		0.180	0.215
0	0.213	0.203	0.223	0.203	0.193	0.213
1	0.208	0.198	0.218	0.201	0.191	0.211
2	0.206	0.196	0.216	0.199	0.189	0.209
3	0.196	0.186	0.206	0.191	0.181	0.201
4	0.193	0.183	0.203	0.190	0.180	0.200

## PACKING

The capsules are packed in polyethylene bags. A bag contains 0.1 million capsules for size 0,1,2 and 0.2 million for sizes 3 and 4. These bags are placed and packed in seven ply corrugated boxes with thermocol sheets covering all side of the box. This ensures that packing is moisture and heat proof and protects the capsules from possible variation of surrounding temperature and humidity conditions. Each box is assigned a number for identification; a label containing various packing details such as size, colour, batch no., weight, quantity etc. is pasted on it.



## **GENERAL PRECAUTIONS, TRANSPORTATION & STORAGE CONDITIONS**

Capsules should be stored between 20° C to 25° C (59° F to 77° F) temperature and within 40% and 60% relative humidity, Protect capsules form moisture. Keep capsule bags sealed when not in use. Keep capsules away from any direct source of heat & light. Avoid sudden transfer of capsules from high temperature to low temperature zone.

## **CAPSULE FILLING**

Many factors can contribute to efficient filling of capsules.

Optimum conditions recommended for the filling operations are 23° C. +/- 2° C and relative humidity of 50 % +/- 5 %. Under these conditions the capsule will maintain the recommended moisture content to avoid brittleness and retain the ideal dimensions required for the filling machine.

## **A WORD ABOUT ELECTRO-STATIC CHARGE**

The use of plastic containers or scoops can cause electro-static charge to build up on the capsule and result in problems during filling. Hence it is recommended to use metal scoops or containers.



## **BASIC TROUBLESHOOTING**

### **LUMP FORMATION**

The recommended storage temperature for capsules is 20°C to 25°C at humidity levels between 45% to 55%. Any deviation in these conditions or exposure of capsules to any direct source of heat and light may be a cause of lump formation. The sudden transfer of capsules from high temperature to low temperature zone will also cause lump formation.

### **BRITTLENESS**

Check the storage conditions. The capsules may lose moisture if not stored in proper temperature and humidity conditions. Moisture level below 12.5% can lead to brittleness.

### **MICROBIAL COUNT**

Mishandling or exposure to air may increase the microbial count. While taking out a sample/part from the packed box, make sure that capsules are not taken out directly by hands. Scoop should be used. After taking out a part, box should be repacked properly.

### **NON-SEPARATION**

Check vacuum pressure and clean filter regularly on filling machine.

### **DENTS**

The joining length set on the filling machine may not be in agreement with the one specified by manufacturer.

### **RECTIFICATION**

Set finger of the filling machine properly.

### **TELESCOPING**

Non alignment of cap and body dish..