

TECHNICAL SPECIFICATION



MEDI-CAPS LIMITED





MEDI-CAPS LIMITED

Quality Policy

We at Medi-Caps Limited are committed for continual improvement in our product /services and total customer satisfaction by meeting the regulatory /standard requirement.

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 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 for money.
4. We shall have ongoing program of training for all our employees in order to update their competence.



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INTRODUCTION

Medi-Caps Limited an ISO-9001-2000 certified company is in successful nineteenth year of production of Hard Gelatin Capsule Shells IP. We are registered under Drug Master File (DMF) and our registration number is 18110. Since our inception in 1986 we have focused on the production of finest gelatin capsules in

SIZES :

00

0

0EL

1

1EL

2

3

4

which are widely used in packaging of drugs, vitamins, antibiotics & cosmetics etc.

MANUFACTURING FACILITIES AT MEDI-CAPS LIMITED

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 0 to 4 are manufactured in the company. As the company is having WHO GMP certification the Standard Operating Procedures (SOPs) are followed meticulously all over the factory to produce Quality product. As the 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 materials, in-process production and final capsules are subjected to rigorous quality check in a tightly controlled QA deptt. to ensure delivery capsules of best quality to our esteemed customers. The company has a large bonded store room with controlled temperature and humidity conditions to ensure safe storage of manufactured capsules.



GENERAL INFORMATION

SIZE

Capsules are manufactured in size 00, 0, 0e1, 1, 1e1, 2, 3, & 4 with various colours of caps & body and different locking features.

COLOURS

The company maintains stocks of capsules of standard color shades that are commonly used in Pharma industry. Capsules are also manufactured with colour shades as per the requirement of the customers. In such cases, color samples are developed at our well-equipped preparation room and sent for approval to the customer. The manufacturing process starts only after the customer approves colour shades developed at Medi Caps Limited.

TYPES

The type of capsules depends upon the type of locking facility used. We manufacture capsules having following types locking features in capsules :-

- A) SINGLE LOCK CAPSULES**
- B) SELF-LOCK (DOUBLE LOCK) CAPSULES**
- C) EASY - FIT CAPSULES**

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 lock ring on the cap as well as on the body. The closed joined length is within narrow range for these types of capsules. Different sizes have different joined length (JL). Therefore the capsule filling machines are to be set as per JL. If capsules are locked below the JL, denting may occur and if locked above JL, the capsule may not lock altogether.

C) EASY - FIT CAPSULES : Apart from all the features of double lock capsules mentioned above the body of the capsules have taper at the cut end allowing it to enter in to the cap without fouling at the cut edge of cap preventing in telescoping of capsules.

COMPOSITION

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

- A) H.S. Grade Gelatin.**
- B) Purified water.**
- C) Food colours like Erythrosine, Carmoisine, Ponceau 4 R, Brilliant Blue, Indigo Carmine, Tartrazine and Sunset Yellow.**
- D) Yellow Red Iron Oxide and Black Iron Oxide.**
- E) Titanium Dioxide.**



PRINTING

Capsules may be printed for product identification as per customer requirement. The printing at MCL is linear (straight) printing, circular spin printing (circular printing with orientation) on state-of-the-art high speed printing machines. The customer has a choice to choose from the different printing colours. 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 to stringent applicable standards. Gelatin, D.M. water and other raw materials are tested as per respective specified tests in Indian pharmacopoeia, British Pharmacopoeia and U.S Pharmacopoeia.

IN PROCESS QUALITY CONTROL (IPQC)

All parameters like temperature, humidity and viscosity are continuously monitored & controlled to have weight and moisture contents in capsules within specified limits. All the machines are fitted with vibratory sorting attachments, which automatically removes loose and mini cap/body and other major defective capsules from production. The samples are drawn at fixed interval during production so as to monitor length, weight, wall thickness, dome thickness, shoulder thickness etc. In the machine room, the capsules are subjected to visual quality checks periodically for critical, major and minor defects (Details of these defect are included later in the manual). On detecting defects at any stage of quality checks especially at the machine room, corrective actions are taken immediately.

SORTING

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



FINAL TESTING

Printed or unprinted capsules after sorting are sent for final quality control check. Statistical quality control tools are used during inspection and final testing. A random sample is taken for testing in the laboratory for compliance with IP and customer specifications. Each box is finally checked for visual defects, machine performance and moisture content before packing so that the customer gets the best quality capsules.

QUALITY AUDITS

Based on analysis of quality control data, a continuous study is made to prevent repetition of defects so that improvement in the quality is continuously maintained in our plant. We assure that the capsules that are supplied have high conformance to specifications and therefore are having inbuilt quality.

R & D DEPARTMENT

To ensure nearly zero defect quality and for regular upgradation, we have in-house R & D Department which is continuously involved in research and studies of new technologies and geared 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, dimensional 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)
Telescoped	Dents (Large)	Black Spots
Uncut Body	Double Cap	Bubbles
Split Capsules	Uncut Cap	Scratches
Ring inside Capsules	Loose Body	Specks
Foreign Capsules	Loose Cap	Uneven Cut



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 1 to 2.5 lac capsules. Then defective capsules are sorted on inspection machine and are categorized into 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 % in the sample. If it is more than 1.5 % then it is sent for resorting till we get the defect level within the above limit.

PRINTING DEFECTS:-

DEFINITION OF PRINTING DEFECTS

Critical Defects	Major Defects
A printing defect that prevents legend from being normally identified.	Printing defect will fall into this category , provided that the legend is legible.

CATEGORISATION OF PRINTING DEFECTS

Critical Defects	Major Defects
Missing Print Illegible Print Multiple Print	Smudged Ink Incomplete Letters Incomplete Messages Ink Spots Ink Lines Displaced Print Light Print Dark Print

**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 approx. 1 Lac to 2.5 Lacs capsules. Then defective capsules are inspected on inspection machine and are categorized into critical ,major and minor defects. The acceptance level of defects is as under :-

Critical - Not more than 0.05 %

Major - Not more than 1.00 %

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 this limit.

MOISTURE CONTENT

The Moisture content is maintained 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 loose 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 1996Appendix 7.1 or equivalent)

MICROBIAL LIMITS

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



ACCEPTANCE CRITERION

The sampled capsules are inspected for defects spreading them on a vibrator sorting machine. Inspection should be with naked eyes and inspection time should range between 2 to 3 minutes for 1000 capsules.



EVALUATION CRITERIA OF DIMENTIONS

For measuring 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 45 % to 60 % are recommended.

WEIGHT

A dipping process determines the weight of the capsules. The weight of individual capsules varies around a target value. The table given below shows the desired target weight in milligrams for capsules of each size on an average of 100 capsules :

EMPTY CAPSULE WEIGHT

EMPTY CAPSULE WEIGHT

SIZE	LOT AVERAGE Weight mg./capsule	TOLERANCE
00	118	±10 %
0 EL	110	±10 %
0	96	±10 %
1 EL	81	±10 %
1	76	±10 %
2	63	±10 %
3	50	±10 %
4	40	±10 %

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 :-

LENGTH

Target			
SIZE	CAP	BODY	TOLERANCE
00	11.8	20.3	± 0.5
0 EL	11.99	20.98	± 0.5
0	11.18	18.72	± 0.5
1 EL	10.49	17.7	± 0.5
1	10.01	16.72	± 0.5
2	9.17	15.34	± 0.5
3	8.23	13.48	± 0.5
4	7.47	12.34	± 0.5

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, liquid etc. The quantity of material that can be filled into the capsule depends upon the nature of the material. The capacity available of capsule body is as mentioned below:

APPROXIMATE THEOROTICAL CAPACITY IN ml

SIZE	VOLUME (ml)
00	0.97
0 EL	0.78
0	0.67
1 EL	0.54
1	0.48
2	0.37
3	0.27
4	0.20

Note :

For filling of powder, the approximate filled 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

Target			
SIZE	CAP	BODY	TOLERANCE
00	8.41	8.07	± 0.06
0 el	7.63	7.32	± 0.06
0	7.63	7.32	± 0.06
1 el	6.91	6.62	± 0.06
1	6.91	6.62	± 0.06
1 el	6.91	6.62	± 0.06
2	6.34	6.07	± 0.06
3	5.81	5.56	± 0.06
4	5.31	5.06	± 0.06

Note:

The outside diameter measurement are to be taken with the help of special go, no-go 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:

DOUBLE WALL THICKNESS

Target			
SIZE	CAP	BODY	TOLERANCE
00	0.208	0.197	± 0.018
0 el	.205	.195	± 0.018
0	0.205	0.195	± 0.018
1 el	0.2	0.163	± 0.018
1	0.2	0.163	± 0.018
2	0.198	0.191	± 0.018
3	0.196	0.188	± 0.018
4	0.194	0.182	± 0.018

PACKING

The wall thickness of capsules are fine tuned to meet specific requirement of the customer based on machines, formulation used, pin design and also on our past experience on the filling machines.

The capsules are packed in bubble bags.

The pack size for each size of capsules is as follows.

00	0.75 lac
0el	1.0 lac
0	1.0 lac
1el	1.25 lacs
1	1.25 lacs
2	1.50 lacs
3	2.50 lacs
4	3.00 lacs

These bags are placed and packed in five or seven ply corrugated boxes with thermocol sheets covering on 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 .

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 45% and 55% relative humidity. Protect capsules from 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 contribute to efficient filling of the 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 capsules 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 relative humidity between 45% to 55%. Any deviation in these conditions or exposure of capsules to any direct source of heat or light may cause lump formation. The sudden transfer of capsules from high temperature to low temperature zone will also cause lump formation.

BRITTLINESS

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 capsules from the packed box, make sure that capsules are not taken out directly by hands. Scoop should be used. After taking out a part of the capsules, box should be repacked properly.

NON-SEPARATION

Check vacuum pressure and clean filter bag regularly on the filling machine.

DENTS

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

RECTIFICATION

Set finger of the filling machine properly.

TELESCOPING

Non alignment of cap and body joiner block.