Phone No : 2783400, 2783401 2783392
Fax No : 2783311
E-Mail : ipclab@vsnl.net
Website : www.ipc.gov.in

INDIAN PHARMACOPOEIA COMMISSION
MIN. OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA
SECTOR -23, RAJ NAGAR, GHAZIABAD - 201002

No. IPC/7021/IP-2014/AL-004 **Dated:** 28-11-2016

To,

1. **DCG (I)/ CDSCO, Zonal Offices**
2. **All State Drug Controllers**
3. **Members of Scientific Body of the IPC**
4. **Members of Sub-committee of Scientific Body of the IPC**
5. **Government Analysts**
6. **Director of Drug Laboratories**
7. **IDMA/OPPI/BDMA/FSSAI/Small Scale Industry Associations**

AMENDMENT LIST – 004 for IP 2014

As you are aware that the 7th edition of Indian Pharmacopoeia has become official from 1st April, 2014. Based on scientific inputs, Hard Cellulose Capsule Shell monograph is incorporated as Amendment list – 004 and is issued for notice and immediate compliance.

Yours faithfully,

(Dr. G. N. Singh)
Secretary-cum-Scientific Director

Encl:
Amendment List – 004 for IP 2014

CC to: Publication Division to put up on IPC website.

Hard Cellulose Capsule Shells

Hard Cellulose Capsule Shells are soluble containers for incorporation of drugs and/or medicaments, usually in the form of powders, pellets or granules, semisolids or liquids, and are commonly intended for oral administration. The shells are acted upon by digestive fluids and the filled contents are released. The shells are composed of Hydroxypropylmethylcellulose or any other cellulose derivatives and water.

The capsule shell may contain gelling agents, gelling aids and other additives such as plasticizers, humectants, surfactants, dispersing agents, gliding agents, lubricating agents, flavouring agents, antimicrobial agents, sweetening agents, opacifying agents and one or more colouring agents permitted under the Drugs and Cosmetics Rules,1945.

Category: Pharmaceutical aid.

Description: Hard Cellulose Capsule Shells consist of two cylindrical, telescoping pieces (cap and body), one end of which is rounded and closed, and the other end is open. Shapes other than cylindrical can also be formed as per the requirements. The two pieces are coloured or uncoloured, of identical or different colours, transparent, translucent or opaque, and printed or unprinted or bear other surface markings. The cap overlaps the body and maintains a tight friction closure. The closure may be strengthened by suitable means.

The shells are of various sizes, usually designated by different numbers, 5 being the smallest and 000 the biggest. Shells of special lengths, shapes and designations are also available. The shells are smooth and uniform in size, shape and colour. Guidelines on dimensions in respect of different sizes of commonly used capsules are given in the table (5.8.2).

Identification

A. Add capsules, quantity equivalent to 1.0 g under constant stirring, into 50 ml of *carbon dioxide-free water* previously heated to 90°. Allow to cool, dilute to 100 ml with *carbon dioxide-free water* and continue stirring until solution is complete (solution A). If the capsules are not transparent, centrifuge the solution A & consider only supernatant liquid as solution A for further tests. Heat 10 ml of solution A in a water-bath with stirring. At temperatures above 50°, the solution becomes cloudy or a flocculent precipitate is formed. On cooling, the solution becomes clear or slightly opalescent.

B. To 10 ml of solution A add 10 ml of *1 M sodium hydroxide* or *1 M hydrochloric acid*; in either case the mixture remains stable.

C. To 10 ml of solution A add 0.3 ml of *2 M acetic acid* and 2.5 ml of a 10 per cent w/v solution of *tannic acid*; a yellowish white, flocculent precipitate is produced which dissolves in *6 M ammonia*.

D. Place 1 ml of solution A on a glass plate. After evaporation of the *water* a thin film is produced.

E. Without heating add 20 ml of solution A in 15 ml of a 70 per cent w/w solution of *sulphuric acid*, pour the solution with stirring into 80 ml of iced *water*. In a test-tube kept in ice, mix thoroughly 1 ml of the solution with 8 ml of *sulphuric acid*, added drop wise. Heat in a water-bath for exactly 3 minutes and cool immediately in ice. When the mixture is cool, carefully add 0.6 ml of a solution containing 3 g of *ninhydrin* in 100 ml of a 4.55 per cent w/v solution of *sodium metabisulphite*, mix well and allow to stand at 25°; a pink colour is produced immediately which becomes violet within 100 minutes.

F. Boil one capsule shell with 20 ml of *water*, allow to cool and centrifuge. To 5 ml of the supernatant liquid add 1 ml of *picric acid solution*; no precipitate is produced. Distinction from gelatin.

Tests

Odour. Keep 100 capsule shells in a well-closed bottle for 24 hours at a temperature between 30° and 40°; the shells do not develop any foreign odour.

NOTE — In order to ensure that the quality of the shells is not affected by temperature and humidity, the capsule shells should be conditioned at a temperature of 25° ± 2° and a relative humidity of 50 ± 5 per cent for not less than 12 hours before conducting the test for Average weight.

Average weight. Weigh 100 capsule shells and determine the average weight of a capsule. The average weight is within ± 10 per cent of the target weight shown in Table 1(Target weight for shells of special lengths, shapes and designations may be decided upon mutually between the manufacturer of the Hard cellulose Capsule Shells and the user).

Table 1-Average Weight of Hard Cellulose Capsule Shells

Size	Target average weight (mg)
000	163
00	123
0	98
1	78
2	64
3	50
4	40
5	28

Disintegration (2.5.1).Not more than 15 minutes, using discs.

Microbial contamination (2.2.9). Total microbial count not more than 1000 cfu per g, total yeast and mould count not more than 100 cfu per g, 1g is free from *Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa* and 10g is free from *Salmonella* and *Shigella.*

Heavy metals (2.3.13). 2.0 g complies with the limit test for heavy metals, Method B (10 ppm) or determined by ICPMS (2.4.42)

Arsenic (2.3.10). Dissolve 3.3 g of capsule shells in 20 ml of *carbon dioxide free water* and dilute to 50.0 ml with *carbon dioxide free water.* The resulting solution complies with the limit test for arsenic (3 ppm) or determined by ICPMS (2.4.42).

Loss on drying (2.4.19). 3.0 to 9.0 per cent, determined on 1g by drying in an oven at 105° for 4 hours or to constant weight.

Storage. Store protected from moisture at a temperature not exceeding 30°

Labelling The label states (1) the size of the capsule shells; (2) that only permitted colours, if any, have been used; (3) the storage conditions.