Phytomenadione Tablets

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Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls the quality of the product(s) they manufacture. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to lab.ipc@gov.in, with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.

Document History and Schedule for the Adoption Process

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Further follow-up action as required.	

Phytomenadione Tablets

Phytonadione Tablets

Phytomenadione Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of phytomenadione, $C_{31}H_{46}O_2$.

Usual strength. 10 mg.

Identification

In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

Tests

Disintegration (2.5.1). Not more than 30 minutes.

Uniformity of dosage units (2.5.4). Complies with the test stated under Uniformity of dosage units (2.5.4).

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14).

NOTE —Protect the solutions from light.

Test solution. Weigh and powder 20 tablets. Disperse a quantity of powder containing 40 mg of Phytomenadione in *ethanol*, with the aid of ultrasound and dilute to 100.0 ml with *ethanol*. Dilute 5.0 ml of the solution to 20.0 ml with *ethanol*, filter.

Reference solution. A 0.01 per cent w/v solution of *phytomenadione IPRS* in *ethanol*.

Chromatographic system
- a stainless steel column 30 cm × 3.9 mm, packed with octadecylsilane bonded to porous silica (10 µm) (Such as MicroBondapak C18),
- mobile phase: a mixture of 95 volumes of *ethanol* and 5 volumes of *water*,
- flow rate: 1.5 ml per minute,
- spectrophotometer set at 254 nm,
- injection volume: 10 µl.

[Note- The peaks of Z-isomer and E-isomer coelute.]

Inject the reference solution. The test is not valid unless the column efficiency is not less than 915 theoretical plates, the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{31}H_{46}O_2$ in the tablets.

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