Melatonin 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. 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 arnd-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.	

Melatonin Tablets

Melatonin Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of melatonin, $C_{13}H_{16}N_2O_2$.

Usual strength. 3 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 reference solution (a).

Tests

Dissolution (2.5.2).
Apparatus No. 2 (Paddle),
Medium. 500 ml of *water*,
Speed and time. 50 rpm and 30 minutes.
Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography (2.4.14).

Test solution. Use the filtrate, dilute if necessary, with the dissolution medium.

Reference solution. Dissolve a weighed quantity of *melatonin IPRS* in the dissolution medium and dilute with the dissolution medium to obtain a solution having a known concentration similar to the expected concentration of the test solution.

Chromatographic system
- a stainless steel column 15 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (such as Kromasil 100 C18),
- mobile phase: a mixture of 25 volumes of *acetonitrile* and 75 volumes of a buffer prepared by dissolving 0.5 g of *potassium dihydrogen orthophosphate* in 1000 ml of *water*, adjusted to pH 3.5 with *orthophosphoric acid*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 222 nm,
- injection volume: 10 µl.

Inject the reference solution and the test solution.

Calculate the content of $C_{13}H_{16}N_2O_2$ in the medium.

Q. Not less than 75 per cent of the stated amount of $C_{13}H_{16}N_2O_2$.

Related Substances. Determine by liquid chromatography (2.4.14).

Solvent mixture. 25 volumes of mobile phase A and 75 volumes of mobile phase B.

Test solution. Disperse a quantity of powdered tablets containing 25mg of Melatonin in the solvent mixture and dilute to 25.0 ml with the solvent mixture, filter.

Reference solution (a). A 0.0005 per cent w/v solution of *melatonin IPRS* in the solvent mixture.

Reference solution (b). A solution containing 0.01 per cent w/v of *melatonin IPRS* and 0.002 per cent w/v of *melatonin related compound A IPRS* in the solvent mixture.

Chromatographic system
- a stainless steel column 15 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (such as Kromasil 100 C18),
- mobile phase: A. *acetonitrile*,
  B. a buffer solution prepared by dissolving 0.5 g of *potassium dihydrogen orthophosphate* in 1000 ml of *water*, adjusted to pH 3.5 with *orthophosphoric acid*,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 222 nm,
- injection volume: 10 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile Phase B (per cent v/v)
0	25	75
7	25	75
15	80	20
18	25	75
25	25	75

Name	Relative retention time
Melatonin related compound A[1]	0.4
Melatonin	1.0

[1]2-(5-methoxy-1*H*-indol-3-yl)ethanamine.

Inject reference solution (b). The test is not valid unless the resolution between the peaks due to melatonin related compound A and melatonin is not less than 4.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent for the melatonin peak.
Inject reference solution (a) and the test solution. In the chromatogram obtained with the test solution, the area of any secondary peak is not more than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.1 per cent) and the sum of the areas of all the secondary peaks is not more than twice the area of the principal peak in the chromatogram obtained with reference solution (a) (1.0 per cent).

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

Other tests. Complies with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14), use the chromatographic system as described under Dissolution.

Test solution. Weigh and powder 20 tablets. Disperse a quantity of powdered tablets containing 25.0 mg of Melatonin in the mobile phase and dilute to 25.0 ml with the mobile phase. Dilute 5.0 ml of the solution to 50.0 ml with the mobile phase, filter.

Reference solution (a). A 0.01 per cent w/v solution of *melatonin IPRS* in the mobile phase.

Reference solution (b). A solution containing 0.01 per cent w/v of *melatonin IPRS* and 0.002 per cent w/v of *melatonin related compound A IPRS* in the mobile phase.

The relative retention time with reference to melatonin for melatonin related compound A is about 0.4.

Inject reference solution (a) and (b). The test is not valid unless the resolution between the peaks due to melatonin related compound A and melatonin is not less than 4.0 in the chromatogram obtained with reference solution (b) and the relative standard deviation of replicate injections is not more than 2.0 per cent in the chromatogram obtained with reference solution (a).

Inject reference solution (a) and the test solution.

Calculate the content of $C_{13}H_{16}N_2O_2$ in the tablets.

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