Flunixin Meglumine Injection

Published on: 05 January, 2023 **Last date for comments:** 06 March, 2023

This draft proposal contains monograph text for inclusion in the Indian Pharmacopoeia (IP). The content of this draft document is not final, and the text may be subject to revisions before publication in the IP. This draft does not necessarily represent the decisions or the stated policy of the IP or Indian Pharmacopoeia Commission (IPC).

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

Description	Details
Document version	1.0
Monograph proposed for inclusion	IP Addendum 2024
Tentative effective date of monograph	April, 2024
First draft published on IPC website for public comments	05 January, 2023
Draft revision published on IPC website for public comments	-
Further follow-up action as required.	

Flunixin Meglumine Injection

Flunixin Meglumine Injection is a sterile solution of Flunixin Meglumine in Water for Injections.

Flunixin Meglumine Injection contains not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of flunixin, $C_{14}H_{11}F_3N_2O_2$. It may contain phenol or another suitable preservative.

Usual strengths. 50 mg per ml

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 (a).

Tests

pH (2.4.24). 7.8 to 9.0.

Related substances. Determine by liquid chromatography (2.4.14).

Solvent mixture. 70 volumes of *methanol* and 30 volumes of *water*.

Test solution. Pool the contents of 5 vials and prepare a composite sample. Dilute an amount of pooled sample containing 500 mg of flunixin to 250.0 ml with the solvent mixture. Dilute 5.0 ml of the solution to 50.0 ml with the solvent mixture, filter.

Reference solution (a). A 0.033 per cent w/v solution of *flunixin meglumine IPRS* in the solvent mixture.

Reference solution (b). Dilute 1.0 ml of reference solution (a) to 100.0 ml with the solvent mixture.

Reference solution (c). A solution containing 0.033 per cent w/v of *flunixin meglumine IPRS* and 0.002 per cent w/v of *phenol* in the solvent mixture.

Reference solution (d). A 0.00167 per cent w/v solution of *flunixin meglumine IPRS* in solvent mixture. Dilute 1.0 ml of the solution to 100.0 ml with the solvent mixture.

Chromatographic system
- a stainless steel column 15 cm x 4.6 mm packed with octadecylsilane bonded to porous silica (5µm), (Such as Inertsil ODS-3),
- mobile phase: a mixture of 70 volumes of *methanol*, 30 volumes of *water* and 1 volume of *acetic acid*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 275 nm,
- injection volume: 20 µl.

The relative retention time with reference to flunixin, for phenol is about 0.25.

Inject reference solution (c) and (d). The test is not valid unless the resolution between the peaks due to phenol and flunixin meglumine is not less than 17 in the chromatogram obtained with reference solution (c), the tailing factor is not more than 2.0, the relative standard deviation for replicate injections is not more than 10.0 per cent and the signal to noise ratio is not less than 10 in the chromatogram obtained with reference solution (d).

Inject reference solution (b), (d) and the test solution. In the chromatogram obtained with the test solution, the area of any secondary peak is not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (1.0 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 (b) (2.0 per cent). Ignore any peak due to phenol (if present) at relative retention time of about 0.25 with reference to the principal peak and any peak with an area less than the area of the principal peak in the chromatogram obtained with the reference solution (d) (0.05 per cent).

Sterility (2.2.11). Complies with the test for sterility.

Bacterial endotoxins (2.2.3). Not more than 4.54 Endotoxin Unit per mg of flunixin.

Other tests. Comply with the tests stated under Parenteral Preparations (Injections).

Assay. Determine by liquid chromatography (2.4.14) as described under Related substances with the following modifications.

Inject reference solution (c). The test is not valid unless the resolution between the peaks due to phenol and flunixin meglumine is not less than 17, 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 reference solution (a) and the test solution.

Calculate the content of flunixin, $C_{14}H_{11}F_3N_2O_2$ in the injection.

1 mg of the flunixin meglumine, $C_{21}H_{28}F_3N_3O_7$ is equivalent to 0.603 mg of flunixin, $C_{14}H_{11}F_3N_2O_2$.

Storage. Store in multiple-dose containers, at a temperature not exceeding 30°

Labelling. The label states the quantity of flunixin meglumine in the terms of the equivalent amount of flunixin. Label injection to indicate that it is for veterinary use only.