Draft Proposal for Comments and Inclusion in The Indian Pharmacopoeia

Mesalazine Gastro-resistant Tablets

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This draft proposal contains general chapter 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. 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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Mesalazine Gastro-resistant Tablets

Mesalamine Gastro-resistant Tablets

Mesalazine Gastro-resistant Tablets contain not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of mesalazine, $C_7H_7NO_3$.

Usual strengths. 250 mg; 400 mg.

Identification

A. Disperse a quantity of powdered tablets containing 25 mg of Mesalazine in 15 ml of *0.01 M hydrochloric acid*, with the aid of ultrasound for 50 minutes, with additional vortex mixing at 10 minutes intervals and dilute to 25.0 ml with *0.01 M hydrochloric*, filter. Dilute 1.0 ml of the filtrate to 50.0 ml with *0.01 M hydrochloric acid*. When examined in the range 190 nm to 400 nm (2.4.7), the resulting solution shows absorption maxima at 302 nm and 232 nm and minima at 258 nm and 219 nm.

B. 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 (b).

Tests

Mesalazine impurities A and C. Determine by liquid chromatography (2.4.14).

NOTE — Use freshly prepared solutions.

Test solution. Disperse a quantity of the powdered tablets containing 50 mg of Mesalazine in mobile phase A, with the aid of ultrasound for 10 minutes and dilute to 50.0 ml with mobile phase A with additional vortex mixing for 10 minutes, filter.

Reference solution (a). Mix 1.0 ml of a 0.002 per cent w/v solution of *4-aminophenol IPRS* (mesalazine impurity A) in mobile phase A with 1.0 ml of 0.002 per cent w/v of *mesalazine impurity C IPRS* (2-aminophenol) in mobile phase A and dilute to 100.0 ml with mobile phase A.

Reference solution (b). Dilute 1.0 ml of the test solution to 200.0 ml with mobile phase A. Mix 1.0 ml of this solution with 1.0 ml of 0.0005 per cent w/v solution of *mesalazine impurity C IPRS* in mobile phase A.

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with end-capped octadecylsilane bonded to porous silica (3 µm) (such as Nucleosil C18),
- mobile phase: A. a 0.22 per cent w/v of *perchloric acid* and 0.1 per cent w/v of *orthophosphoric acid* in *water*,
  B. a 0.17 per cent w/v of *perchloric acid* and 0.1 per cent w/v of *orthophosphoric acid* in *acetonitrile*,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 220 nm,
- injection volume: 20 µl.

Time (in min)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	100	0
8	100	0
25	40	60
30	100	0
40	100	0

Name	Relative retention time
Mesalazine impurity A	0.5
Mesalazine impurity C	0.9
Mesalazine (Retention time: about 9 minutes)	1.0

Inject reference solution (b). The test is not valid unless the resolution between the peaks due to the mesalazine impurity C and mesalazine is not less than 3.0.

Inject reference solution (a) and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to mesalazine impurity A and mesalazine impurity C, each of, is not more than the area of corresponding peak in the chromatogram obtained with reference solution (a) (200 ppm).

Mesalazine impurity K. Determine by liquid chromatography (2.4.14).

Test solution. Transfer a quantity of the powdered tablets containing 50 mg of Mesalazine to a 25-ml volumetric flask, add 2 ml of *0.01 M sodium hydroxide*, 5 drops of *1 M sodium hydroxide* and 15 ml of mobile phase, mix for 20 minutes, with the aid of ultrasound and dilute to volume with mobile phase, filter.

Reference solution. A 0.00000278 per cent w/v solution of *aniline hydrochloride* in the mobile phase.

Chromatographic system
- a stainless steel column 25 cm x 4 mm, packed with end-capped octadecylsilane bonded to porous silica (5 µm) (such as LiChrospher RP 18e),
- column temperature: 40°,
- mobile phase: a mixture of 85 volumes of a solution containing 0.141 per cent w/v of *potassium dihydrogen orthophosphate* and 0.047 per cent w/v of *disodium hydrogen orthophosphate dihydrate*, adjusted to pH 8.0 with *1 M sodium hydroxide* and 15 volumes of *methanol*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 205 nm,
- injection volume: 50 µl.

The retention time of mesalazine impurity K is about 15 minutes.

Inject the reference solution and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to mesalazine impurity K is not more than the area of the principal peak in the chromatogram obtained with the reference solution (10 ppm).

Related substances. Determine by liquid chromatography (2.4.14).

NOTE — Prepare the solutions immediately before use.

Test solution. Disperse a quantity of the powdered tablets containing 50 mg of Mesalazine in 30 ml of *0.01 M hydrochloric acid* with the aid of ultrasound for 10 minutes and dilute to 50.0 ml with *0.01 M hydrochloric acid*, mix using a vortex mixer, filter.

Reference solution (a). A 0.0001 per cent w/v solution of *mesalazine IPRS* in *0.01 M hydrochloric acid*.

Reference solution (b). A solution containing 0.1 per cent w/v of *mesalazine IPRS* and 0.00015 per cent w/v, each of, *mesalazine impurity J IPRS*, *mesalazine impurity F IPRS* and *mesalazine impurity P IPRS* in *0.01 M hydrochloric acid.*

Reference solution (c). A solution containing 0.0003 per cent w/v of *mesalazine impurity H IPRS* and 0.0001 per cent w/v, each of, *mesalazine impurity E IPRS*, *mesalazine impurity G IPRS*, *mesalazine impurity L IPRS*, *mesalazine impurity M IPRS*, *mesalazine impurity N IPRS*, *mesalazine impurity O IPRS* and *mesalazine impurity R IPRS* in *0.01 M hydrochloric acid.*

Chromatographic system
- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to amorphous organosilica polymer (5 µm) (such as XTerra MS C18),
- column temperature: 40°,
- mobile phase: A. a 0.69 per cent w/v solution of *sodium dihydrogen orthophosphate monohydrate*, adjusted to pH 6.2 with *dilute sodium hydroxide*,
  B. a mixture of 40 volumes of *acetonitrile* and 60 volumes of mobile phase A,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 240 nm,
- injection volume: 20 µl.

Time (in min)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	100	0
8	100	0

20	85	15
40	25	75
60	0	100
61	100	0
70	100	0

Name	Relative retention time	Correction factor
Mesalazine impurity O[1]	0.55	0.6
Mesalazine impurity J[2]	0.6	2.0
Mesalazine impurity E[3]	0.8	1.3
Mesalazine	1.0	---
Mesalazine impurity F[4]	1.36	---
Mesalazine impurity G[5]	1.4	1.4
Mesalazine impurity P[6]	1.5	0.6
Mesalazine impurity L[7]	2.0	4.5
Mesalazine impurity M[8]	3.3	1.7
Mesalazine impurity H[9]	3.5	1.4
Mesalazine impurity R[10]	5.1	1.3
Mesalazine impurity N[11]	5.5	---

[1] sulfanilic acid,
[2] 3,5-diaminosalicylic acid,
[3] 4-aminosalicylic acid,
[4] 3-aminosalicylic acid,
[5] 2,5-dihydroxybenzoic acid,
[6] 5-amino-2-hydroxy-3-(4-sulphophenyl) benzoic acid,
[7] 2-chlorobenzoic acid,
[8] 2-chloro-5-nitrobenzoic acid,
[9] salicylic acid,
[10] 3-nitrosalicylic acid,
[11] 5-nitrosalicylic acid.

Inject reference solution (b) and (c) to identify the peaks due to mesalazine impurities J, F, P, and mesalazine impurities E, G, H, L, M, N, O and R, respectively.

Inject reference solution (b). The test is not valid unless the peak-to-valley ratio is not less than 3.0, where H_p is the height above the baseline of the peak due to mesalazine impurity F and H_v is the height above the baseline of the lowest point of the curve separating this peak from the peak due to mesalazine.

Inject reference solution (a) and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to mesalazine impurity H is not more than 3 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.3 per cent), the area of any peak corresponding to mesalazine impurity E, mesalazine impurity F, mesalazine impurity G, mesalazine impurity J, mesalazine impurity L, mesalazine impurity M, mesalazine impurity P and mesalazine impurity R, each of, is not more than 1.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.15 per cent), the area of any other secondary peak is not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (0.1 per cent) and the sum of areas of all the secondary peaks is not more than 5 times the area of principal peak in the chromatogram obtained with reference solution (a) (0.5 per cent). Ignore any peak with an area less than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.05 per cent).

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

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Weigh and powder 20 tablets. Disperse a quantity of the powder containing 25 mg of Mesalazine in 15 ml of *0.1 M hydrochloric acid* with the aid of ultrasound for 50 minutes with additional vortex mixing at 10 minutes intervals and dilute to 25.0 ml with *0.1 M hydrochloric acid*, filter. Dilute 1.0 ml of the filtrate to 50.0 ml with *0.1 M hydrochloric acid.*

Reference solution (a). A 0.1 per cent w/v solution of *mesalazine IPRS* in *0.1 M hydrochloric acid*.

Reference solution (b). Dilute 1.0 ml of reference solution (a) to 50.0 ml with *0.1 M hydrochloric acid.*

Reference solution (c). A 0.01 per cent w/v solution of *mesalazine impurity F IPRS* in *0.1 M hydrochloric acid.* Dilute 1.0 ml of the solution to 100.0 ml with reference solution (a).

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with end-capped octadecylsilane bonded to amorphous organosilica polymer (5 µm),
- column temperature: 40°,
- mobile phase: a 0.69 per cent w/v solution of *sodium dihydrogen orthophosphate monohydrate,* adjusted to pH 6.2 with *dilute sodium hydroxide solution*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 240 nm,
- injection volume: 20 µl.

Inject reference solution (c). The test is not valid unless the peak-to-valley ratio is not less than 3.0, where H_p is the height above the baseline of the peak due to mesalazine impurity F and H_v is the height above the baseline of the lowest point of the curve separating this peak from the peak due to mesalazine.

Inject reference solution (b) and the test solution.

Calculate the content of $C_7H_7NO_3$ in the tablets.

Storage. Store at a temperature not exceeding 30°.