Quality standards

Edition: BP 2025 (Ph. Eur. 11.6 update)

Piperazine Citrate Tablets

General Notices

Action and use

Antihelminthic.

DEFINITION

Piperazine Citrate Tablets contain Piperazine Citrate.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of anhydrous piperazine citrate, (C₄H₁₀N₂)₃,2C₆H₈O₇

81.6 to 96.8% of the stated amount of Piperazine Citrate.

IDENTIFICATION

Extract a quantity of the powdered tablets containing 1 g of Piperazine Citrate with 20 mL of <u>water</u> and filter. The filtrate complies with the following tests.

- A. Dilute 1 mL to 5 mL with <u>water</u>, add 0.5 g of <u>sodium hydrogen carbonate</u>, 0.5 mL of <u>potassium hexacyanoferrate(III)</u>. <u>solution</u> and 0.1 mL of <u>mercury</u>, shake vigorously for 1 minute and allow to stand for 20 minutes; a reddish colour slowly develops.
- B. Mix 4 mL with 1 mL of <u>hydrochloric acid</u>, add 0.5 g of <u>sodium nitrite</u>, heat to boiling, cool in ice for 15 minutes, scratching the side of the container with a glass rod to induce crystallisation and filter. The <u>melting point</u> of the crystals, after washing with 10 mL of iced <u>water</u> and drying at 100° to 105°, is about 159°, <u>Appendix V A, Method I</u>.
- C. Yield the reactions characteristic of citrates, Appendix VI.

ASSAY

Weigh and powder 20 tablets. Dissolve as completely as possible a quantity of the powder containing 0.2 g of Piperazine Citrate in 10 mL of <u>water</u>, filter and wash the filter with three 5 mL quantities of <u>water</u>. To the combined filtrate and washings add 3.5 mL of 0.5 M <u>sulfuric acid</u> and 100 mL of <u>picric acid solution R1</u>, heat on a water bath for 15 minutes, allow to stand for 1 hour, filter, wash the residue with <u>piperazine dipicrate solution</u> until the washings are free from sulfate and dry the residue to <u>constant weight</u> at 105° . Each g of residue is equivalent to 0.3935 g of $(C_4H_{10}N_2)_{3}, 2C_6H_8O_7$.

STORAGE

Piperazine Citrate Tablets should be protected from light.

