



British Pharmacopoeia

British Pharmacopoeia Commission Secretariat
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TO WHOM IT MAY CONCERN

RANITIDINE ORAL SOLUTION BP 2018

RELATED SUBSTANCES

It has come to our attention that the solution preparation in the related substances test for Ranitidine Oral Solution in the BP 2018 contains an error.

The solution preparation will be amended as follows, the changed text has been highlighted:

- (1) Prepare a solid phase extraction cartridge containing a C18 sorbent (Sep-Pak C18 cartridges are suitable) by passing 10 mL of methanol followed by 20 mL of 0.5M ammonia through the cartridge; attach the tip of a suitable syringe to the cartridge. Transfer a weighed quantity of the oral solution containing the equivalent of 15 mg of ranitidine to the barrel of the syringe, add 2 mL of 0.5M ammonia to the syringe, insert the plunger and slowly force the mixture through the cartridge, discarding the eluant; repeat with two 4-mL quantities of 0.5M ammonia discarding the eluant. Pass two 5-mL quantities of a mixture of 25 volumes of 0.1M hydrochloric acid and 75 volumes of methanol through the cartridge and collect the eluant; add 40 mL of absolute ethanol to the collected eluant, evaporate the resulting solution to dryness at a temperature not exceeding 30° under reduced pressure and dissolve the residue in 2 mL of water.
- (2) Dilute 1 volume of solution (1) to 50 volumes with water.
- (3) Dilute 1 volume of solution (1) to 100 volumes with water.
- (4) Dilute 1 volume of solution (1) to 200 volumes with water.
- (5) Dilute 1 volume of solution (3) to 5 volumes with water.
- (6) Dissolve the contents of a vial of ranitidine impurity J EPCRS in 1 mL of solution (1) containing 0.15% w/v of ranitidine hydrochloride BPCRS.

Please accept this as a notice of intent to amend the monograph on behalf of the British Pharmacopoeia Commission. This letter is for information only and does not represent a legally-enforceable standard. The revised monograph will be published in a future edition of the British Pharmacopoeia - the current target publication is the BP 2020, which will come into force 1st January 2020.

If you have any questions concerning this letter, please do not hesitate to contact the British Pharmacopoeia Secretariat.

Yours faithfully,

MR JAMES POUND

Secretary & Scientific Director

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