## **KEY TO MONOGRAPHS**

Carbimazole EUROPEAN PHARMACOPOEIA 11.8 Version date of the text 01/2021:0884 Text reference number corrected 11.8 Modification to be taken into account as soon as possible and not later than the end of the month following the month of publication of Ph. Eur. 11.8 CARBIMAZOLE<sup>(1)</sup> Carbimazolum Link to further information on the text (e.g. Knowledge database) for smartphones/tablets with camera and barcode reader app Footnote mainly for harmonised texts C,H,,N,O,S CAS number [22232-54-8] M\_ 186.2 **DEFINITION** Ethyl 3-methyl-2-thioxo-2,3-dihydro-1H-imidazole-1-Chemical name in accordance carboxylate. with IUPAC nomenclature rules Content: 98.0 per cent to 102.0 per cent (dried substance). Black and white diamonds appear in harmonised texts only. **♦**CHARACTERS See chapter 5.8. Pharmacopoeial Appearance: white or yellowish-white, crystalline powder. harmonisation for more information Solubility: slightly soluble in water, soluble in acetone and in ethanol (96 per cent). IDENTIFICATION Application of the first and second First identification: B. identification is defined  $\Diamond$  Second identification: A, C. in the General Notices (chapter 1) A. Melting point (2.2.14): 122 °C to 125 °C. B. Infrared absorption spectrophotometry (2.2.24) Preparation: discs. Reference standard available Comparison: carbimazole CRS from the EDQM (see https://crs.edqm.eu) ♦ C. Thin-layer chromatography (2.2.2) Test solution. Dissolve 10 mg of the substance to be examined in methylene chloride R and dilute to 10 mI Reagent described in chapter 4 with the same solvent Reference solution. Dissolve 10 mg of carbimazole CRS in methylene chloride R and dilute to 10 mL with the same Further information on certain reagents Plate: TLC silica gel GF<sub>254</sub> plate R available in the Knowledge database Mobile phase: acetone R, methylene chloride R (20:80 V/V). (https://go.edqm.eu/knowledge) Application: 10 µL. Development: over 3/4 of the plate. Drying: in air for 30 min. Detection: examine in ultraviolet light at 254 nm. Results: the principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution. **TESTS Related substances**. Liquid chromatography (2.2.29) Reference to a general chapter Test solution. Dissolve 5.0 mg of the substance to be examined in 10.0 mL of a mixture of 20 volumes of Footnote is mainly included for acetonitrile R and 80 volumes of water R. Use this solution harmonised texts within 5 min of preparation.

(1) This monograph has undergone pharmacopoeial harmonisation. See chapter 5.8. Pharmacopoeial harmonisation.