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1 introduction after the revision of the note for guidance on the investigation on bioavailability and bioequivalence in 2002 it appears that some harmonisation in the interpretation of critical parts of the guideline is needed this is the aim of the current question answers document which focuses on demonstration of bioequivalence 2

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answer a clarification micronization is a process where the size of the solid drug particles is reduced to 1 10 microns by spray drying or by using air attrition methods drugs such as griseofulvin and several steroidal and sulfa drugs are there whose bioavailability is increased by micronization 5

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clarification chemical equivalence of drug products is said when the drugs contain the same active ingredient the amount of the active ingredient must be the same when two or more drug products contain the same active ingredient giving the same pharmacologic effect is known as therapeutic equivalence 3

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the term bioavailability refers to the a relationship between the physical and chemical properties of a drug and the systemic absorption of the drug b measurement of the rate and amount of therapeutically active drug that reaches the systemic

circulation c

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question 9 which of the following statements about iodine is correct a 50 of adults consume iodine at levels below the rni b dairy products are a poor source of iodine c the iodine content of organic milk is generally lower that the level in non organic milk d uk dietary reference values recommend an increase in iodine intake in

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a bioavailability describes the proportion of the drug administered that is metabolised very quickly and thus is not available to induce a physiological effect b bioavailability describes the ability of the administered drug metabolites to cause undesirable physiological effects

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