

2. Is it safe and suitable for the intended purpose?

This is an official preparation, therefore the formula is safe and suitable for purpose. The dose of 10 ml three times a day before food is consistent with the recommended dosage (*British National Formulary* 51st edn, p 499).

3. Calculation of formula for preparation

Prepare 150 ml of Alkaline Gentian Mixture BP.

Product formula

(from the *British Pharmacopoeia* 2004, p 2453)

	Master	100 ml	50 ml	150 ml
Concentrated Compound Gentian Infusion BP	100 ml	10 ml	5 ml	15 ml
Sodium Bicarbonate BP	50 g	5 g	2.5 g	7.5 g
Double Strength Chloroform Water BP	500 ml	50 ml	25 ml	75 ml
Potable water	to 1000 ml	to 100 ml	to 50 ml	to 150 ml

Interim formula for Double Strength Chloroform Water BP

Concentrated Chloroform Water BPC 1959	5 ml
Potable water	to 100 ml

4. Method of preparation**a. Solubility where applicable**

Sodium Bicarbonate BP is soluble 1 in 11 in water (*British Pharmacopoeia* 1988, p 509). Therefore to dissolve 7.5 g Sodium Bicarbonate BP, a minimum of $7.5 \times 11 = 82.5$ ml of water would be required. As this is greater than 50% of the mixture, a solution of Double Strength Chloroform Water BP and water would be used for dissolution.

b. Vehicle/diluent

Double Strength Chloroform Water BP and potable water would be used as the vehicle as per the product formula.

c. Preservative

Double Strength Chloroform Water BP is included in this product as the preservative as per the product formula.

d. Flavouring when appropriate

No extra flavouring is required. In addition to preservative action Double Strength Chloroform Water BP will give some flavouring and act as a sweetener, therefore helping to counteract the bitter taste of the Concentrated Compound Gentian Infusion BP.