Sulfamethoxazole-trimethoprim: paediatric extemporaneous unlicensed formulations

Technical recommendation of the European Drug Shortage Formulary Working Party

Foreword

About this document

In view of the recurring difficulties encountered by some member states with the supply of paediatric products containing sulfamethoxazole-trimethoprim (British Approved Name: co-trimoxazole), and in line with its terms of reference, the European Drug Shortage Formulary Working Party (EDSForm WP) has compiled a list of existing licensed medicines, recommendations and unlicensed pharmaceutical preparations that have been or are being prepared to alleviate the lack of age-appropriate licensed products.

The present technical recommendation is the result of this compilation exercise and should be understood and used as an overview of current practices. Its content has not been formally approved by the European Pharmacopoeia Commission or by the European Committee on Pharmaceuticals and Pharmaceutical Care and represents the opinion of the experts of the EDSForm WP alone.

Use of information enclosed in this document

The aim of this technical recommendation is to assist healthcare professionals in their risk-assessment and decision-making processes. The quality of the formulations listed in this document has not been verified by the EDSForm WP, and they should only be used after the performance of a proper risk assessment, which takes into account the level of evidence of the source.

The EDSForm WP used predefined criteria to assess the level of supporting evidence for the unlicensed pharmaceutical preparations that are described below. Three levels of evidence – high, medium and low – were assigned (see below), and formulations that did not satisfy the minimum criteria (e.g. potential safety considerations, absence of critical data) were not included in the technical recommendation.

- High-evidence formulation: the formulation described in the bibliographical source can be easily implemented (national regulatory requirements notwithstanding) and is supported by validated data from a reliable or standardised source.

- Medium-evidence formulation: the data supporting the formulation described in the bibliographical source contain several gaps, which should be included in the risk assessment carried out by the pharmacist or responsible person.

- Low-evidence formulation: the formulation described in the bibliographical source contains significant gaps in the data, contains non-validated data or has not been tested. These gaps should be included in the risk assessment carried out by the pharmacist or responsible person.

The data given in the tables and related appendices below are reproduced from the original sources in part only. Users are advised to refer to the source for more comprehensive information and are reminded to check that the data presented in this document or in other documents to which it refers comply with their own local/national requirements.

Although every care has been taken in compiling and checking the information contained in the tables and appendices below, neither the EDSForm WP nor the EDQM can be held responsible for any errors or inaccuracies they may contain.

Use of unlicensed pharmaceutical preparations

The EDSForm WP and the EDQM emphasise that the use of licensed medicines should always be preferred to unlicensed pharmaceutical preparations. However, as stated in the European Pharmacopoeia (Ph. Eur.) general monograph on *Pharmaceutical preparations (2619)*, "when deciding to use an unlicensed preparation all health professionals involved (e.g. the prescribing practitioners and/or the preparing pharmacists) have, within their area of responsibilities, a duty of care to the patient receiving the pharmaceutical preparation". The healthcare professionals concerned remain fully responsible for the assessment of the risks and benefits for each patient.

The terms "stock preparations" and "extemporaneous preparations" are used as defined in Ph. Eur. general monograph *2619*.

Contents

Information on licensed products

Licensed sulfamethoxazole-trimethoprim oral suspensions are indicated in children or in adults who are unable to swallow tablets. It has been reported that these products are in short supply in several of the member states in which they are authorised.

The products whose composition is given below are provided either as an example or because they are used as starting materials in the unlicensed preparations described later in this document. Some of these unlicensed pharmaceutical preparations may use licensed products as starting materials; examples of the composition of these licensed products are provided. Other compositions are possible, and the user should always verify that the composition of the licensed product they intend to use is appropriate.

Licensed medicines - Oral suspension			
Product [1]	**Strength**	**Excipients**	**Ref.**
BACTRIM® 40 mg/mL + 8 mg/mL, oral suspension	1 mL contains 40 mg sulfamethoxazole and 8 mg trimethoprim, 630 mg **sorbitol** (E420), 0.5 mg **methyl hydroxybenzoate** (E218), 0.1 mg **propyl hydroxybenzoate**, 4.8 mg **propylene glycol** (E1520) and 1.8 mg **ethanol**	Sorbitol (E420), microcrystalline cellulose, carmellose sodium, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), polysorbate 80, banana flavouring (contains propylene glycol (E1520)), vanilla flavouring (contains ethanol) and purified water	(3)
Licensed medicines – Tablets			
BACTRIM FORTE® 800 /160 mg, tablets	1 tablet contains 800 mg sulfamethoxazole and 160 mg trimethoprim and < 1 mmol of sodium	Povidone, sodium carboxymethyl starch (type A), magnesium stearate, sodium docusate	(4)
BACTRIM® 400 /80 mg, tablets	1 tablet contains 800 mg sulfamethoxazole and 160 mg trimethoprim	Povidone, sodium carboxymethyl starch (type A), magnesium stearate, sodium docusate	(5)
Sulfamethoxazol/Trimetoprim SAD, AMGROS, Denmark 400 /80 mg, tablets	1 tablet contains 200 mg sulfamethoxazole and 40 mg trimethoprim	Avicel® PH101 (granulation fluid), Avicel® PH102, crospovidone (type A), Kollidon® CL, magnesium stearate MF 2V, talc	(17)

[1] Several pharmaceutical forms and strengths of BACTRIM® are available in the following member states: Belgium, Estonia, France, Greece, Italy, Latvia, Luxembourg, Netherlands, Norway, Poland, Portugal and Sweden. In some countries, it is available under the brand names Co-Trimoxazole and Eusaprim (6).

Pharmaceutical preparations containing sulfamethoxazole-trimethoprim: general considerations

Regarding sulfamethoxazole-trimethoprim

Sulfamethoxazole-trimethoprim is a combination of two synthetic antibiotics in the proportion of 5:1 (7). Sulfamethoxazole and trimethoprim are practically insoluble and very slightly soluble in water, respectively, and have high bioavailability (BCS class II) (1). It is therefore expected that the handling of the pharmaceutical forms (crushing of tablets, etc.) during preparation of the formulation will have an impact on bioavailability.

Based on the literature and various recommendations, in the absence of a licensed powder for oral suspension and if the dose is easily obtained from a full- or half-tablet, it is possible to crush the tablet or half-tablet immediately before administration and to mix it with soft food or water (2). Each dose must be administered with or soon after eating to reduce the risk of stomach upset. Patients on long-term treatment should be advised to drink sufficient amounts of water to maintain adequate urination and prevent crystalluria (8).

If using a suspension, the bottle must be shaken well before measuring each dose.

As per the US Pharmacopeia (USP), the pH of compounded sulfamethoxazole-trimethoprim ranges from 5.0 to 6.5 (9).

Regarding the handling of sulfamethoxazole-trimethoprim

Safety precautions: when crushing the tablets or handling the active substance, healthcare professionals should take appropriate measures to **prevent exposure to the potentially harmful active substance** (e.g. using dedicated or disposable equipment, following appropriate cleaning procedures and protecting from dust by wetting with suspension vehicle and using careful trituration). An example Safety Data Sheet for trimethoprim can be found here.

The sulfamethoxazole-trimethoprim active substance should not be handled by people with a trimethoprim allergy (10)**.**

Existing unlicensed pharmaceutical preparations: overview

Formulations listed in national formularies or sanctioned by national pharmacopoeia authorities

Denomination	Pharmaceutical form	Strength	Starting material	Excipients/ Vehicle	Stability	Assigned shelf life	Comments	Level of evidence	Ref.
Source: Danish Health Authority									
Danish formulation – oral suspension #1	Oral suspension	1 mL contains 40 mg sulfamethoxazole and 8 mg trimethoprim	API	**Sorbitol** (E420), microcrystalline cellulose, carmellose sodium, Avicel® RC 591, saccharin sodium, **methyl parahydroxybenzoate** (E218), **propyl parahydroxybenzoate** (E216), star anise oil, **ethanol (96%), glycerol (85%), purified water**	**Physicochemical stability data available.** In-use or microbiological stability data not available	**2 years** 15-25 °C	Suitable for large batches See Appendix 1	High	(18)

Formulations listed in scientific literature

Denomination	Pharmaceutical form	Strength	Starting material	Excipients/ vehicle	Stability	Assigned shelf life	Comments	Level of evidence	Ref.
Source: Can J Hosp Pharm. 2021;74(4):327-33									
St Jean – oral suspension #1	Oral suspension	1 mL contains 40 mg sulfamethoxazole and 8 mg trimethoprim	API	Oral Mix Oral Mix SF	No in-use or microbiological stability data available	**90 days** 5-25 °C	See Appendix 2	Medium	(11)

Source: Advances in Natural and Applied Sciences 2010;4(3): 377-81									
Kumar – oral suspension #1	Oral suspension	1 mL contains 40 mg sulfamethoxazole and 8 mg trimethoprim	API	**Glycerin**, colloidal silicon dioxide, polysorbate 80, demineralised water	No in-use or microbiological stability data available	**2 years** 30 °C	See Appendix 3	Medium	(12)
Source: Compounding Today 2017; Int J Pharm Compd. 2014;18(5): 415									
IJPC – oral suspension #1	Oral suspension	1 mL contains 40 mg sulfamethoxazole and 8 mg trimethoprim	API	**Ethanol (95%), sodium benzoate, methyl parahydroxybenzoate** (E218), citric acid (anhydrous), sodium carboxymethylcellulose, flavouring agent, **glycerin**, microcrystalline cellulose, polysorbate 80, saccharin sodium (anhydrous), **sorbitol 70% solution**, purified water	No in-use or microbiological stability data available. Shelf life assigned as per USP<795>	**14 days** 2-8 °C	See Appendix 4	Low	(13, 14)

Formulations listed in other sources

Denomination	Pharmaceutical form	Strength	Starting material	Excipients/ vehicle	Stability	Assigned shelf life	Comments	Level of evidence	Ref.
Source: Lekarne Maribor formulary									
Lerkarne Maribor – oral suspension #1	Oral suspension	1 mL contains 40 mg sulfamethoxazole and 8 mg trimethoprim	Tablets	**Simple syrup**	Stability data not available	**14 days** 2-8°C In polyethylene terephthalate (PET) or amber glass bottle	See Appendix 5	Low	(15)

Source: Handbook of Pharmaceutical Manufacturing Formulations, Third Edition, Vol. 3; 2020									
Handbook of Formulations – oral suspension #1	Oral suspension	1 mL contains 40 mg sulfamethoxazole and 8 mg trimethoprim	API	Magnesium aluminium silicate, colloidal silicon dioxide (Aerosil 200), **propylene glycol**, carboxymethylcellulose sodium, **glycerin**, povidone K30, polysorbate 80, **sorbitol 70% solution**, saccharin sodium, citric acid, **sucrose**, **methyl parahydroxybenzoate (E218)**, **propyl parahydroxybenzoate (E216)**, raspberry red colour, banana flavouring, apricot flavouring and purified water	Stability data not available	Suitable for large batches	See Appendix 6	Low	(16)
Handbook of Formulations – oral suspension #2	Oral suspension	1 mL contains 40 mg sulfamethoxazole and 8 mg trimethoprim	API	Carrageenan (Hydrogel 843T), tragacanth, saccharin sodium dihydrate, anise oil, **methyl parahydroxybenzoate** (E218), **propyl parahydroxybenzoate** (E216), **alcohol dehydrated**, **sorbitol solution**, **glycerin**, purified water	Stability data not available	Suitable for large batches	See Appendix 7	Low	(16)
Handbook of Formulations – oral suspension #3	Oral suspension	1 mL contains 80 mg sulfamethoxazole and 16 mg trimethoprim	API	Kollidon® CL-M, **sucrose**, purified water, vanillin, chocolate flavouring	Stability data not available	Suitable for large batches	See Appendix 8	Low	(16)
Handbook of Formulations – oral suspension #4	Oral suspension	1 mL contains 80 mg sulfamethoxazole and 16 mg trimethoprim	API	**Sucrose**, Lutrol F127 or Lutrol F68, purified water, vanillin, chocolate flavouring	Stability data not available	Suitable for large batches	See Appendix 9	Low	(16)

Appendices

Appendix 1: Danish Formulation – oral suspension #1

Source: Data on analytical procedures and specifications for quality control and on stability was transmitted directly to the EDSForm WP; to obtain access, please submit a request via the EDQM HelpDesk.

1. Formulation

Composition	Quantity (g) or volume (mL) Per 1000 mL of preparation
Sulfamethoxazole	40 g
Trimethoprim	8 g
Microcrystalline cellulose and carmellose sodium AVICEL® RC 591	12 g
Saccharin sodium	500 mg
Methyl parahydroxybenzoate	625 mg
Propyl parahydroxybenzoate	540 mg
Star anis oil	125 mg
Ethanol (96%)	4.35 g
Sorbitol	408 g
Glycerol (85%)	95 g
Water, purified	q.s. 1173 g

1000 mL of the final preparation corresponds to 1173 g.

2. Other information

Bill of materials given for a 1 L batch. Preparation of the formulation requires a high shear mixer.

Appendix 2: St Jean *et. al* – oral suspension #1

Source: Saint-Jean I, Friciu MM, Monfort A, MacMahon J, Forest J-M, Walker S, Leclair G. Stability of Extemporaneously Compounded Suspensions of Trimethoprim and Sulfamethoxazole in Amber Plastic Bottles and Amber Plastic Syringes. Can J Hosp Pharm 2021 Fall;74(4):327-33.

Data from the original source only partially reproduced here. Users are advised to refer to the source for more comprehensive information.

1. Formulation

Composition	Quantity (g) or volume (mL) Per 100 mL of preparation
Sulfamethoxazole	4 g
Trimethoprim	800 mg
Oral Mix or Oral Mix SF	100 mL

2. Other information

It was not possible to prepare acceptable solutions from the commercial tablets due to the development of a persistent foam at the surface of all suspensions prepared from tablets, which could result in inconsistent dosing.

Appendix 3: Kumar *et al.* – oral suspension #1

Source: Kumar A, Arifuzzaman S, Al Arif H, Chakma P, Kahali S, Chowdhury MH, Tazul M, Rahmatullah, M. Replacement of Propylene Glycol with Water from Desloratadine Syrup and Co-trimoxazole Suspension and its Impact on Their Stability. Adv Nat Appl Sci. 2010;4(3):377-81.

Data from the original source only partially reproduced here. Users are advised to refer to the source for more comprehensive information.

1. Formulation

Composition	Quantity (g) or volume (mL) Per 100 g of preparation
Sulfamethoxazole	4 g
Trimethoprim	800 mg
Glycerin	3 g
Colloidal silicon dioxide	33 mg
Polysorbate 80	50 mg
Water, demineralised	q.s. 100 mL

Appendix 4: IJPC – oral suspension #1

Source: Compounding Today (2017), Formula 3193 and Allen LV Jr. Sulfamethoxazole and Trimethoprim Oral Solution. Int J Pharm Compd. 2014;18(5):415.

Data from the original source only partially reproduced here. Users are advised to refer to the source for more comprehensive information.

1. Formulation

Composition	Quantity (g) or volume (mL) Per 100 mL of preparation
Sulfamethoxazole	4 g
Trimethoprim	800 mg
Ethanol (95%)	0.26 mL
Methyl parahydroxybenzoate	100 mg
Sodium benzoate	100 mg
Carboxymethylcellulose sodium	500 mg
Citric acid (anhydrous)	500 mg
Flavouring	q.s.
Glycerin	10 mL
Microcrystalline cellulose	1 g
Polysorbate 80	2 g
Saccharin sodium	50 mg
Sorbitol 70% solution	60 mL
Water, purified	q.s. 100 mL

2. Other information

Confirm that the pH is 5.0-6.5.

Appendix 5: Lekarne Maribor - oral suspension #1

Source: Data shared with EDSForm WP directly.

1. Formulation

Composition	Quantity (g) or volume (mL) Per 100 mL of preparation
Sulfamethoxazole-trimethoprim 400/80 mg, tablets	Sulfamethoxazole-trimethoprim 400/80 mg, tablets 10 tablets
Simple syrup	100 mL

2. Other information

Grind the tablets to a powder and add a portion of the simple syrup to form a paste. While mixing, slowly add the remaining amount of simple syrup so that a uniformly smooth suspension is formed.

Additional warnings on the label: “Shake well before use!” and “Refrigerate!”.

Appendix 6: Handbook of Formulations - oral suspension #1

Source: Niazi SK. Handbook of Pharmaceutical Manufacturing Formulations, Third Edition, Vol. 3, Liquid Products. Boca Raton, USA: CRC Press; 2020.

Data from the original source only partially reproduced here. Users are advised to refer to the source for more comprehensive information.

1. Formulation

Composition	Quantity (g) or volume (mL) Per 1000 mL of preparation
Sulfamethoxazole	40 g
Trimethoprim	8 g
Magnesium aluminium silicate	4 g
Carboxymethylcellulose sodium	4.5 g
Glycerin	70 g
Propylene glycol	80 g
Povidone K30	1 g
Polysorbate 80	4 g
Colloidal silicon dioxide (Aerosil® 200)	2.5 g
Sorbitol 70% solution	75 g
Saccharin sodium	1 g
Citric acid	0.6 g
Sucrose	440 g
Methyl parahydroxybenzoate	1 g
Propyl parahydroxybenzoate	0.3 g
Raspberry red colour	7 mg
FD&C Red No. 40	5 mg
Banana flavouring	1 g
Apricot flavouring	1 g
Water, purified	q.s. 1 L

2. Other information

Bill of materials given for a 1 L batch. Preparation of the formulation requires a high shear mixer.

Confirm the pH is 5.5-5.8 at 25 °C.

Appendix 7: Handbook of Formulations - oral suspension #2

Source: Niazi SK. Handbook of Pharmaceutical Manufacturing Formulations, Third Edition, Vol. 3, Liquid Products. Boca Raton, USA: CRC Press; 2020.

Data from the original source only partially reproduced here. Users are advised to refer to the source for more comprehensive information.

1. Formulation

Composition	Quantity (g) or volume (mL) Per 1000 mL of preparation
Sulfamethoxazole	40 g
Trimethoprim	8 g
Carrageenan (Hydrogel 843T)	0.5 g
Tragacanth	3.75 g
Sorbitol 70% solution	582.80 g
Saccharin sodium dehydrate	0.5 g
Anise oil	0.125 g
Methyl parahydroxybenzoate	0.625 g
Propyl parahydroxybenzoate	0.54 g
Alcohol, dehydrated	0.435 g
Glycerin	80.75 g
Water, purified	q.s. 1 L

2. Other information

Bill of materials given for a 1 L batch. Preparation of the formulation requires an oven and a high shear mixer.

Appendix 8: Handbook of Formulations –oral suspension #3

This formulation is twice as concentrated as the other formulations listed in this document.

Source: Niazi SK. Handbook of Pharmaceutical Manufacturing Formulations, Third Edition, Vol. 3, Liquid Products. Boca Raton, USA:CRC Press; 2020.

Data from the original source only partially reproduced here. Users are advised to refer to the source for more comprehensive information.

1. Formulation

Composition	Quantity (g) or volume (mL) Per 1000 mL of preparation
Sulfamethoxazole	80 g
Trimethoprim	16 g
Kollidon® CL-M	30 g
Sucrose	100 g
Water purified	q.s. 1 L
Vanillin	2 g
Chocolate flavouring	2 g

2. Other information

Bill of materials given for a 1 L batch. Preparation of the formulation requires a high shear mixer.

Appendix 9: Handbook of Formulations - oral suspension #4

This formulation is twice as concentrated as the other formulations listed in this document.

Source: Niazi SK. Handbook of Pharmaceutical Manufacturing Formulations, Third Edition, Vol. 3, Liquid Products. Boca Raton, USA:CRC Press; 2020.

Data from the original source only partially reproduced here. Users are advised to refer to the source for more comprehensive information.

1. Formulation

Composition	Quantity (g) or volume (mL) Per 1000 mL of preparation
Sulfamethoxazole	80 g
Trimethoprim	16 g
Lutrol F127 or Lutrol F68	30 g
Sucrose	5 g
Water purified	q.s. 1 L
Vanillin	q.s.
Chocolate flavouring	q.s.

2. Other information

Bill of materials given for a 1 L batch. Preparation of the formulation requires a high shear mixer.

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18. Data on analytical procedures and specifications for quality control and on stability was transmitted directly to the EDSForm WP.