

 World Health Organization	REGULATION AND PREQUALIFICATION DEPARTMENT		
	VACCINE PREQUALIFICATION TEAM		
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)			
EuTYPH-C Inj. Multi-dose Typhoid Conjugate Vaccine EuBiologics Co. Ltd., Republic of Korea			
Ref. No.: PQ-FVP-2025-0014 -WHOPAR-0X			
Approved on: 19 Aug 2026	Published on: 16 Sep 2026	Last Update: n/a	Version: 1

What is EuTYH-C Inj Multi-dose (Typhoid Conjugate Vaccine)

EuTYPH-C Inj. Multi-dose is a colorless to pale yellow transparent solution containing *Salmonella typhi* Ty2 purified Vi polysaccharide conjugated to recombinant CRM197 protein, and it is indicated for active immunization against diseases caused by *Salmonella typhi* in children, adolescents, and adults aged 6 months to 45 years.

The vaccine consists of *Salmonella typhi* purified Vi polysaccharide conjugate bulk as drug substances produced from *Salmonella typhi* Serotype 2. The Polysaccharide is conjugated to CRM₁₉₇ which is used as a carrier protein.

The final formulation contains *Salmonella typhi* Ty2 conjugated with CRM197 and is preserved with 2- Phenoxyethanol.

EuTYPH-C Inj. Multi-dose is a solution for intramuscular injection in a multi-dose vial. The vaccine is a colorless to pale yellow transparent solution. Each 0.5 mL dose is supplied in a multi-dose vial containing five doses(2.5mL).

One vial(2.5mL) of EuTYPH-C Inj. Multi-dose contains:

Components	Quantity
Active ingredients: Salmonella typhi Ty2-derived Vi-CRM197 conjugate bulk	125 µg
Excipients: Sodium dihydrogen phosphate heptahydrate Disodium hydrogen phosphate monohydrate Sodium chloride Polysorbate 80 2- Phenoxyethanol WFI	4.95 mg 0.90 mg 21.95 mg 0.125 mg 25 mg q.s.

EuTYPH-C Inj. Multi-dose is filled in type I glass vials sealed with a chlorobutyl rubber stopper and secured by an aluminum and polypropylene flip-off cap.

The drug substances are manufactured at EuBiologics Co., Ltd. in the Republic of Korea. The site is responsible for manufacturing of the *Salmonella Typhi* master seed lot (MSL) and working seed lot (WSL). the CRM197 MSL and WSL, Vi polysaccharide bulk, recombinant CRM197 protein bulk, and the EuTYPH-C Inj. drug substance (Vi–CRM197 conjugate bulk), and also conducts all quality control, stability testing, and quality assurance.

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The drug product is manufactured at Korea Vaccine Co., Ltd, Republic of Korea. EuBiologics Co., Ltd. is responsible for the quality control (QC) testing and quality assurance (QA) activities for EuTYPH-C Inj. Multi-dose, while Korea Vaccine Co., Ltd. performs the final bulk formulation, aseptic filling, and secondary packaging operations.

What is EuTYPH-C Inj. Multi-dose used for?

EuTYPH-C Inj. Multi-dose is indicated for active immunization against diseases caused by *Salmonella typhi* in children, adolescents, and adults aged 6 months to 45 years.

How is EuTYPH-C Inj. Multi-dose used?

EuTYPH-C Inj. Multi-dose is administered as a single 0.5 mL intramuscular injection into the deltoid muscle. For children aged 6 months to under 2 years, the vaccine should be injected into the anterolateral aspect of the thigh. Care should be taken to avoid injection into the gluteal region or near nerves.

What is EuTYPH-C Inj. Multi-dose characteristics?

The vaccine should be stored at 2°C ~ 8°C. Do not freeze. The expiry date of the vaccine is 24 months from the date of manufacture.

Cold chain volume per dose is 2.09 cm³/ dose in the secondary carton box of multidose (5-dose/vial) presentation.

The vial of EuTYPH-C Inj. Multi-dose bears a Vaccine Vial Monitor (VVM) type 30 affixed to vial label.

Who is the regulatory authority responsible for its oversight vis a vis WHO?

EuTYPH-C Inj. Multi-dose is manufactured and licensed in the Republic of Korea by EuBiologics Co., Ltd. The National Institute of Food & Drug Safety Evaluation (NIFDS), Korea performs testing of EuTYPH-C Inj. Multi-dose batches and issues Analysis Reports. The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea is responsible for regulatory oversight of EuTYPH-C Inj. Multi-dose.

How has EuTYPH-C Inj. Multi-dose been studied from the clinical point of view?

Clinical data provided were from three clinical trials.

- Phase I open-label comparative study in healthy Filipino adults, assessing safety/tolerability and immunogenicity versus Typhar-TCV and Typhim Vi.
- Phase II/III observer-blinded, randomized, multicenter, non-inferiority and safety study in the 444 Philippines across ages 6 months–45 years, including batch-to-batch consistency trials.

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- Phase III observer-blind, randomized, controlled study in Kenya and Senegal across 3,219 subjects ages 6 months–45 years, assessing safety, non-inferiority (9–12 months), lot-to-lot consistency (multi-dose), and co-administration with MR and YF vaccines.

Efficacy of the vaccine is extrapolated from comparative immunogenicity data with a WHO prequalified TT conjugated typhoid fever vaccine. There are no prelicensure efficacy studies.

Immunogenicity of the vaccine was established in the phase II/III and phase III trials. ELISA is commonly used to measure the total anti-Vi IgG in serum, and the proportion of subjects exhibiting at least a 4-fold increase in anti-Vi IgG from baseline is used for comparative evaluation.

Lot-to-lot consistency of the multidose vial formulation was measured in the phase III trial by anti-Vi IgG GMTs on Day 28. Lot-to-lot consistency was demonstrated.

No serious AEs were reported in the phase I trial. Phase II/III trial reported one pneumonia requiring hospitalisation. The phase III trial reported 16 SAEs in 14 subjects, mainly infections and infestations (9 events in 8 subjects). One person died after a uterine rupture after delivery, which was confirmed to be unrelated to the vaccine.

Phase I trial reported comparable number of subjects with at least one reaction (14-16/25 subjects). Most frequently reported was pain and tenderness at the injection site, and headache as most common a systemic reaction.

Phase II/III trial reported 130 subjects with unsolicited TEAEs, of which 87 subjects within 28 days, with no differences between the arms. No severe unsolicited TEAEs were reported.

Phase III trial reports 2,499 TEAEs in 1,411/3,219 subjects. Solicited local and systemic reactions (such as injection site pain and fever) within 7 days after vaccination, were reported for 2.6% to 3.7% in the vaccine arms and in 2.7% in the control arm.

Other information about evaluation of EuTYPH-C Inj. Multi-dose.

As part of the prequalification process for EuTYPH-C Inj. Multi-dose the Common Technical Document and the responses provided by the manufacturer to observations made by WHO have been reviewed for quality, safety and efficacy by a team of WHO experts, and found to meet WHO requirements of WHO Technical Report Series **TRS No 1030**, Annex 2, 2020; Recommendations to assure the quality, safety and efficacy of typhoid conjugate vaccines.

In addition to the information submitted to the WHO by EuBiologics Co., Ltd, the decision of WHO prequalification has also been based on the outcome of the desk assessment of the manufacturing facility based on the National Regulatory Authority inspection.