Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO International Standard
2ND INTERNATIONAL STANDARD 2025
Beta-2-Microglobulin
NIBSC code: 19/302
Instructions for use
(Version 1.0, Dated 11/11/2025)

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1. INTENDED USE

The 2nd WHO IS for Beta-2-Microglobulin (B2M), coded 19/302, consists of 1 mL freeze dried human serum. This preparation was established by the Expert Committee on Biological Standardisation (ECBS) of the World Health Organisation in October 2025 [1].

The 2nd WHO IS for B2M, coded 19/302, was evaluated and value assigned relative to the WHO 1st IS for B2M, coded B2M, in an international collaborative study involving nineteen laboratories in nine countries. A total of twenty different methods were used to estimate B2M potency using automated assay platforms or manual ELISA kits. The overal robust geometric mean potency of 19/302 was 103 IU per ampoule, with inter-laboratory variability, expressed as % GCV, of 7.2%[1].

This preparation is intended for the calibration of secondary or working beta-2-microglobulin standards (local standards). It is recommended that local standards should be compared to 19/302 using a dilution range of each preparation in the same test. Linearity of both response curves should be established and the B2M activity of local standards should then be expressed in IU.

The latest ECBS report is available from the WHO (www.who.int/). Document number: WHO/BS/2025.2492 [1]

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.
The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBsAg, anti-HIV and HCV RNA. As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in opening ampoules or vials, to avoid cuts.

3. UNITAGE

The product coded 19/302 has an assigned unitage of 103 International Units per ampoule.

4. CONTENTS

Country of origin of biological material: United Kingdom.
This preparation contains 1.0 mL serum from 20 healthy donors, purchased from TCS Biosciences. The material was dispensed into glass DIN ampoules, lyophilised and sealed under nitrogen according to the procedures recommended by WHO at Medicine and Healthcare products Regulatory Agency (MHRA). The mean weight of the dispensed solution was 1.0091 g, with a filling imprecision (coefficient of variation, CV) of 0.15%. The residual moisture of the final lyophilised product was 0.47% (N = 12).

The freeze-dried pooled serum contains a nominal mass content of 1.4 µg per ampoule.

5. STORAGE

Store unopened ampoules at -20℃ or below
Please note because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

DIN ampoules have an 'easy-open' coloured stress point, where the narrow ampoule stem joins the wider ampoule body. Various types of ampoule breaker are available commercially. To open the ampoule, tap the ampoule gently to collect material at the bottom (labelled) end and follow manufactures instructions provided with the ampoule breaker.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution
The contents of the ampoule should be reconstituted in buffer or saline. If the ampoule is dissolved in 1 mL of buffer or saline the solution will contain 103 IU/ mL. Allow several minutes for complete reconstitution, with occasional vortexing. If it is found necessary, the solution may be cleared by centrifugation after 1 hour at room temperature.

Usage and Reference:
Preparation 19/302 is intended for the calibration of secondary or working B2M standards. To esure traceability and comparability of results, we recommend user's express potency in International Units and calibate their assays accordingly.

8. STABILITY

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label.

NIBSC follows the policy of WHO with respect to its reference materials. It is the policy of WHO not to assign an expiration date to their International reference materials. They remain valid with assigned activity and status until withdrawn or amended.

Accelerated degradation studies on 19/302 have been carried-out after storage of ampoules at -70°C, -20°C, 4°C, 20°C, 37°C, and 45°C for 3 years and 5 months. The accelerated thermal degradation samples were assayed relative to the -70°C condition using a commerical ELISA kit. The data was successfully fitted to the Arrhenius equation which demonstrated an estimated potency loss of <0.1% per year indicating that 19/302 is suitable stable at -20°C or below and +4°C for distribution.

Once reconstituted, diluted, or aliquoted, users should determine the stability of the material according to their own method of preparation, storage, or use.

9. REFERENCES

[1] The latest ECBS report is available from WHO (www.who.int/). Document number: WHO/BS/2025.2492

10. ACKNOWLEDGEMENTS

We would like to thank all participants that took part in the international collaboratorive study.

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WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

World Health Organization

11. FURTHER INFORMATION

Further information can be obtained as follows;
This material: enquiries@nibsc.org
WHO Biological Standards:
http://www.who.int/biologicals/en/
JCTLM Higher order reference materials:
http://www.bipm.org/en/committees/jc/jctlm/
Derivation of International Units:
http://www.nibsc.org/standardisation/international_standards.aspx
Ordering standards from NIBSC:
http://www.nibsc.org/products/ordering.aspx
NIBSC Terms & Conditions:
http://www.nibsc.org/terms_and_conditions.aspx

12. CUSTOMER FEEDBACK

Customers are encouraged to provide feedback on the suitability or use of the material provided or other aspects of our service. Please send any comments to enquiries@nibsc.org

13. CITATION

In all publications, including data sheets, in which this material is referenced, it is important that the preparation's title, its status, the NIBSC code number, and the name and address of NIBSC are cited and cited correctly.

14. MATERIAL SAFETY SHEET

Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified

Physical and Chemical properties			
Physical appearance: Lyophilised		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	Yes	Irritant:	Unknown
Flammable:	No	Handling: See caution, Section 2	
Other (specify):	Preparation contains material of human origin		

Toxicological properties	
Effects of inhalation:	Not established, avoid inhalation
Effects of ingestion:	Not established, avoid ingestion
Effects of skin absorption:	Not established, avoid contact with skin

Suggested First Aid	
Inhalation:	Seek medical advice
Ingestion:	Seek medical advice
Contact with eyes:	Wash with copious amounts of water. Seek medical advice
Contact with skin:	Wash thoroughly with water.

Action on Spillage and Method of Disposal
Spillage of ampoule contents should be taken up with absorbent material wetted with an appropriate disinfectant. Rinse area with an appropriate disinfectant followed by water. Absorbent materials used to treat spillage should be treated as biological waste.

15. LIABILITY AND LOSS

In the event that this document is translated into another language, the English language version shall prevail in the event of any inconsistencies between the documents.
Unless expressly stated otherwise by NIBSC, NIBSC's Standard Terms and Conditions for the Supply of Materials (available at http://www.nibsc.org/About_Us/Terms_and_Conditions.aspx or upon request by the Recipient) ("Conditions") apply to the exclusion of all other terms and are hereby incorporated into this document by reference. The Recipient's attention is drawn in particular to the provisions of clause 11 of the Conditions.

16. INFORMATION FOR CUSTOMS USE ONLY

Country of origin for customs purposes*: United Kingdom * Defined as the country where the goods have been produced and/or sufficiently processed to be classed as originating from the country of supply, for example a change of state such as freeze-drying.
Net weight: 0.0855 g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable. **Attached:** No

17. CERTIFICATE OF ANALYSIS

NIBSC does not provide a Certificate of Analysis for WHO Biological Reference Materials because they are internationally recognised primary reference materials fully described in the instructions for use. The reference materials are established according to the WHO Recommendations for the preparation, characterization and establishment of international and other biological reference standards https://www.who.int/publications/m/item/annex2-trs932(revised 2004). They are officially endorsed by the WHO Expert Committee on Biological Standardization (ECBS) based on the report of the international collaborative study which established their suitability for the intended use.