

European Pharmacopoeia Assays

Birch pollen allergen, Bet v 1

InBio has participated in the European Directorate for Quality of Medicines and HealthCare (EDQM) Biological Standardization Program BSP090 to establish the reference standards for 2 major allergens, Phl p 5a and Bet v 1 and to validate the standard ELISA methods for inclusion in a European Pharmacopoeia (Ph.Eur.) Chapter. Subsequently, InBio had developed and validated a [Bet v 1 EP assay](#) as an alternative to the method described in the General Chapter 2.7.36. Supporting data can be found here ([Assay Validation](#) and [Spike recovery](#)).

The assay uses monoclonal antibodies 5B4 and 6H4 which have been found suitable during the BSP090 project, as detailed in the knowledge database of the General Chapter 2.7.36 of the Ph.Eur. These antibodies may be purchased from InBio, in limited quantity, for the purpose of comparing and validating manufacturer's in-house Bet v 1 assays. Users are required to demonstrate and document the comparability of their assay to satisfy the competent authority.

For more information, please contact [Dr. Hayley Mills](#). For technical inquiries about Bet v 1 ELISA 2.0 EP, please contact [Bryan Smith](#).

Timothy pollen allergen, Phl p 5

InBio has developed a [Phl p 5 ELISA 2.0](#) method which has been successfully evaluated by the EDQM in a multi-centre ring trial as a suitable method for measuring [Phl p 5](#)¹. The General Chapter describing the Phl p 5-specific ELISA is scheduled to be adopted by the [Ph. Eur. Commission in 2023](#)².

References

1 – <https://pubmed.ncbi.nlm.nih.gov/34241919/>

2 – <https://pubmed.ncbi.nlm.nih.gov/36579359/>