

Annex to declaration of accreditation (scope of accreditation)
Normative document: EN ISO/IEC 17025:2017
Registration number: **L 098**

of **Rijksinstituut voor Volksgezondheid en Milieu (RIVM), Centre for Health Protection (KvK: 30276683)**

This annex is valid from: **27-11-2024** to **01-09-2028**

Replaces annex dated: **18-07-2024**

Location(s) where activities are performed under accreditation

Head Office

Antonie van Leeuwenhoeklaan 9
3721 MA
Bilthoven
The Netherlands

Location	Abbreviation/ location code
Antonie van Leeuwenhoeklaan 9 3721 MA Bilthoven The Netherlands	Bi

No.	Material or product	Type of activity ¹	Internal reference number	Location
Department for Product Composition				
1	Pharmaceutical dosage forms	Assessment of the external features (color, form, size); visual inspection	GZB-650 in house method	Bi
2	Tablets and capsules	Dissolution test of pharmacologically active substances; paddle and basket method	GZB-633 in house method Capsules EP-monograph nr 0016 Tablets: EP-monograph nr 0478	
3	Liquids	Determination of relative density using a digital density meter; electromagnetically induced oscillation Range: 0 - 1,6 g/cm ³ ; 15-30 °C	GZB-651 in house method	
4	Aqueous solutions and dosage forms	Determination of pH	GZB-638 in house method	

This annex has been approved by the Board of the Dutch Accreditation Council, on its behalf,

J.A.W.M. de Haas

¹ If there is a referral to a code starting with NAW, NAP, EA or IAF, this concerns a scheme mentioned on the [RvA-BR010-lijst](#).
If no date or version number is mentioned for a normative document, the accreditation concerns the most current version of the document or scheme.

Annex to declaration of accreditation (scope of accreditation)
 Normative document: EN ISO/IEC 17025:2017
 Registration number: **L 098**

of **Rijksinstituut voor Volksgezondheid en Milieu (RIVM), Centre for Health Protection (KvK: 30276683)**

This annex is valid from: **27-11-2024 to 01-09-2028**

Replaces annex dated: **18-07-2024**

No.	Material or product	Type of activity ¹	Internal reference number	Location
5	Pharmaceutical substances and products	Determination of the identity; infrared absorption spectrophotometry Range: 200 – 4000 cm ⁻¹	GZB-657 and GZB-658 in house method	Bi
6		Determination of identity, purity and content; high performance liquid chromatography (HPLC)	GZB-619 in house method	
7		Determination of the content; UV-VIS absorption spectrophotometry	GZB-621 in house method	
8		Identification of compounds and their quantitative determination using UPLC-Orbitrap	GZB-661 in house method	
9	Cigarettes	Determination of total and nicotine-free dry particulate matter (NFDPM); Gravimetric method	GZB-745 ISO 4387	
10	Fine-cut tobacco	Determination of total and nicotine-free dry particulate matter (NFDPM); Gravimetric method	GZB-746 ISO 15592-3	
11	Cigarettes and Fine-cut tobacco	Determination of nicotine content in smoke condensates; Gas-chromatographic method	GZB-747 ISO 10315	
12		Determination of water content in smoke condensates; Gas-chromatographic method	GZB-748 ISO 10362-1	
13		Determination of carbon monoxide in the vapour phase of cigarette smoke; NDIR method	GZB-749 ISO 8454	
14	Tobacco product labelling	Determination of measures by using a Vernier caliper and text labelling; visual inspection	GZB-757 tabakswet	

Department Biologicals, Screening and Innovation

15	Immunological products	Determination of the potency of influenza vaccine; SRD	GZB-001 in house method	Bi
16		Determination of the purity of monovalent influenza bulks; SDS-PAGE and Coomassie staining	GZB-025 in house method	

of **Rijksinstituut voor Volksgezondheid en Milieu (RIVM), Centre for Health Protection (KvK: 30276683)**

This annex is valid from: **27-11-2024 to 01-09-2028**

Replaces annex dated: **18-07-2024**

No.	Material or product	Type of activity ¹	Internal reference number	Location
17		Determination of the potency of the diphtheria component in DTP-vaccines; Vero cell assay	GZB-033 in house method	
18		Determination of the potency of the tetanus component in tetanus containing vaccines; Toxin Binding Inhibition (ToBi) test	GZB-031 in house method	
19		Determination of the identity and potency of the varicella component in vaccines; plaque assay in MRC-5 cell cultures	GZB-059 in house method	
20	Immunological products	Determination of the identity of the polysaccharides in pneumococcal vaccine; nephelometry	GZB-045 in house method	
21		Determination of the potency of inactivated polio vaccine; ELISA	GZB-046 in house method	
22	Immunological products	Determination of the potency of hepatitis B antigen in hepatitis B vaccine; ELISA	GZB-065 in house method	
23		Determination of the identity of diphtheria and tetanus antigens containing vaccines; ELISA	GZB-057 in house method	
24		Determination of the potency, identity and thermal stability of the rubella component in vaccines; CCID50	GZB-175 in house method	
25		Determination of the potency of human papilloma virus (HPV) types 6,11,16,18, 31, 33, 45, 52 and 58 in vaccines; ELISA	GZB-070 in house method GZB-193 in house method	
26		Determination of the purity and percentage intact L1-protein in monovalent bulks of human papilloma virus vaccine; SDS-PAGE and Coomassie staining quantitatively (purity)	GZB-174 in house method	Bi
27		Determination of the identity and potency of rotavirus vaccine; replication in Vero cell cultures followed by PCR	GZB-069 in house method	

of **Rijksinstituut voor Volksgezondheid en Milieu (RIVM), Centre for Health Protection (KvK: 30276683)**

This annex is valid from: **27-11-2024 to 01-09-2028**

Replaces annex dated: **18-07-2024**

No.	Material or product	Type of activity ¹	Internal reference number	Location
28		Determination of the potency, identity and thermal stability of the measles component in vaccines; CCID50	GZB-178 in house method	
29		Determination of the potency, identity and thermal stability of the mumps component in vaccines; CCID50	GZB-179 in house method	
30	Immunological products	Determination of the potency of a corona vaccine; plaque assay in HEK293 cell cultures	GZB-198 in house method	
31		Determination of the identity of a corona vaccine; PCR	GZB-197 in house method	
32	Immunological products, blood products	Visual inspection and determination of dissolution time	GZB-012 in house method	
33	Immunological products, blood products	Determination of bacterial endotoxin in influenza vaccine and pneumococcal vaccine; Kinetic turbidimetric bacterial endotoxin test (BET)	GZB-014 EP monograph 2.6.14	
34	Blood products	Determination of the molecular size of immunoglobulin and albumin preparations; HPLC-SEC	GZB-024 EP monograph 255, 918	
35		Determination of the protein composition of immunoglobulin preparations; electrophoresis	GZB-026 EP monograph 918	
36		Determination of the potency of blood coagulation factor IX; the one-stage clotting assay method	GZB-035 EP monograph 2.7.11	
37		Determination of the absence of thrombin in human prothrombin complex concentrates; fibrinogen assay	GZB-013 EP monograph 554	Bi
38		Determination of the absence of activated coagulation factors in human coagulation factor IX and prothrombin complex preparations; NAPTT assay	GZB-016 EP 2.6.22	

Annex to declaration of accreditation (scope of accreditation)
 Normative document: EN ISO/IEC 17025:2017
 Registration number: **L 098**

of **Rijksinstituut voor Volksgezondheid en Milieu (RIVM), Centre for Health Protection
 (KvK: 30276683)**

This annex is valid from: **27-11-2024** to **01-09-2028**

Replaces annex dated: **18-07-2024**

No.	Material or product	Type of activity ¹	Internal reference number	Location
39		Determination of the total protein content of immunoglobulin preparations; A280nm	GZB-062 in house method	
40		Determination of prekallikrein activator (PKA) activity in albumin preparations; chromogenic substrate assay	GZB-044 EP monograph 2.6.15	
41		Determination of HBsAg in plasma pools; ELISA	GZB-183 in house method	
42	Blood products	Determination of HIV 1/2 antibodies in plasma pools; ELISA	GZB-184 in house method	
43		Determination of anti-A and anti-B haemagglutinins in immunoglobulin preparations; direct haemagglutination assay	GZB-190 EP monograph 2.6.20	
44	Blood products	Determination of hepatitis C RNA in plasma pools; PCR	GZB-011 EP monograph 2.6.21	