

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
Department for Product Composition and Department for Biologicals, Screening and
Innovation (KvK: 30276683)**

This annex is valid from: **01-03-2023** to **01-09-2024**

Replaces annex dated: **17-09-2021**

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	

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.

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4	Aqueous solutions and dosage forms	Determination of pH	GZB-638 in house method	Bi	
5	Pharmaceutical substances and products	Determination of the identity; infrared absorption spectrophotometry Range: 200 – 4000 cm ⁻¹ Qualitatively (identity)	GZB-657 and GZB-658 in house method		
6		Determination of identity and purity; thin layer chromatography (TLC) Qualitatively (identity)	GZB-610 in house method		
7		Determination of identity, purity and content; high performance liquid chromatography (HPLC) Qualitatively (identify) Quantitatively (purity)	GZB-619 in house method		
8		Determination of the content; UV-VIS absorption spectrophotometry Quantitatively (purity)	GZB-621 in house method		
9		Determination of identity; Raman-spectrophotometry Qualitatively (identify)	GZB-662 EP 2.2.48		
10		Determination of identity of potency enhancing compounds including control of genuineness; NIR Qualitatively (identify)	GZB-654 and GZB-705 in house method		
11		Determination of identity and, if applicable, quantitative determination of known and unknown compounds; liquid chromatography and mass spectrometry (UPLC-QTOF MS) Qualitatively (identify) Semi-quantitatively (purity)	GZB-762 in house method		
12	Cigarettes	Determination of total and nicotine-free dry particulate matter (NFDPM); Gravimetric method	GZB-745 ISO 4387		Bi
13	Fine-cut tobacco	Determination of total and nicotine-free dry particulate matter (NFDPM); Gravimetric method	GZB-746 ISO 15592-3		

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14	Cigarettes and Fine-cut tobacco	Determination of nicotine content in smoke condensates; Gas-chromatographic method	GZB-747 ISO 10315	
15		Determination of water content in smoke condensates; Gas-chromatographic method	GZB-748 ISO 10362-1	
16		Determination of carbon monoxide in the vapour phase of cigarette smoke; NDIR method	GZB-749 ISO 8454	
17	Tobacco product labelling	Determination of measures by using a Vernier caliper and text labelling; visual inspection	GZB-757 tabakswet	

Department Biologicals, Screening and Innovation

18	Immunological products	Determination of the potency of influenza vaccine; SRD	GZB-001 in house method	Bi
19		Determination of the purity of monovalent influenza bulks; SDS-PAGE and Coomassie staining	GZB-025 in house method	
20		Determination of the potency of the diphtheria component in DTP-vaccines; Vero cell assay	GZB-033 in house method	
21		Determination of the potency of the tetanus component in tetanus containing vaccines; Toxin Binding Inhibition (ToBi) test	GZB-031 in house method	
22		Determination of the identity and potency of the varicella component in vaccines; plaque assay in MRC-5 cell cultures	GZB-059 in house method	
23	Immunological products	Determination of the identity of the polysaccharides in pneumococcal vaccine; nephelometry	GZB-045 in house method	Bi
24		Determination of the potency of inactivated polio vaccine; ELISA	GZB-046 in house method	
25		Determination of the purity of hepatitis B surface antigen (HBsAg) in purified form III; SDS-PAGE and Western Blot	GZB-054 in house method	

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26	Immunological products	Determination of the potency of hepatitis B antigen in hepatitis B vaccine; ELISA	GZB-065 in house method	
27		Determination of the identity of diphtheria and tetanus antigens containing vaccines; ELISA	GZB-057 in house method	
28		Determination of the potency, identity and thermal stability of the rubella component in vaccines; CCID50	GZB-175 in house method	
29		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	
30		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	
31		Determination of the identity and potency of rotavirus vaccine; replication in Vero cell cultures followed by PCR	GZB-069 in house method	
32		Determination of the potency, identity and thermal stability of the measles component in vaccines; CCID50	GZB-178 in house method	
33		Determination of the potency, identity and thermal stability of the mumps component in vaccines; CCID50	GZB-179 in house method	
34		Immunological products	Determination of the potency of a corona vaccine; plaque assay in HEK293 cell cultures	
35	Determination of the identity of a corona vaccine; PCR		GZB-197 in house method	
36	Immunological products, blood products	Visual inspection and determination of dissolution time	GZB-012 in house method	

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37	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	
38	Blood products	Determination of the molecular size of immunoglobulin and albumin preparations; HPLC-SEC	GZB-024 EP monograph 255, 918	
39		Determination of the protein composition of immunoglobulin preparations; electrophoresis	GZB-026 EP monograph 918	
40		Determination of the potency of blood coagulation factor IX; the one-stage clotting assay method	GZB-035 EP monograph 2.7.11	
41		Determination of the absence of thrombin in human prothrombin complex concentrates; fibrinogen assay	GZB-013 EP monograph 554	
42		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	
43		Determination of the total protein content of immunoglobulin preparations; A280nm	GZB-062 in house method	
44		Determination of prekallikrein activator (PKA) activity in albumin preparations; chromogenic substrate assay	GZB-044 EP monograph 2.6.15	
45		Determination of HBsAg in plasma pools; ELISA	GZB-183 in house method	
46	Blood products	Determination of HIV 1/2 antibodies in plasma pools; ELISA	GZB-184 in house method	Bi
47		Determination of anti-A, anti-B and anti-D haemagglutinins in immunoglobulin preparations; direct haemagglutination assay	GZB-190 EP monograph 2.6.20, 2.6.26	

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48	Blood products	Determination of hepatitis C RNA in plasma pools; PCR	GZB-011 EP monograph 2.6.21	