

BUREAU OF INDIAN STANDARDS

Program of Work

MHD 20 : Medical Biotechnology and Medical Nanotechnology

Scope: a) Standardization in the field of medical biotechnology, including but not limited to Biobanks and Bioresources, analytical methods (including Chemical and Biological), products (including tissue-engineered medical products), delivery systems, etc. b) Standardization in the field of medical nanotechnology, including but not limited to products, processes and test methods.

Liaison: **ISO TC-276 (P): Biotechnology** **ISO TC-276 SC-1 (P): Analytical methods** **ISO TC-276 SC-2 (P): Microphysiological systems and Organ-on- Chip**

Published Standards

S.No	IS No.	TITLE	Reaffirm M-Y	No. of Amds	Eqv.
1	IS/ISO/TR 13121:2011 ISO/TR 13121 : 2011 <i>Reviewed In : 2023</i> <i>ISO/TR 13121:2011</i>	Nanotechnologies - Nanomaterial risk evaluation	June, 2023	-	Identical under single numbering
2	IS/ISO/TR 17302:2015 ISO/TR 17302:2015 <i>ISO/TR 17302:2015</i>	Nanotechnologies Framework for identifying vocabulary development for nanotechnology applications in human healthcare		-	Identical under single numbering
3	IS 17707:2021 ISO/TS 22082:2020 <i>ISO/TS 22082:2020</i>	Nanotechnologies Assessment of nanomaterial toxicity using dechorionated zebrafish embryo		-	Identical under dual numbering
4	IS 17711:2021 ISO 21973:2020 <i>ISO 21973:2020</i>	Biotechnology General requirements for transportation of cells for therapeutic use		-	Identical under dual numbering
5	IS 18152:2023 ISO/TR 12885:2018 <i>ISO/TR 12885:2018</i>	Nanotechnologies Health and safety practices in occupational settings		-	Identical under dual numbering
6	IS 18514:2024 ISO 22412:2017 <i>ISO 22412:2017</i>	Particle size analysis Dynamic light scattering DLS		-	Identical under dual numbering
7	IS 18607:2024 ISO 24421:2023 <i>ISO 24421:2023</i>	Biotechnology Minimum requirements for optical signal measurements in photometric methods for biological samples		-	Identical under dual numbering
8	IS 18609:2024 ISO 20399:2022 <i>ISO 20399:2022</i>	Biotechnology Ancillary materials present during the production of cellular therapeutic products and gene therapy products		-	Identical under dual numbering
9	IS 18617:2024 ISO 23033:2021 <i>ISO 23033:2021</i>	Biotechnology Analytical methods General requirements and considerations for the testing and characterization of cellular		-	Identical under dual numbering

		therapeutic products			
10	IS 18644:2024 ISO/TS 23565:2021 ISO/TS 23565:2021	Biotechnology Bioprocessing General requirements and considerations for equipment systems used in the manufacturing of cells for therapeutic use		-	Identical under dual numbering
11	IS 18856:2024 ISO 19007:2018 ISO 19007:2018	Nanotechnologies In vitro MTS assay for measuring the cytotoxic effect of nanoparticles		-	Identical under dual numbering
12	IS 18857:2024 ISO/TR 22019:2019 ISO/TR 22019:2019	Nanotechnologies $i_L^{1/2}$ Considerations for performing toxicokinetic studies with nanomaterials		-	Identical under dual numbering
13	IS 18902:2024 ISO/TR 19057:2017 ISO/TR 19057:2017	Nanotechnologies $i_L^{1/2}$ Use and application of acellular in vitro tests and methodologies to assess nanomaterial bioburden		-	Identical under dual numbering
14	IS/ISO 20391-1:2018 ISO 20391-1:2018 ISO 20391-1:2018	Biotechnology Cell counting Part 1: General guidance on cell counting methods		-	Identical under single numbering
15	IS/ISO 20391-2:2019 ISO 20391-2:2019 ISO 20391-2:2019	Biotechnology Cell counting Part 2: Experimental design and statistical analysis to quantify counting method performance		-	Identical under single numbering
16	IS/ISO 20395:2019 ISO 20395:2019 ISO 20395:2019	Biotechnology Requirements for evaluating the performance of quantification methods for nucleic acid target sequences qPCR and dPCR		-	Identical under single numbering
17	IS/ISO 20397-1:2022 ISO 20397-1:2022 ISO 20397-1:2022	Biotechnology Massively parallel sequencing Part 1: Nucleic acid and library preparation		-	Identical under single numbering
18	IS/ISO 20397-2:2021 ISO 20397-2:2021 ISO 20397-2:2021	Biotechnology Massively parallel sequencing Part 2: Quality evaluation of sequencing data		-	Identical under single numbering
19	IS/ISO 20404:2023 ISO 20404:2023 ISO 20404:2023	Biotechnology Bioprocessing General requirements for the design of packaging to contain cells for therapeutic use		-	Identical under single numbering
20	IS/ISO/TS 20660:2019 ISO/TS 20660 : 2019 ISO/TS 20660:2019	Nanotechnologies Antibacterial Silver Nanoparticles Specification of Characteristics and Measurement Methods		-	Identical under single numbering
21	IS/ISO/TS 23367-1:2022 ISO/TS 23367-1:2022 ISO/TS 23367-1:2022	Nanotechnologies Performance characteristics of nanosensors for chemical and biomolecule detection Part 1: Detection performance		-	Identical under single numbering
22	IS/ISO 29701:2010 ISO 29701 : 2010 Reviewed In : 2023 ISO 29701:2010	Nanotechnologies - Endotoxin test on nanomaterial samples for in vitro systems - Limulus amoebocyte lysate (Lal) test	June, 2023	-	Identical under single numbering
23	IS/IEC/TS 80004-5:2011	Nanotechnologies - Vocabulary: Part 5 nano/bio interface	September, 2024	-	Identical under single numbering

	ISO/TS 80004-5 : 2011 Reviewed In : 2024 ISO/TS 80004-5				
24	IS/IEC/TS 80004-7:2011 ISO/TS 80004-7 : 2011 Reviewed In : 2024 ISO/TS 80004-7	Nanotechnologies - Vocabulary: Part 7 diagnostics and therapeutics for healthcare	September, 2024	-	Identical under single numbering

Standards under Development

Projects Approved		
Sl. No.	Doc No.	Title
No Records Found		

Preliminary Draft Standards		
Sl. No.	Doc No.	Title
No Records Found		

Drafts Standards in WC Stage		
Sl. No.	Doc No.	Title
No Records Found		

Draft Standards Completed WC Stage		
Sl. No.	Doc No.	Title
1	MHD 20 (27906)	Extracellular Vesicles - Characterization

Finalized Draft Indian Standard		
Sl. No.	Doc No.	Title
No Records Found		

Finalized Draft Indian Standards under Print		
Sl. No.	Doc No.	Title
No Records Found		

Total Published Standards:8 Total Standards Under development:1		
---	--	--

Aspect Wise Report

Product : 4

Code of Practices : 6

Methods of Test : 8

Terminology : 3

Dimensions : 0

System Standard : 0

Safety Standard : 1

Others : 0

Service Specification : 0

Process Specification : 2

Annexure-I :List of Indian Standards Withdrawn/Superseded

Sl. No.	IS No. & Year	Title
1	IS/ISO/TR 12885:2008 ISO/TR 12885 : 2008 Reviewed In : 2018 ISO/TR 12885:2008	Medical Biotechnology And Medical Nanotechnology
2	IS 17647 (Part 1):2021 ISO 20399-1:2018 ISO/IEC 11160-2:2021	Biotechnology - Ancillary materials present during the production of cellular therapeutic products Part 1 General requirements
3	IS 17647 (Part 2):2021 ISO/TS 20399-2: 2018	Biotechnology - Ancillary materials present during the production of cellular therapeutic products Part 2 Best practice guidance for ancillary material suppliers
4	IS 17647 (Part 3):2021 ISO 20399-3:2018 ISO 25720:2009	Biotechnology - Ancillary materials present during the production of cellular therapeutic products Part 3 Best practice guidance for ancillary material users

Annexure-II :List of Indian Product Standards

Sl. No.	IS No. & Year	Title
1	IS 18514:2024 ISO 22412:2017	Particle size analysis Dynamic light scattering DLS
2	IS 18644:2024 ISO/TS 23565:2021	Biotechnology Bioprocessing General requirements and considerations for equipment systems used in the manufacturing of cells for therapeutic use
3	IS/ISO 20404:2023 ISO 20404:2023	Biotechnology Bioprocessing General requirements for the design of packaging to contain cells for therapeutic use
4	IS/ISO/TS 23367-1:2022 ISO/TS 23367-1:2022	Nanotechnologies Performance characteristics of nanosensors for chemical and biomolecule detection Part 1 Detection performance