

BUREAU OF INDIAN STANDARDS

Program of Work

MHD 20 : Medical Biotechnology and Medical Nanotechnology

Scope: To formulate Indian Standard on equipment, nanomaterial for implants, nanotechnology based formulations and delivery systems used in Medical Biotechnology and Medical Nanotechnology.

Liaison: **ISO TC-276 (P): Biotechnology ISO TC-276 SC-1 (P): Analytical methods**

Published Standards

S.No	IS No.	TITLE	Reaffirm M-Y	No. of Amds	Eqv.
1	IS/ISO/TR 13121 : 2011 ISO/TR 13121 : 2011 Reviewed In : 2023 ISO/TR 13121:2011	Nanotechnologies - Nanomaterial risk evaluation	June, 2023	-	Identical under single numbering
2	IS/ISO/TR 17302 : 2015 ISO/TR 17302:2015 ISO/TR 17302:2015	Nanotechnologies Framework for identifying vocabulary development for nanotechnology applications in human healthcare		-	Identical under single numbering
3	IS 17707 : 2021 ISO/TS 22082:2020 ISO/TS 22082:2020	Nanotechnologies Assessment of nanomaterial toxicity using dechorionated zebrafish embryo		-	Identical under dual numbering
4	IS 17711 : 2021 ISO 21973:2020 ISO 21973:2020	Biotechnology General requirements for transportation of cells for therapeutic use		-	Identical under dual numbering
5	IS 18152 : 2023 ISO/TR 12885:2018 ISO/TR 12885:2018	Nanotechnologies Health and safety practices in occupational settings		-	Identical under dual numbering
6	IS 18514 : 2024 ISO 22412:2017 ISO 22412:2017	Particle size analysis Dynamic light scattering DLS		-	Identical under dual numbering
7	IS 18607 : 2024 ISO 24421:2023 ISO 24421:2023	Biotechnology Minimum requirements for optical signal measurements in photometric methods for biological samples		-	Identical under dual numbering
8	IS 18609 : 2024 ISO 20399:2022 ISO 20399:2022	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 ISO 23033:2021	Biotechnology Analytical methods General requirements and considerations for the testing and characterization of cellular therapeutic products		-	Identical under dual numbering
10	IS 18644 : 2024 ISO/TS 23565:2021	Biotechnology Bioprocessing General requirements and		-	Identical under dual numbering

	ISO/TS 23565:2021	considerations for equipment systems used in the manufacturing of cells for therapeutic use			
11	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
12	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
13	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
14	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
15	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
16	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
17	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
18	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
19	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
20	IS/IEC/TS 80004-5 : 2011 ISO/TS 80004-5 : 2011 Reviewed In : 2018 ISO/TS 80004-5	Nanotechnologies - Vocabulary: Part 5 nano/bio interface	May, 2018	-	Identical under single numbering
21	IS/IEC/TS 80004-7 : 2011 ISO/TS 80004-7 : 2011 Reviewed In : 2018 ISO/TS 80004-7	Nanotechnologies - Vocabulary: Part 7 diagnostics and therapeutics for healthcare	May, 2018	-	Identical under single numbering

Standards under Development

Projects Approved

SI. No.	Doc No.	Title
<i>No Records Found</i>		

Preliminary Draft Standards

SI. No.	Doc No.	Title
<i>No Records Found</i>		

Drafts Standards in WC Stage

SI. No.	Doc No.	Title
<i>No Records Found</i>		

Draft Standards Completed WC Stage

SI. No.	Doc No.	Title
1	MHD 20 (25726)	Nanotechnologies In vitro MTS assay for measuring the cytotoxic effect of nanoparticles
2	MHD 20 (25728)	Nanotechnologies Use and application of acellular in vitro tests and methodologies to assess nanomaterial biodurability
3	MHD 20 (25729)	Nanotechnologies Considerations for performing toxicokinetic studies with nanomaterials

Finalized Draft Indian Standard

SI. No.	Doc No.	Title
<i>No Records Found</i>		

Finalized Draft Indian Standards under Print

SI. No.	Doc No.	Title
<i>No Records Found</i>		

Total Published Standards:8 Total Standards Under development:3

Aspect Wise Report

Product : 4
Code of Practices : 4
Methods of Test : 7
Terminology : 3
Dimensions : 0
System Standard : 0
Safety Standard : 1
Others : 0
Service Specification : 0
Process Specification : 2
Unclassified : 0

Annexure-I :List of Indian Standards Withdrawn/Superseded

SI. 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	Biotechnology - Ancillary materials present during the production of cellular therapeutic products Part 1 General requirements

	ISO/IEC 11160-2:2021	
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

SI. 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