

ISO 15747:2026-05 (E)

Plastic containers for intravenous injections

Contents		Page
Foreword		iv
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Requirement	3
4.1	Physical requirements	3
4.1.1	General	3
4.1.2	Manufacturing process compatibility	3
4.1.3	Resistance to temperature, pressure and leakage	3
4.1.4	Resistance to dropping	3
4.1.5	Transparency	3
4.1.6	Water vapour permeability	3
4.1.7	Particulate contamination	3
4.1.8	Cover	3
4.1.9	Access port -- Penetration ability of the insertion point	4
4.1.10	Access port -- Adhesion strength of the infusion device and impermeability of the insertion point	4
4.1.11	Access port -- Tightness of the injection point	4
4.1.12	Hanger	4
4.1.13	Identification	4
4.2	Chemical requirements	4
4.2.1	General	4
4.2.2	Requirements for the raw container or the sheeting	4
4.2.3	Requirements for the test fluid	5
4.3	Biological requirements	5
4.3.1	General	5
4.3.2	Impermeability for microorganisms	5
4.3.3	Migration	5
5	Application of tests	5
Annex A (normative) Physical tests		6
Annex B (normative) Chemical tests		9
Annex C (normative) Biological tests		12
Annex D (normative) Reference spike		14
Annex E (informative) Rationale, guidance and history of the development of this document		16
Annex F (informative) Sustainability		19
Annex G (informative) Attributive and variable testing		21
Bibliography		22