



## PRODUCT MANUAL FOR MTP SUCTION APPARATUS-ELECTRICALLY OPERATED ACCORDING TO IS 7080 (PART 3):1992

*This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure coherence of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations, 2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification licence/certificate.*

<b>1.</b>	<b>Product</b>	:	IS 7080 (Part 3) :1992
	<b>Title</b>	:	MTP Suction Apparatus - Electrically Operated
	<b>No. of Amendments</b>	:	3
<b>2.</b>	<b>Sampling Guidelines:</b>		
<b>a)</b>	<b>Raw material</b>	:	As per Cl. 5 of IS 7080 (Part 3)
<b>b)</b>	<b>Grouping guidelines</b>	:	Each Type (Type A & Type B) shall be tested separately for considering GoL/CSoL
<b>c)</b>	<b>Sample Size</b>	:	One Suction Apparatus
<b>3.</b>	<b>List of Test Equipment</b>	:	Please refer ANNEX –A
<b>4.</b>	<b>Scheme of Inspection and Testing</b>	:	Please refer ANNEX –B
<b>5.</b>	<b>Possible tests in a day:</b>		
	(i) Shape and Dimension (Cl. 4) (ii) Construction (Cl. 6) (iii) General Requirements (Cl. 7) (iv) Safety Requirements (Cl. 8) (v) Workmanship and Finish (Cl. 9) (vi) Adhesion Test (Cl. 10.1) (vii) Leakage Test (Cl. 10.2) (viii) Vacuum Test (Cl. 10.3) (ix) Vibration Test (Cl. 10.4) (x) Noise Test (Cl. 10.7)		
<b>6.</b>	<b>Scope of the Licence:</b>		
	“Licence is granted to use Standard Mark as per IS 7080 (Part 3):1992 with the following scope:		
	Name of the product	MTP Suction Apparatus - Electrically Operated	
	Type	Type A/ Type B	
	Cannula Type	Stainless Steel/ Flexible Karman Type	

**ANNEX A****List of Test Equipment***Major test equipment required to test as per the Indian Standard*

<b>Sl. No.</b>	<b>Tests used in with Clause Reference</b>	<b>Test Equipment</b>
1.	Dimensions (Cl. 4.1)	Vernier calipers, Scale
2.	Rubber Components (Cl. 5.2)	Hot air Oven
3.	Castor Wheel (Cl. 5.9)	Castor resistance tester.
4.	Stability (Cl 7.2)	Stability test apparatus with inclined platform of 10 degree
5.	Sterilization (Cl. 7.5, Cl. 10.6)	Auto Clave.
6.	Mass (Cl. 7.8)	Weighing machine.
7.	Protection against Electric Shock (Cl. 8.1)	Test probe B, 13 and 41 of IS 1401, pin, Voltmeter, mill-ammeter, force gauges.
8.	Electrical Insulation & Leakage Current at Operating Temp. (Cl. 8.1)	Leakage current meter, isolation transformer, HV test supply.
9.	Stability and Mechanical Hazards (Cl. 8.1))	Inclined plane, masses, force gauges.
10.	Mechanical Strength (Cl. 8.1)	Impact hammer, Hardened steel pin, Force gauges.
11.	Supply Connections (Cl. 8.1)	Flexing test apparatus, Cord anchorage force & torque tester, Cold chamber.
12.	Terminals (Cl. 8.1)	Torque screwdriver.
13.	Earthing (Cl. 8.1)	Earth continuity tester.
14.	Screws and Connections (Cl. 8.1)	Torque gauge.
15.	Resistance to Rusting (Cl. 8.1)	Humidity Chamber with Temp and Humidity Controller, Measuring Cylinder 500 ml, Ammonium Chloride, Carbon Tetrachloride, Distilled Water.
16.	Adhesion test (Cl. 10.1)	Cellulose tape, Bevel angle protractor.
17.	Performance Test (Cl. 10.4)	Manometer, Vacuum Gauge, Stop Watch, Air Flow Meter.
18.	Noise measurement (Cl 10.6)	Sound level meter using frequency weighting characteristics -A.

*The above list is indicative only and may not be treated as exhaustive.*

## **ANNEX B**

### **Scheme of Inspection And Testing**

**1. LABORATORY** - A laboratory shall be maintained which shall be suitably equipped (as per the requirement given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the methods given in the specification.

**1.1** The manufacturer shall prepare a calibration plan for the test equipment.

**2. TEST RECORDS** – The manufacturer shall maintain test records for the tests carried out to establish conformity.

**3. LABELLING AND MARKING** – As per the requirements of IS 7080 (Part 3)

**4. CONTROL UNIT** – All MTP Suction Apparatus of the same Type, assembled in a week shall constitute a control unit.

**5. LEVELS OF CONTROL** - The tests as indicated in column 1 of Table 1 and the levels of control in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and appropriate records maintained in accordance with paragraph 2 above.

**5.1** All the production which conforms to the Indian Standards and covered by the licence should be marked with Standard Mark.

**6. REJECTIONS** – Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act, 2016

**TABLE 1**

<b>(1)</b>				<b>(2)</b>	<b>(3)</b>		
<b>Test Details</b>				<b>Test equipment requirement R: required (or) S: Sub-contracting permitted</b>	<b>Levels of Control</b>		
<b>Cl.</b>	<b>Requirement</b>	<b>Test Method</b>			<b>No. of Sample</b>	<b>Frequency</b>	<b>Remarks</b>
		<b>Clause</b>	<b>Reference</b>				
4	<b>Shape and Dimensions</b>						
4.1	Cannula	4.1	IS 7080 (Part 3)	R	One	Each Consignment	-
5	<b>Materials</b>						
	Metal Parts	5.1	IS 7080 (Part 3)	S	One	Each Consignment	Please see Note 1
	Rubber Components	5.2		S	One		
	Glass Parts	5.3		S	One		
	Plastic Parts	5.4		S	One		
	Fibreglass Parts	5.5		S	One		
	Aluminium Parts	5.6		S	One		
	Cannula	5.7		S	One		
	Tubing	5.8		S	One		
	Castor Wheels	5.9		S	One		
6	<b>Construction (excluding material)</b>						
	Cannula	6.1	IS 7080 (Part 3)	-	Each Unit	-	-
	Base	6.2		-		-	
	Handle	6.3		-		-	
7	General Requirements	7.1 to 7.3, 7.5 to 7.12, 7.14 to 7.16	IS 7080 (Part 3)	R	One	Each Control Unit	-
	Vacuum gauge	7.4		R	Each Gauge	Each Consignment	Please see Note 1
8	<b>Safety Requirements</b>						
	Protection against electric shock	8	IS 302 (Part 1)	R	Each Unit	-	-
	Electrical insulation and leakage current at operating temperature	13		R	Each Unit	-	-

	Stability and mechanical hazards	20		R	One	Each Control Unit	-
	Mechanical Strength	21		S	One	Once in 3 months	-
	Supply Connections	25		S	One	Once in 3 months	-
	Terminals	26		S	One	Once in a month	-
	Earthing	27		S	One	Once in a month	-
	Screws and connections	28		S	One	Once in 3 months	-
	Resistance to rusting	31		S	One	Once in a month	-
9	<b>Workmanship and Finish</b>						
	Cannula	9.1	IS 7080 (Part 3)	R	Each Unit	-	-
	Valves and Stopcocks	9.2		R	Each Unit	-	-
	--	9.3		R	Each Unit	-	-
	Components	9.4, 9.5		S	One	Each Control Unit	Please see Note 1
10	<b>Tests</b>						
	Adhesion test	10.1	IS 7080 (Part 3)	R	One	Each Control Unit	-
	Leak proof test	10.2		R	Each Unit	-	-
	Tubing	10.3		R	Each Unit	-	-
	Suction Mechanism	10.4		R	Each Unit	-	-
	Mechanical Strength	10.5		R	Each Unit	-	-
	Repeated Steam Sterilization	10.6		R	One	Each Control Unit	-
	Noise test	7.13,10.7		R	One	Each Control Unit	-

Note-1: No further testing is required, if accompanied with test certificate or ISI marked.

Note-2: Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empaneled by the Bureau.

Note-3: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control unit/batch/lot and submit his own levels of control in column 3 with proper justification for approval by B.O. Head.