File No. File no GEM/TP/2017-18/SUTURE

Major Product Category - : Sutures and Related Products : UNSPSC Code : 423122

Sub-Category - : SUTURE **UNSPSC Code : 42312201**

S.No	Parameters	Character/ Numerical	Value 1	Value 2	Value 3	Value 4	Value 5	Validation Rule	Whether Filter required	Unit	Remarks	
1	Governing Specification	Ch	USP 39									
2	category of suture	Ch	absorbabale	Non absorbable								
3	Construction	Ch	Monofilament	Multifilament								
4	Suture Material	Ch	Stainless Steel Sutures	Polyglycolic Acid	Polyglactin	Polyester	Polyglecaprone		YES			
			Plain Catgut	Chromic Catgut	Polydiaxanone	Nylon	Polypropylene					
			Polyamide	Black Braided Silk	polyglycolic acid antibacterial coated	Polyglecaprone Antibacterial Coated	Polyglactin antibacterial coated					
5	Coating	Ch	with coating	without coating								
6	Coating Material	Ch				To indicate coating if used or otherwise indicate as not applicable						
7	Number of strands	N	1	2								
6	Suture Length	N	38	45	70	75	76		YES	cm		
			76	90	100	150	152					
			2500 (Reel)	110	20	60						
7	Suture Size	Ch	10	9	8	7	6		YES			
			5	4	3	2	1					
			1-0	2-0	3-0	4-0	5-0					
			6-0	7-0	8-0	9-0	10-0					
			11-0	12-0								
8	Needle	Ch	With	Without								
9	Needle Length	Ch	10	12	13	16	17		YES	mm		
			20	22	25	26	30					
			30 Heavy	35	36	30	40					
			2x45	45	48	50	60					
			NA									
10	Type of Needles	Ch	Conventional	Reverse cutting	Reverse cutting super point	R.C. Double armed	straight cutting		YES			
			Taper cut	Taper cut undyed	Taper cut single arm	Tapercut Double arm	Heavy visiblack needle					
			Round bodied	Round bodied heavy	Round bodied single	Round bodied double	Oval Round bodied					
			Round bodied &Reverse cutting double armed	Curved cutting	Trocar point heavy	other types	Not Applicable					
11	Needle Curvature		1/2 circle	3/8 circle	5/8 circle	1/4 circle	Not Applicable					

S.No	Parameters	Character/ Numerical	Value 1	Value 2	Value 3	Value 4	Value 5	Validation Rule	Whether Filter required	Unit	Remarks	
			Others									
12	Sterilised		YES									
13	Sterilisation Method	Ch										To declare
14	Shelf Life	Ch										To declare
15	No. of Sutures in a Pack	N	6	12	4							
16	Sutures confirming to provisions of Drug and Cosmetic act	Ch	YES									
16	date of drug licence	Ch										To declare
18	WHETHER DRUG LICWENCE VALID	Ch	YES									
19	Whether non conviction certificate issued by drug authorities available	Ch	YES									
20	Date of non conviction certificate	Ch										to declare
21	To indicate whether holding rGMP issued under revised Schedule-`M' of Drugs & Cosmetics Act 1940 as amended Or WHO-GMP(for manufacturers only) as per norms amended up to date issued by Licensing Authority Or other certifications in respect of the OEM.	Ch										to declare
22	Packing as per Drug act provisions and USP	CH	YES									
23	Each packing shall be marked as under:- a. Nomenclature of the stores b. Manufacturers name, address, c. Drug license No., d. Month of manufacturing, e. Expiry f. Batch No and lot No (if applicable) g. Any other particulars required under Drug Act 1940 amended up to date h. Quantity contained therein i. Manufacturers name or trade Mark,	Ch	YES									

S.No	Parameters	Character/ Numerical	Value 1	Value 2	Value 3	Value 4	Value 5	Validation Rule	Whether Filter required	Unit	Remarks	
24	Copies of in house Test report to be forwarded with each supply	Ch	YES									
25	Cartons shall be marked with manufacturers name, batch no and month of manufacture and use before. If indentor specifies any special marking in supply order (eg.CGHS, Railways, CRPF etc) same shall be provided.	Ch	YES									
26	All packs must indicate the date of manufacture and expiry. In addition all supplies shall have a remaining self life of at least three - fourth (3/4th) of the stipulated shelf life at the time of delivery.	Ch	YES									
27	If any batch must be recalled because of problems with product quality or adverse reactions to the item, the supplier will be responsible to notify the purchaser,reactions to the item, the supplier will be responsible to notify the purchaser,providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable quality or withdraw and give a full refund of the value Batch has been taken off the Market due to safety problems.	Ch	YES									
28	Test report from drug controller approved laboratories available.	Ch	YES									
29	Test Report number	Ch								*		To declare
30	Date of issue of Test Report by Laboratory	Ch								*		To declare
31	Name and address of laboratory	Ch								*		To declare

TP Creator | Moderator | Approver

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Pl post it on forum.