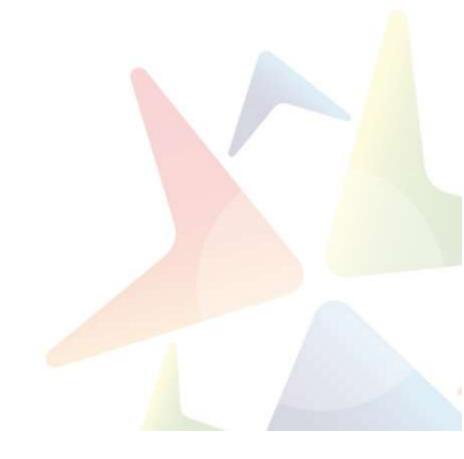


Consultative Meeting Notification 89/2017

Buyer-Seller Consultation on Sutures and Suture Related Products dated 18/12/17

Presented by:

Date:





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Minutes of the Consultative meeting held on 18.12..2017 at 3.30 PM under Chairmanship of Shri A V Muralidharan Dy CEO (GeM) at ISQM Hall ,Office of Government e Market (SPV), Jeevan Tara Building, Parliament Street, New Delhi regarding product category **Sutures.**

Following participated in the meeting:

Seller Side:

- 1. M/s Jhonson & Jhonson (Medical) Gurgaon
- 2. M/s Global Medsupplies(P) Ltd Delhi
- 3. M/s Futura Surgicare Bangalore

Buyer side:

- 1. Dr Vidhi Chowdhary, Associate Professor Lady Hardinge Medical College Delhi
- 2. 2.Dr Manoj Andley Professor Surgery Lady Hardinge Medical College Delhi
- 3. Shri Sanjeev, Stores Department National Institute of Biologicals, Noida, MOHFW
- 4. Smt Anuradah, Stores Department, AIIMS, Delhi
- 5. Shri Dharmender Prasad, Stores Department AIIMS, Delhi

The existing technical parameters indicated for sutures were reviewed and as per discussions it was decided to make following changes:

The governing specifications may be indicated as USP,IP and BP instead of USP 39
presently indicated so that all existing standards to the latest versions are covered



- 2. A parameter regarding how rate is indicated to clear that rate per foil is to be indicated by seller to avoid confusion of some sellers indicate per foil rate and some per pack
- 3. For Parameter construction at serial no 3 instead of multifilament option braided is to be used as same is the common nomenclature
- 4. Regarding suture material parameter at serial no 4 it was noted that all the existing and commonly used varieties are covered and only poly diaxnone anti bacterial coated is to be added
- 5. Against Suture length at serial no 8 options of 35,115, 120,140,160 and 180 to be added
- 6. The important parameter of suture dia is to be added with options from sizes as 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
- 7. For needle length at serial no 9 options of 4mm,6mm,8mm 6.5mm,3.5mm and 9.3mm to be added and option of not applicable to be given
- 8. Regarding type of needles it was decided to add blunt point, j shaped ,SKII Needle, spatulated and precision cutting. The not applicable option to be retained for sutures without needle .
- 9. A parameter no of strands in a suture foil may be added with option of 1,2,4 and 10 and 2,4 and 10 options are for cardiac sutures which can be indicated as a hint
- 10. Regarding no of sutures in a pack with existing options 6,10,4,12,24,and 36 to be added and this can be indicated as number of suture foils in a pack
- 11. .Regarding drug license as per latest amendment in drug act the licenses which are existing get automatically renewed on depositing fees and are valid unless revoked. Hence drug license no only need to be asked and validity is not required
- 12. For non conviction certificate the parameter may be indicated as confirmation regarding non conviction in case of OEM as well as seller if different from OEM and furnishing a copy of recent non conviction certificate not older than 6 months issued by drug authorities if demanded by buyer
- 13. Regarding certifications COPP also may be added as same is required for supplying imported sutures
- 14. .The requirement of in house test report in parameter 25 to be amplified to indicate batch in house test report

Golden Parameter proposed by participants are as under:

1. Suture Material



- 2 .Suture length
- 3. Suture Diameter
- 4. Needle length
- 5. Type of needles
- 6 .Needle curvature

As per discussions it was decided to make following deletions from existing TP

- 1. To deletes parameter regarding coating
- 2. To delete parameter regarding coating material
- 3. The parameter regarding number of strands
- 4 .The parameter regarding sterilization method as standard practice is ETO sterilization which is followed by all
- 5 .The requirement of test reports from NABL/ILAC/Government approved labs as the important aspect is batch in house test reports copy of which is to be forwarded with each supplies to consignee. The in house test reports shall take care of test report aspects and such reports are more relevant for batches of production than a test report done for a particular sample at some point of time.

Regards

GeM-Admin