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No. AIIMS/R/HS/Pharmacy/2018/787/RC/ Dated: - 27/03/2018

Corrigendum

Tender ID No. 2018_IMSRP_310884_1**,**

With reference to above Tender ID No, the following amendment is issued:

S. No.	Item Name	Existing Tender Specification	To be read as
1	Page No. 17 and Page No. 5 Technical specification	1. The product should contain (per 100 gm) 2-Propanalol – 0.45 gm, 1- Propanalol 30.0 gm and Ethyl Hexadecyl Dimethyl Ammonium (Macetronium) Ethyl Sulphate – 0.2 gm 2. Should contain Emollients and Moisturizers (Humectant) 3. The bottle should have 500ml volume with dispenser and should have a mechanism to squirt out 1.5 to 2 ml / push. 4. The product should manufactured in ISO 13845 Certified facility. 5. It should have full documented compliance with the following supported by Govt. certified labs or third party Certification. a. ISO 10993: Bio compatibility for skin irritation Skin sensitization and HCIPT (Human Cumulative Irritance Patch Test.) b. EN 1500 : Hygienic Hand Disinfection. c. EN 12791 : Surgical Hand Disinfection d. EN 13727 or EN 1040-2005 : Bactericidal e. EN 13624 or EN 1275-2005 : Yeasticidal f. EN 14348 : Mycobacterial g. EN 14476: Adenovirus h. It should be effective against Enveloped and non-enveloped viruses. 6. It should have apprised efficacy in compliance with American Standard Test Methods (ASTM test method #2315) for bactericidal and Yeasticidal (vide USP36) (USFDA) 7. Should have WHO's good Manufacturing Practices 8. Sample must be submitted at the time of tender submission.	1. The product must contain (per 100 gm) 2-Propanalol – 45.0 gm, 1- Propanalol 30.0 gm as an active ingredient 2. Should contain Emollients and Moisturizers (Humectant) 3. The bottle should have 500ml volume with dispenser and should have a mechanism to squirt out 1.5 to 2 ml / push. 4. The product should manufactured in ISO 13845 Certified facility. 5. It should have full documented compliance with the following supported by Govt. certified labs or third party Certification. a. ISO 10993: Bio compatibility for skin irritation Skin sensitization. b. EN 1500 : Hygienic Hand Disinfection. c. EN 12791 : Surgical Hand Disinfection d. EN 13727 or EN 1040-2005 : Bactericidal e. EN 13624 or EN 1275-2005 : Yeasticidal f. EN 14348 : Mycobacterial g. EN 14476: Adenovirus h. It should be effective against Enveloped and non-enveloped viruses. 6. It should have apprised efficacy in compliance with American Standard Test Methods (ASTM test method #2315) for bactericidal and Yeasticidal (vide USP36) (USFDA*****) 7. Should have WHO's good Manufacturing Practices 8. Sample must be submitted at the time of tender submission. **9. Product is required with 5% quantity (SS good quality) bed side holder/ hanger of total quantity of Handrubs** **Note:- *USFDA is not mandatory**
	Remarks: An undertaking to be submitted by manufacturer stating that the product that will be quoted and supplied against the tender has compliance towards the specification for quality standards (as per point No.5 and 6) along with the documentary proof.		
2	-	Last date of submission of tender on **03-04-2018** at 6.00 pm and opening of tender on **05-04-2018**	Last date of submission of tender **on 05-04-2018** at 6.00 pm and opening of tender on **07-04-2018**

All other terms and condition will remain unchanged.

Vetted by:-

Dr. Ujjwala N. Gaikwad
Associate Professor (Microbiology)

Rishi Gupta
Stores Officer(H)

Minutes of Pre-bid Meeting

Sub: Tender No. AIIMS/R/HS/Pharmacy/2018/787/RC for the supply of Alcohol Based Hand rub
Ref: Pre-bid meeting held on 07.03.2018 at Medical College Building AIIMS Raipur

The following Bidders' representative attended the pre-bid meeting:

Sr. No.	Name	Organization/Firm
1	Shri Amit Borse	M/s Bio-Shields

Following Bidders seek clarifications vide their email:

Sr. No.	Organization/Firm
1	M/s Sirmaxo Chemicals Pvt. Ltd.

Proceeding of the pre-bid meeting is as follows:-

1. At the outset, a briefing about the scope of services and purpose of the pre-bid meeting were deliberated.
2. Thereafter, prospective bidders were requested to put up their queries related to scope and terms and conditions given in the Bidding Document.
3. The queries from prospective bidders were appropriately responded. The representatives were also requested to send their queries in writing through e-mail within 2 days.
4. The responses to queries sought from prospective bidders in writing and those asked during the meeting have been compiled.
5. The Amendments made pursuance to the Bidding Documents shall be issued separately.

Deliberation:-

Sr. No.	**Page no. /Clause no. as per bid documents**	**Queries**	**Discussions /Remarks**	**Recommendation / Response**
1	Page no. 17 Sr. 1, point no.1	As per WHO guidelines for Hand Hygiene there are many compositions recommended such as Chlorhexidine Gluconate with 70 % Ethanol and skin emollients; Chlorhexidine Gluconate Triclosan with 75% 1- Propanol and 2- Propanol with skin emollients; 2 types of alcohol with strength of 70-75%. We request to reevaluate these composition and allow us to participate in this tender enquiry.	1. The composition may be amended to the following: "The product must contain (100gm) 2-Propanol-45 gm & 1-propanol – 30 gm as an active ingredient" 2. Point No. 1 of technical specification Page no. 17 may be suitably amended	**The suitable corrigendum in this regard to be followed.**

Dr. Ajay Dani	Neeresh Sharma	Dr. Ujjwala N. Gaikwad	S.K. Nema
(MS)	(DDA)	(Associate Professor)	(Accounts Officer)

2.	Page no. 17 Sr.1, point no.6	We do not have documentary evidence of US-FDA/ASTM STANDARDS compliance, being Non mandatory for medical devices by Government of India circular at that particular instance. However, we do follow liquid suspension time-kill test on ATCC strains (ASTM) and validate the biocidal activity of our products manufactured under the license of FDA (Schedule M Category) Thus requesting you to consider the bid and please refer our copies of Certificates of Analysis, Validation Method for above cited clarification.	1. Specifications asking for USFDA may be removed while other certifications remain unchanged 2. The certificates of analysis & validation method submitted by vendor are not as per the requirement and hence not acceptable. 3. The word- USFDA against point no. 6 Page no. 17to be omitted. 4. The USFDA certificate is not mandatory	**The suitable corrigendum in this regard to be followed.**
3.	-	The manufacturer must have their own manufacturing facility and not on loan license/ third party manufacturing. It is with a view for ensuring quality.	Irrelevant query and no comments made	Irrelevant query hence not agreed
4.	-	Various qualifying documents as listed in Technical Specifications should be for the facility from which the product is manufactured, offered in the tender and is going to be supplied on tender.	Irrelevant query and no comments made	Irrelevant query hence not agreed
5.	Page no. 17 Sr. 1, point no.5	Various product quality related certificates viz. **ISO 10993 and EN reports** should be in place for the product which is offered in tender and would be supplied on the tender. The certificates of products of original foreign company should not be considered and accepted if the imported product is not offered in tender. All the quality Certificates as per Technical Specifications should be for the Indian made product which will be manufactured in India and which is going to be offered and supplied.	An undertaking from the manufacturer may be asked stating that the product that will be quoted & supplied against the tender has compliance towards the specifications for quality standards as asked under point. No.5 and 6 of the technical specifications along with the documentary proof.	**The suitable corrigendum in this regard to be followed.**

6.	Page no. 17 Sr. 1, point no.5 (a)	As you have asked ISO 10993 Certificate for Bio compatibility for skin irritation and sensitization, HCIPT test reports may not be insisted. One of the two should be asked since WHO recommends dermal tolerance and skin reactions/sensitivity for Alcohol based Hand rubs but does not insist on specific test. AIIMS, Raipur is one of the premier institutes having legacy of AIIMS. In order to ensure best quality of Alcohol Hand Rub, please consider above points and include the same.	May be accepted, We can remove the clause asking for HCIPT test reports while preserving the ISO 10993 certification	**The suitable corrigendum in this regard to be followed.**

Remarks: The technical committee further observed that the item- 'Alcohol Based Hand rub' is required with MS-SS stand to hold the bottles for **5%** quantity (of the total quantity of Hand rubs) hence suitable corrigendum in this regard to be followed.

Dr. Ajay Dani (MS)	Neeresh Sharma (DDA)	Dr. Ujjwala N. Gaikwad (Associate Professor)	S.K. Nema (Accounts Officer)