राजस्थान चिकित्सा सेवा निगम स्वास्थ्य भवन,सी-स्कीम, जयपुर

फोन नः 0141-2223887, फैक्स नः 0141-2228065

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क्रमांक : F-8 ()/RMSC/EPM/ M-3/13-14/ NIB-43/

^{दिनांकः} 7-05-2014

CORRIGENDUM/ADDENDUM

<u>Subject</u>: -Amended technical Specifications and other terms and conditions of Bid document alongwith Annexures for the procurement of Drug Testing Laboratory under NIT F-8 ()/RMSC/EPM/ M-3/13-14/ NIB-43/ 2464 Dated: 20.02.2014

In Reference to subject cited above and NIB-43, The Technical Specification of item (Annexure-C) is here by Amended as below.

NIB-43

Specifications after Pre-bid Meeting Changes made are made BOLD

1. Specifications for Dissolution Rate Test Apparatus (12+2 Bowl)

Programmable tablet/capsule dissolution tester as per latest IP/BP/USP with all standard Polycarbonate Jars, Jar lids, **fan paddles/immersion pump**, basket paddles with basket in acrylic bath with heater.

Microprocessor controlled automatic dissolution rate test apparatus with a comprehensive self check routine which is initiated when power is switched on, with alphanumeric waterproof keyboard or equivalent display facility and following features/specifications:-

- 1. Quick interchangeable between USP 1 and 2 Method of testing.
- 2. Suitable for sustained and controlled release pharmaceutical products.
- 3. Microprocessor controlled electronic speed controller with automatic preselection.
- 4. Speed range: 20 to 200 rpm or better with ±1% accuracy
- 5. Water bath should be made of acrylic/equivalent material with capacity to accommodate at least 14 bowls having a normal capacity of 1000 ml each of drawing system and On-Off.
- 6. The test vessels should be made of UV resistant Borosilicate glass or other suitable transparent material.
- 7. Temperature range should be Ambient to 39.9 C or above with minimum stability of ± 0.5 C with auto calibration system and that should not start until required temperature is achieved.
- 8. Output: (A) RS 232 port for PC connectivity (B) Print out of test parameters and report.
- 9. Evaluation software suitable to evaluate the dissolution profile and percent dissolved values of the sample. The evaluation software should have facilities to programmed parameter and process report. The software should make the system GLP and Pharmacopeial compliance
- 10. Time interval Selector- In steps of 1 minute.
- 11. Temperature sensor Pt 100
- 12. Dissolution process time-1 min to 24 hours and more.
- 13. Method storage: 10 programs or more with parameters.
- 14. Bowl temperature system for 12 Bowls.

15. PQ/IQ/OQ Documents should be provided.

16. System should be PC compatible.

EXTRA ACCESSORIES (other than standard accessories):

- (i) PTFE coated paddles-14 nos.
- (ii) Gold plated baskets with basket holder-14 nos.

(iii) As per U.S.P Apparatus 5 (Paddle over disc) & Apparatus 6 (Cylinder) - One Set each

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- (iv) Sinkers for capsules- 32 nos.
- (v) Chemical resistant poly carbonate bowls-14 nos.
- (vi) Calibration/Validation Kit containing following or equivalent facility kit:-
 - (a) Temperature indicator to measure bowl temperature during analysis (Thermometer)—01.It should be certified.
 - (b) Tachometer to check paddle speed -01.It should be certified.
 - (c) Wobbling test kit to measure wobbling of the paddle-01
 - (d) Calibration tablets as per USP): Prednisolone Tablets: 30 tablets 30 tablets

vii) Bowl stand for eight bowls-02 NOS.

<u>Computer Specifications: (Higher configuration will be preferred)</u> Make: HP/Dell/IBM

Form factor: Tower; Processor: Intel i3 (3rd generation)

Display Size : 18.5" TFT screen

Memory: 2 GB DDR3; Hard Drive: 500GB SATA

Optical drive: Multidrive DVD writer; Wireless: Wifi 802.11 b/g/n Ethernet:10/100/1000 Ethernet; Graphics: Intel HD Graphics Connectivity: Serial port required for instrument connectivity Cord less Multimedia Keyboard, Optical Mouse with mouse pad

Printer: Heavy duty Laser Printer with minimum 20 ppm print speed.

Operating System : Genuine Windows 8 / Windows 7 with media and documentation and certificate of Authenticity. Preloaded latest Licensed Antivirus Software

Specifications after Pre-bid Meeting Changes made are made BOLD

2. Specifications For Digital Refractometer

Digital Refractometer with the following features & specifications:

- 1. Measurement Scales: Refractive Index, BRIX (% Sucrose), Temperature Corrected BRIX
- 2. Range: 1.33 1.70 RI or better
- 3. Brix : 0 100 (% sucrose)

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- 4. Reproducibility & Accuracy: ± 0.0001 RI, ± 0.1 BRIX or better
- 5. Sample Compartment: Easy to clean prism
- 6. Optical Wavelength: 589 nm
- 7. Ambient Temperature Limit: 5°C to 40°C
- 8. Temperature Control Range: 5°C to 95°C
- 9. Calibration: Multipoint calibration with NIST Traceable standards. Minimum two calibration point liquids should be provided with certificate.
- 10. Display: LCD Screen
- 11. Output: RS 232 and USB port for PC connectivity or datasheets printouts
- 12. Documents: PQ/IQ/OQ/Calibration certificates etc.
- 13. Software should be upgradable for 21 CFR compliances



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Table-1

List of equipments and instruments (NIB No. 43)

S. No.	Name of Equipment & Instruments (Catalogues)	Estimated Quantity (In no.)	Bid Security for Non SSI Units	Bid Security for SSI Units
1.	Melting Point Apparatus	01 (One)	4000	1000
2.	Filtration Unit (Autoclavable)	07 (Seven)	5000	1500
3.	Disintegration Test Apparatus	01 (One)	1200	300
4.	Muffle Furnace :	01 (One)	1500	500
5.	Ultrasonic Cleaner (Sonicater)	02 (Two)	2500	600
6.	Dissolution Rate Test Apparatus (12+2 Bowl)	01 (One)	24000	6000
7.	Digital Refractometer	01 (One)	18000	4500

BID FORM FOR RATE CONTRACT OF MEDICAL EQUIPMENT AND INSTRUMENT

Bid Security: - As per table-1

Annexure-B

- A. General Terms and Conditions
- 11. Bid Security:
- (i) Bid shall be accompanied with a bid security **as per table -1**. Bids submitted without sufficient bid security will be summarily rejected.
- (iii) Firms which are registered as micro or SSI Unit of Rajasthan with Commissioner of Industries, shall furnish the amount of bid security **as per table -1**. In respect of items for which they are registered to manufacture, shall submit an attested copy of acknowledge of EM-II issued by DIC, with an affidavit on non-judicial stamp paper worth Rs. 10/- as per Annexure-J.

E-bids are invited as per following revised time schedule:-

Last Date for Sale of Bid	Last Date of Receipt of Bid	Date of Opening of Technical	
Form	Form	Bid	
30-May-2014	30-May-2014	30-May-2014	
11:00 AM	01:00 PM	03:00 PM	

Please note that all above amendments in technical specifications/bid conditions is the integral part of Annexure-C and bid document. This corrigendum/ addendum shall be signed and annexed with bid document. This bears the approval of M.D., RMSCL, Jaipur.

Executive Director (EPM)

RMSC, Jaipur

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