संचालनालय स्वास्थ्य सेवायें
मध्यप्रदेश

क्र./औ.प्र./2014/3326 भोपाल/दिनांक- 05/11/14

प्रति,

समस्त मुख्य चिकित्सा एवं स्वास्थ्य अधिकारी,
समस्त सिविल सर्जन सह मुख्य अस्पताल अधीक्षक,
समस्त फार्मासिस्ट जो मुख्य चिकित्सा एवं स्वास्थ्य अधिकारी एवं
सिविल सर्जन सह मुख्य अस्पताल अधीक्षक के औषधि स्टोर में पदस्थ है।

विषयः—औषधियों के परीक्षण हेतु सेम्पलिंग के निर्देश बाबत्।

संदर्भः—पूर्व के पत्र कमांक/औ.प्र./2014/2450 दिनांक 11.06.14

औषधियों की गुणवत्ता सुनिश्चित करने के लिए केवल WHO-GMP प्रमाणित निर्माता जिनके पास Certificate of Pharmaceutical Product (COPP) है, उनकी ही निविदा राज्य स्तर पर आमंत्रित कर दर निर्धारित की जाती है। WHO-GMP प्रमाणित दवाएं ही विदेश में निर्यात की जाती है। निर्माता से औषधि प्रदाय के साथ NABL Lab Test की रिर्पोट प्राप्त कर ही उपयोग/भुगतान किया जाए।

दवा नीति 2009 के अनुसार दवा के प्राप्ति के 03 दिवस के अंदर औषधियों के सेम्पल लेकर गुणवत्ता जांच हेतु संचालनालय द्वारा अधिकृत NABL Lab में परीक्षण हेतु भेजा जाना है। अतः आपको निर्देशित किया जाता है कि औषधि प्राप्त होने के 03 दिवस में ही सेम्पल लेकर परीक्षण हेतु अधिकृत लेब में भेजे। औषधि परीक्षण उपरान्त NABL Lab की निर्धारित दरों पर आपको बिल प्राप्त होगा, जिसे प्रमाणित कर संचालनालय को भेजे जिससे उसका भुगतान किया जा सके। संचालनालय द्वारा 08 NABL Lab को गुणवत्ता परीक्षण हेतु अधिकृत किया गया है, जिनकी दरें संलग्न कर आपको भेजी जा रही है।

सभी रोगियों को सूचित किया जाये कि उन्हें सर्वोच्च गुणवत्ता वाली प्रमाणित दवा ही प्रदाय की जा रही है।

संलग्नः—1. दवाओं के सेम्पल लेने की विधि।

2. दरों की सूची।

संचालक
लोक स्वास्थ्य एवं परिवार कल्याण
मध्यप्रदेश

पृ./क्र./औ.प्र./2014/3327 भोपाल/दिनांक - 05/11/14

प्रतिलिपिः–सूचनार्थ प्रेषित।

1. आयुक्त स्वास्थ्य, म.प्र.।
2. अपर संचालक, औ.प्र. स्थानीय कार्यालय।
3. उप संचालक, औ.प्र. स्थानीय कार्यालय।
4. समस्त संभागीय संयुक्त संचालक मध्यप्रदेश।

संचालक
लोक स्वास्थ्य एवं परिवार कल्याण
मध्यप्रदेश

List Of Empanelled Labs (Accrediated by NABL) 2014-15 for 03years

1. Bangalore Test House
   D-36 4th main KSSIDC Industrial Estate , Rajajinagar
   Bangalore -560044
   testhouse@satyam.net.in
   080-23356415/23388895/23502684/23502689

2. Ozone Pharmaceuticals Ltd
   639-640, M.I.E. , Bahadurgarh- 124507
   ozonelab@ozonegp.com
   01276-267792,267137

3. Oasis Test House
   24 A-B , Sardar Patel Industrial Estate Narol, Ahemdabad -382405(Gujarat)
   support@oasistesthouse.com
   +9107925712618

4. International Testing Center
   86, Industrial Area, Phase-I
   Panchkula Haryana- 134109
   itc86@yahoo.com
   0172-2565825, 9814034094

5. Sophisticated Industrial Materials Analytic Labs Pvt. Ltd.
   A- 3/7, Mayapuri Industrial Area, Phase –II , new Delhi – 110067
   testing@simalab.co.in
   011-43848300

6. Standard Analytical Laboratory(ND) Pvt. Ltd
   69, F.I.E. Patparganj, Delhi – 110092
   E.mail: info@testinglaboratoryindia.com
   011-22143265, 9811110672

7. Pharmaffiliates Analytics & Synthetic (P) Ltd
   Plot No. 225, Industrial Area , Phase –II
   Panchkula, Haryana – 134109
   admin@ pharmaffiliates.com

8. Shree Krishna Analytical Services
   A- 5/4 MayaPuriInduatrial Area
   Phase-2, New Delhi
   shreekrishnalab@gmail.com
   011-28115459,41848475, 9811012154

Sampling Operations

Sample Quantum

Sample drawn from each batch of drug must be sufficient in quantity so as to complete the test and analysis as Pharmacopeia /Protocol of test as provided by the supplier, and if required, repeat test by the testing laboratory.

Sampling and testing may be adjusted according to experience with the specific source (e.g. manufacturer or supplier) of the product. When a consignment is composed of two or three batches from the same manufacturer, a single sample taken from each batch may suffice, provided that favourable documented experience has previously been gained with the product and the manufacturer, and that there is evidence from the expiry date, or other information, that the batches were produced at approximately the same time.

Unless otherwise required as per Pharmacopoeia or protocol of test, each portion of sample may contain a quantum of sample as stated below:

Serial No.	Dosage Form	Quantity
01	Tablets	100 Tablets
02	Capsules	100 capsules
03	Syrups	30 Bottles
04	Injection	100 amp of 1 ml each
	Injection	60 amp of 5 ml each
05	Large Volume Infusion	12 Bottles
	Small Volume infusion	20 Bottles
06	Powder for Injection (Sterile)	40 vials
07	Dry Powder for oral suspension	30 Bottles
08	Bulk Drugs	20g in sealed glass bottles (5X4 bottles)
09	Ointment/Gel Tubes	20
10	Eye/Ear Drops	50 vials
11	Inhalers	10 No.
12	Pessaries	60 No
13	Suppositories	60 No.
14	ORS	40 Sachets

Sampling Operations:

Before taking samples, consignments, packages and documentation should be inspected for any sign of damage or inconsistencies which might indicate mix-ups or fraud. In case of suspected fraud, regulatory authority should be informed and also highlighted in Sample Collection Form.

It is important to draw a representative sample of the batch. In order to ensure, ‘n’ sampling plan may be adopted. Sampler /Inspecting official may identify number of shipper packages in a batch. Under this plan sampler/inspecting official may take under root of the number of

packages (n1/2) after arriving at a whole number (if required rounded to near number), and can randomly draw sample. While drawing sample following may also be kept in mind:

1) To ensure that the representative sampling is carried out and the operations in no way contaminate the samples drawn. **The package from which samples have been drawn should be pasted with slips indicating the number of primary packages drawn, names and signatures of the sampler.**

2) The unit dosage pack should not be disturbed in order to ensure stability and integrity of the product. The identity of the product can be concealed by
   a. Defacing the labels of solid dosage forms (strips and pouches)
   b. Removing labels from bottles/vials/ampoules
   c. Scratching the label on tubes/caps of the bottles

3) After completion of sampling, the sampled items of drugs/other items must be signed and marked with the seal of warehouse/stores pharmacist.

4) To carry out the packaging of the samples in such a way that integrity of the samples is maintained during packaging and transportation and that no cross contamination takes place during transit to Laboratory

5) To code mark the samples in such a way that the name of manufacturer does not come in the knowledge of testing laboratory. Enough care must be taken while coding samples so as to protect the quality of the product

All tools and implements used in the sampling should be kept scrupulously clean. Before use they should be thoroughly washed, rinsed with water or a suitable solvent and dried

It is desirable that the collection process need to be supervised to remove risk of substitution or adulteration to rule out false positive or false negative

Packaging of Sample

Quality of the sample of the said drug must be protected by the sampler while drawing, packing and sealing and dispatching the sample to the testing laboratory. **Special protection arrangements are required for thermo labile products. For such materials, Cold chain must be maintained throughout the transit, from sampling site to receipt of the same at the testing laboratory.**

Primary consideration is that the sample should reach the laboratory intact without loss of the sample. Improper packaging results in loss of the sample. Following precautions should be takenin the packaging the samples

a) to ensure the stability of the matrix of the sample and to withstand the rigours of the transportation and the environmental stress
b) There is no breakage
c) There is no deterioration
d) There is no mix-up
e) There is no spillage and leakage

Protected from heat, air, light and moisture, each sample can be placed in a PE plastic zip lock bag and plastic bag can be placed in a labelled envelope to keep out of the light. Depending upon the type of material, the sample size of the consignment and the packs are shrink-wrapped or boxed together, rather than an individual container.