World Journal of Pharmaceutical Sciences
ISSN (Print): 2321-3310; ISSN (Online): 2321-3086
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Available online at: http://www.wjpsonline.org/
Short Communication

Survey, assessment and development of quality standards and parameter's for brand and generic drugs available in the market

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Received: 18-07-2014 / Revised: 25-07-2014 / Accepted: 27-07-2014

ABSTRACT

Quality can be defined as the suitability of the goods or service to the determined qualifications. Quality control tests help to ensure the total quality of the product. The entire dealing process involves stringent tests to make products totally flawless before they are released into the market. But sometimes recalls and complains occur despite such strong control procedures which presents us with an opportunity to do a survey for new or drugs already present in the market & their availability so that it stands up to the reputation with respect to qualitative and quantitative characteristics with which the product must comply throughout its shelf life. The present work deal's with assessment and development of special quality system for the medicines. The specification limits of the finished product at the time of batch release are set by the marketing authorization applicant such that the specifications proposed at the end of shelf life are guaranteed and are established on the basis of a critical review of the data gathered from the batches analyzed and surveyed. Since the markets have opened up due to globalization it is necessary for a product to comply with the standards of the place & throughout the globe.

Keywords: quality, globalization, brand, shelf –life, recall

INTRODUCTION

India is a vast country with diverse and complex socio cultural, economic and political fabric. Notwithstanding this complexity, within a few decades since independence in 1947, the nation has became self-sufficient in catering to the medicine needs of its people and transformed itself from a high medicine price nation to one with relatively low drug prices. However, contemporary challenges like industrial policy reform, economic liberalization and globalization, decontrol measures, and, above all, the World Trade Organization agreement obligations, tend to make the cherished matter of equitable access to essential medicines elusive. The issue of inequitable access and affordability of essential medicines is one of global concern and is being increasingly voiced in India in the backdrop of the ongoing economic changes. Therefore it is a global obligation to ensure availability and affordability of essential medicines. Worldwide, there are a multitude of medicines with a multitude of prices. The same medicine has different prices depending upon the source from which it is procured, the form in which it is marketed (e.g. brand or generic, oral or parenteral, course of treatment pack or bulk pack, etc.), the taxes and duties that are levied by governments and the facilities from which it is procured by patients. It is an extremely complex task, whether for individuals or for governments, to ascertain the optimum availability and best prices for medicines. Therefore it is necessary to monitor these parameters on a regular basis. WHO and HAI have collaborated to develop a methodology for measuring medicines prices and availability. This has already been field tested in a number of countries and is being refined in the process. The availability and pricing of essential medicines in the state of Rajasthan has been assessed earlier following the same methodology.

MATERIALS AND METHODOLOGY

Double distilled water, methanol,0.1N sodium hydroxide, 3 brands of tab (paracetamol) & cap (amoxicillin), 3 brands of suspension (aluminium hydroxide & magnesium hydroxide),3 brands of syrup (dextromethorphan hydrobromide & chlorpheniramine maleate),filter paper,50 & 100ml

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beaker,1ml and 5ml pipette,silica beads, separating funnel,std. samples of amoxicillin & paracetamol, dil.HCL, Conc. HNO3,pot.dihydrogen phosphate , NaOH pellets, pycnometer,silver nitrate all chemicals used were of analytical grade.(merck).

Survey method or techniques, strategies,steps & indicators layout:

Pharmaceutical indicators for monitoring and assessment

- ✓ Survey Planning, design, and Preparation on Indicator-based monitoring strategies.
- ✓ Pharmaceutical components in Level I indicators
- ✓ Level -II indicators
- ✓ Selecting public health facilities & Making random selections
- ✓ Selecting private drug outlets
- ✓ Sampling dosage form & patients for data collection

Preparing the survey for selection and identification.

- ✓ Tailoring the survey reports to statewise situations by choosing key medicines model list, selecting tracer conditions and identifying treatment protocols.
- ✓ Selecting & identifying basket of key medicines or indicator medicines.
- ✓ Identifying medicines to be considered as antibiotics, antipyretics, antacids & cough syrups etc.
- ✓ Identify standard criteria for adequate labelling and patient knowledge
- ✓ Identifying unit price of medicines for obtaining global and regional drug prices [paid by the patient or paid by the facility]

Data processing, analysis and reporting.

- ✓ Computation of Quality of data and information.
- ✓ Collection,analysis and interpretation of indicators.
- ✓ Limitations of the Level II facility survey
- ✓ Indicator measure for Level II facility indicators
- ✓ Performance standards for Level II facility indicators
- ✓ Written report.

TABLETS

Moisture contents of the tablets: The 10 tablets were pre weighted and beads of silica gel(blue) completely were dried in hot air oven at 100C for 3-4 hrs and weighted. Then they were kept in an container i.e,dessicator for 24 hrs and weighted again.the moisture content % was found out by

$$\frac{\text{wt. of silica kept after with tabs-wt. of silica kept before with tabs}}{\text{wt. of silica before kept with tabs}} * 100$$

this technique is developed and can be used if there is no moisture analyser. and the amount should not be more than 0.5% as specified in the monograph.

Thickness of the tablets: The thickness of the tablets were recorded in mm using vernier caliper. The caliper jaws are adjusted and then 10 tablets one by one are introduced inside the jaws of the caliper, then the divison adjustment is made and the point where the jaws tip just touches give the reading then the avg. reading is taken and data is cal.for eg.

A. The main metric scale is read first and this shows that there are 13 whole divisions before the 0 on the hundredths scale. Therefore, the first number is 13.

B. The' hundredths of mm' scale is then read. The best way to do this is to count the number of divisions until you get to the division that lines up with the main metric scale. This is 21 divisions on the hundredths scale.

C. This 21 is multiplied by 0.02 giving 0.42 as the answer (each division on the hundredths scale is equivalent to 0.02mm).

D. The 13 and the 0.42 are added together to give the final measurement of 13.42mm.

Preparation of std. solution of paracetamol: Weigh accurately a quantity of the powder containing about 100mg of Paracetamol, add 50 ml of 0.1 M sodium hydroxide, dilute with 50 ml of water, shake for 15 minutes. Mix & filter. now take 10ml of the filtrate and to the 10.0 ml of the resulting solution add 10 ml of 0.1 M sodium hydroxide, dilute to 90.0 ml with water and mix Measure the absorbance of the resulting solution at the maximum wavelength.

Assay of active ingredients (according to I.P): Weigh and powder 20 tablets. Weigh accurately a quantity of the powder containing about 0.15 g of Paracetamol, add 50 ml of 0.1 M sodium hydroxide, dilute with 50 ml of water, shake for 15 minutes and add sufficient water to produce 100.0 ml. Mix, filter and dilute 10.0 ml of the filtrate to 100.0 ml with water. To 10.0 ml of the resulting solution add 10 ml of 0.1 M sodium hydroxide, dilute to 100.0 ml with water and mix Measure the absorbance of the resulting solution at the maximum at about 247 nm . Calculate the content of $C_8H_9NO_2$ taking 715 as the specific absorbance at 247 nm. The tablet brands were taken marked as A,B&W respectively.

Weight variation of uncoated tablets.(according to USP): The weight variation of the tablets can be measured by weighing 20 each individual tablets and determining the percent difference from the intended amount. Guidelines in the USP 24/NF19 Supplement 1 indicate that each tablet "shall be not less than 90% and not more than 110% of the theoretically calculated weight for each unit.

$$Highest\ weight\ variation = \frac{\text{Highest weight} - \text{Average weight}}{\text{Average weight}} \times 100$$

$$Lowest\ weight\ variation = \frac{\text{Lowest weight} - \text{Average weight}}{\text{Average weight}} \times 100$$

Hardness test: The 10 tablets are tested for hardness by pfizer hardness tester, the tablets are crushed under pressure of kg/cm3 and the avg. value of the tablets is cal.the range shuld not be more than 20kg/cm3 for oral tablets.

Disintegration test: Place one dosage unit in each of the six tubes of the basket and if specified add a disc. Operate the apparatus using water as the immersion fluid unless another liquid is specified and maintain its temperature at 35-39 °C. At the end of the specified time, lift the basket from the fluid and observe the dosage units: all of the dosage units have disintegrated completely. If one or two dosage units fail to disintegrate, repeat the test on 12 additional dosage units. The requirements of the test are met if not less than 16 of the 18 dosage units tested are disintegrated.

Friability test: The friability test is done using a friabilator,20 tabs are weighted=w1.put these tablets into the friabilator and adjust the instrument at 100rpm(25rpm for 4 minutes),weight the tablet which are intact=w2,then the % loss is calculated. It must be less than or equal to 1%.

$$f = \left(1 - \frac{w}{w_0}\right) \times 100$$

where W o and W are the weights of tablets before and after the test

Dissolution test (according to international pharmacopoeia): The apparatus "Paddle" is used for this work.

Preparation of the dissolution medium

- Select the dissolution medium-Phosphate buffer ,Ph-5.8
- At first 900ml of dissolution medium was placed in bath container. The tablet was introduced in to the bath container, the paddle was rotated at 50RPM up to 30 minutes.5ml of sample solution was withdrawn from batch container and again 5ml of fresh dissolution medium was replaced into the bath container to maintain the constant volume.
- Thus the sample withdrawn within the specified time intervals such as 5,10,15,20 & 30 minutes. The obtained sample solution were subjected to 1 in 10 dilutions by using phosphate buffer PH-5.8.The obtained sample solutions optical densities were measured at maximum at about247nm against the blank using spectrophotometer.

The absorbance values were noted

CAPSULES

Moisture contents of granules and shell: The 10 capsules were pre weighted and beads of silica gel(blue) completely were dried in hot air oven at 100C for 3-4 hrs and weighted. Then they were kept in an container i.e, dessicator for 24 hrs and weighted again. the moisture content % was found out by

wt. of silica kept after with tabs-wt. of silica kept before with tabs * 100
wt. of silica before kept with caps

This technique is developed and can be used if there is no moisture analyser. and the amount should not be more than 0.5% as specified in the monograph.for capsules either the capsule as whole can be tested or separately the drug and the shell moisture can be determined also.

Preparation of std. solution of amoxycilllin trihydrate: Weigh accurately a quantity of about 10 mg of amoxicillin, add about 80 ml of the solvent(water) mixture and dissolve by shaking for 15 minutes and mixing if necessary, with the aid of ultrasound. Dilute to 100.0 ml with the solvent mixture and filter. Then take 10ml of this filtrate and dil with 50 ml solvent to get a final resulting solution.Use this solution within 6 hours. The capsule brands were taken marked as C, D &X respectively.cal. the specific absorbance of the content at max wavelenghth.

Assay of active ingredients (according to I.P): Weigh accurately a quantity of the mixed contents of 20 capsules containing about 100 mg of amoxicillin, add about 80 ml of the solvent(water) mixture and dissolve by shaking for 15 minutes and mixing if necessary, with the aid of ultrasound. Dilute to 100.0 ml with the solvent mixture and filter. Use this solution within 6 hours. The capsule brands were taken marked as C, D &X respectively.cal. the content at 272nm.

Weight variation of capsules (according to international pharmacopoeia): Weigh 20 intact

capsules individually, and calculate the average mass. The mass of each capsule should be within ±10% of the average mass. If all the capsules do not fall within these limits, weigh the 20 capsules again, taking care to preserve the identity of each capsule, and remove the contents as completely as possible. Weigh the emptied shells individually and calculate for each capsule the net mass of its contents by subtracting the mass of the shell from the gross mass. Determine the average net content from the sum of the individual net masses. Then determine the difference between each individual net content and the average net content. Deviation of individual net mass from the average net mass should not exceed the limits given below

Net weight = Filled capsule weight – Empty capsule weight

$$\text{Percentage Deviation} = \frac{(\text{Net weight} - \text{Average weight})}{\text{Average weight}} \times 100$$

Size of capsules: The size of the capsules were recorded in mm using vernier caliper,care should be taken that the caliper jaws don't squeeze the top and the lower body part of capsule. The caliper jaws are adjusted and then 10 capsule one by one are introduced inside the jaws of the caliper, then the divison adjustment is made and the point where the jaws tip just touches give the reading then the avg. reading is taken and data is cal. for eg.

A. The main metric scale is read first and this shows that there are 13 whole divisions before the 0 on the hundredths scale. Therefore, the first number is 13.

B. The' hundredths of mm' scale is then read. The best way to do this is to count the number of divisions until you get to the division that lines up with the main metric scale. This is 21 divisions on the hundreths scale.

C. This 21 is multiplied by 0.02 giving 0.42 as the answer (each division on the hundredths scale is equivalent to 0.02mm).

D. The 13 and the 0.42 are added together to give the final measurement of 13.42mm.

Disintegration test: Place one dosage unit in each of the six tubes of the basket and if specified add a disc. Operate the apparatus using water as the immersion fluid unless another liquid is specified and maintain its temperature at 35-39 °C. At the end of the specified time, lift the basket from the fluid and observe the dosage units: all of the dosage units have disintegrated completely. If one or two dosage units fail to disintegrate, repeat the test on 12 additional dosage units. The requirements of the test are met if not less than 16 of the 18 dosage units tested are disintegrated.

Dissolution test (according to international pharmacopoeia): The apparatus "Basket" is used for this work.

Preparation of the dissolution medium

- Select the dissolution medium-double distilled water,Ph-6.8
- At first 900ml of dissolution medium was placed in bath container. The tablet was introduced in to the bath container, the paddle was rotated at 100 RPM up to 1 hr .5ml of sample solution was withdrawn from batch container and again 5ml of fresh dissolution medium was replaced into the bath container to maintain the constant volume.

-Thus the sample withdrawn within the specified time intervals such as 5,10,20,30,40,50,and 60 minutes. The obtained sample solution were subjected to 1 in 10 dilutions by using double distilled water. The obtained sample solutions optical densities were measured at maximum at about 272nm against the blank using spectrophotometer.

The absorbance values were noted

SUSPENSION

Ph: The sample of the suspension was taken in a 50 ml beaker cleaned and dried before properly measuring the ph, the ph was measured using meter Toledo digital ph meter.

Viscosity: The viscosity of the suspension was determined by first finding the specific density with pycnometer and the known and unknown liquids the known liquid was taken as water with unknown liquid as the syrup sample.then the viscosity found out is the kinetic viscosity which is cal. to find out the dynamic viscosity.

$$\nu = \mu / \rho$$

where ν = kinematic viscosity, μ = absolute or dynamic viscosity, ρ = density.

Sedimentation ratio: Determine the sedimentation ratio of each suspension. a sample of aluminium hydroxide was prepared and compared with sample suspension. Shake the suspension vigorously making sure all of the particles are uniformly suspended, and note the time. Observe the boundary between the sediment and the supernatant and record the time it takes for the boundary to pass each 10 ml graduation until the volume of sediment has reached 30 ml. The best way to observe the boundary is to view it directly in front of a light source. You might try viewing it with sunlight from the windows as your light source. You should note whether there is a clear and distinct boundary or no obvious boundary. Record the data

Plot the volume of sediment vs. time and draw the best straight line. The slope will be equal to the sedimentation rate. Redisperse and allow each suspension to sit undisturbed for 24 hours. Then, determine and record the final volume of sediment.
Estimate the degree of caking in each system. After allowing the suspensions to sit for 3 or 4 days, determine the number of times the bottle must be inverted to re suspend all of the particles some suspension may take 15-30 days for observation.
The sedimentation volume, F, is the ratio of the equilibrium
volume of the sediment , Vu, to the total volume of the
suspension , Vo Thus,
F=Vu/Vo

Weight per ml

1.Determine the weight of empty, dry pycnometer m0.
2.Fill about 1/3 of pycnometer volume with objects made of examined material (glass beads or small metal pieces as directed by the teacher) and measure the weight m1.
3.Add water such that pycnometer as well as capillary hole in the stopper is filled with water. Dry the spare water that leaks through the capillary hole with a filter paper and measure total weight m2.
4.Empty pycnometer and filled it with distilled water only. Use the filter paper to dry the spare water again and measure the weight m3.
5. Empty pycnometer. Rinse it once with a liquid whose density you are going to determine next. Fill pycnometer with the liquid as previously and measure the weight m4.
6. Repeat point 5. for several different liquid materials.
7. Clean pycnometer carefully after finishing the experiment. Rinse it with distilled water and let dry.
8. Measure the laboratory temperature t, which determines the temperature of examined liquids and solid objects.

$$\rho_L = \frac{m_L}{m_{H2O}} \cdot \rho_{H2O}$$

SYRUP

Ph: The sample of the syrup was taken in a 50 ml beaker cleaned and dried before properly and the ph was measured using meter Toledo digital ph meter.

Viscosity: The viscosity of the syrup was determined by first finding the specific density using pycnometer and the known and unknown liquids the known liquid was taken as water with unknown liquid as the syrup sample.then the viscosity found out is the kinetic viscosity which is cal. to find out the dynamic viscosity.

$\nu = \mu / \rho$

where ν = kinematic viscosity, μ = absolute or dynamic viscosity, ρ = density.

Sugar conc.: The conc. of the sugar was found out by finding out the viscosity of the sample and then comparing the viscosity with the standard brix of various liquids. The range of the sucrose falling under the particular brix for the particular viscosity of the syrup sample was thus calculated.

Weight per ml

1. Determine the weight of empty, dry pycnometer m0.
2. Fill about 1/3 of pycnometer volume with objects made of examined material (glass beads or small metal pieces as directed by the teacher) and measure the weight m1.
3. Add water such that pycnometer as well as capillary hole in the stopper is filled with water. Dry the spare water that leaks through the capillary hole with a filter paper and measure total weight m2.
4. Empty pycnometer and filled it with distilled water only. Use the filter paper to dry the spare water again and measure the weight m3.
5. Empty pycnometer. Rinse it once with a liquid whose density you are going to determine next. Fill pycnometer with the liquid as previously and measure the weight m4.
6. Repeat point 5. for several different liquid materials.
7. Clean pycnometer carefully after finishing the experiment. Rinse it with distilled water and let dry.
8. Measure the laboratory temperature t, which determines the temperature of examined liquids and solid objects.

$$\rho_L = \frac{m_L}{m_{H2O}} \cdot \rho_{H2O}$$

where mH2O is experimentally determined weight of water (empty pycnometer weight subtracted) and We repeat the procedure for the liquid with unknown density ρL and determine its weight mL (measured weight minus weight of empty pycnometer).

RESULT

Key medicines to treat common disease (A)	in stock (B) Yes(1),No(0)	Expired drugs(C) Yes(1),No(0)
1.PARACETAMOL TAB 2.AMOXYCILLIN CAP 3.ANTACID SUSP 4.COUGH SYRUP 5.PANTOPRAZOLE TAB	1 0 1 1 1	0 1 0 0 0
	[B1] = Sum of B = 4 [B2] = % in stock =80 B1 ÷ 5 x 100 = 4÷5 x 100	[C1] = Sum of C =1 [C2] = % expired =25 C1 ÷ B1 x 100 =1÷ 4 x 100

Medicine Specific Median Price Ratios (in comparison to MSH 2007 median price) and Availability in the Public & Private Sector

MEDICINE	MEDICINE TYPE	MEDIAN	25%ILE	75%ILE	MIN-MAX	% With MED.
PARACETAMOL TAB	BRAND	2.00	1.83	1.99	.85-2.25	94.3
	MOST SOLD	2.00	1.83	1.17		94.3
	LOWEST PRICE	.89	.68	1.38		94.3
AMOXICILLIN	BRAND					5.7
	MOST SOLD	5.60	5.42	5.90	5.30-9.92	77.1
	LOWEST PRICE	5.43	5.96	5.64	3.84-8.47	94.3
ANTACID SUSP	BRAND	1.23	1.23	1.29	1.21-1.43	54.3
	MOST SOLD	1.23	1.22	1.28	0.74-1.36	88.6
	LOWEST PRICE	1.23	1.22	1.28	0.74-1.36	88.6
COUGH SYRUP	BRAND	5.59	5.45	5.71	3.73-6.11	91.4
	MOST SOLD	4.75	4.75	5.04	2.37-5.22	35.5
	LOWEST PRICE	4.75	4.51	4.91	2.37-5.33	35.5
PANTOPRAZOLE TAB	BRAND	5.59	5.45	5.71	3.73-6.11	65.7
	MOST SOLD	4.75	4.75	5.04	2.37-5.72	94.3
	LOWEST PRICE	4.75	4.51	4.91	2.37-5.05	94.3

EVALUATION OF API AND BASIC DRUG TESTS WITH QUALITY PARAMETERS

MELTING POINT RANGE DETERMINATION

- The M.P of reference powder of Paracetamol was found out to be-165-172 ºC
- The M.P of reference powder of Amoxycillin was found out to be-193-200ºC

EXTRATION, SEPERATION & IDENTIFICATION OF DRUGS FROM THE FORMULATIONS

Both the test confirmed the presence of the drug claimed on the label based on the basic tests developed for both the formulations. The method was reffered and verified through various article and literature search.

TABLETS

Moisture contents of the tablets

Moisture content of the tab of brand A-
The moisture content of the brand A was found to be 0.009%

Moisture content of the tab of brand B-
The moisture content of the brand B was found to be 0.01%

Moisture content of the tab of brand W-
The moisture content of the brand W was found to be 0.002%

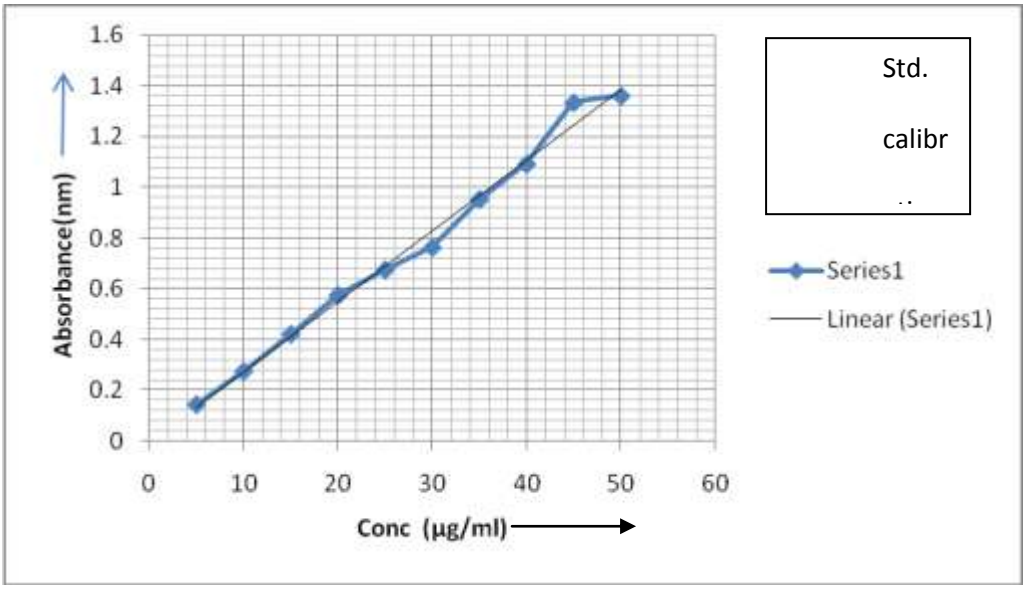
Thickness of the tablets

Thickness of the brand A-4.836mm
Thickness of the brand B-4.638mm
Thickness of the brand W-4.528mm

Assay of active ingredients

Std. calibration curve of pure Paracetamol drug.

Conc (µg/ml)	5	10	15	20	25	30	35	40	45	50
Abs (nm)	.143	.274	.421	.574	.675	.763	.953	1.092	1.335	1.361



The absorbance of the three brand of the paracetamol 500mg drug were
A-0.488nm, B-.507 nm & W-.492nm.thus the amount of drug of paracetamol was found out by the eq.

Abs.of sample ×**dil. of std.** ×**avg. wt of the tab,**
Abs.of std dil. of sample

Therefore,
avg. wt. of brand A tab=0.629gm
Amount of paracetamol (mg) for brand A= 488/715 ×1/100 × 200/188.70 × 100/10 × 100/10 × 0.629
=0.454gm=454mg

avg. wt. of brand A tab=0.633gm
Amount of paracetamol (mg) for brand B= 507/715 ×1/100 × 200/189.9 × 100/10 × 100/10 × 0.633
=0.472gm=472mg

avg. wt. of brand A tab=0.570gm
Amount of paracetamol (mg) for brand A= 478/715 ×1/100 × 200/171 × 100/10 × 100/10 × 0.570
=0.458gm=458mg

Thus all the tablets fall under the limit(90%-110%) of monograph and passes the test.

Weight variation of uncoated tablets

Weight variation of brand A= U.L = +5.72
=L.L = -2.06

Weight variation of brand B= U.L = +1.16
=L.L = -0.63

Weight variation of brand W= U.L = +2.28
=L.L = -2.63

Upper Limit=U.L=highest weight variation
Lower Limit= L.L=lowest weight variation

Hardness test

Hardness of brand A=12kg
Hardness of brand B=11kg
Hardness of brand W=9kg

Disintegration test

Disintegration time for brand A=3 minute 22 sec
Disintegration time for brand B=2 minute 54 sec
Disintegration time for brand W=1 minute 50 sec

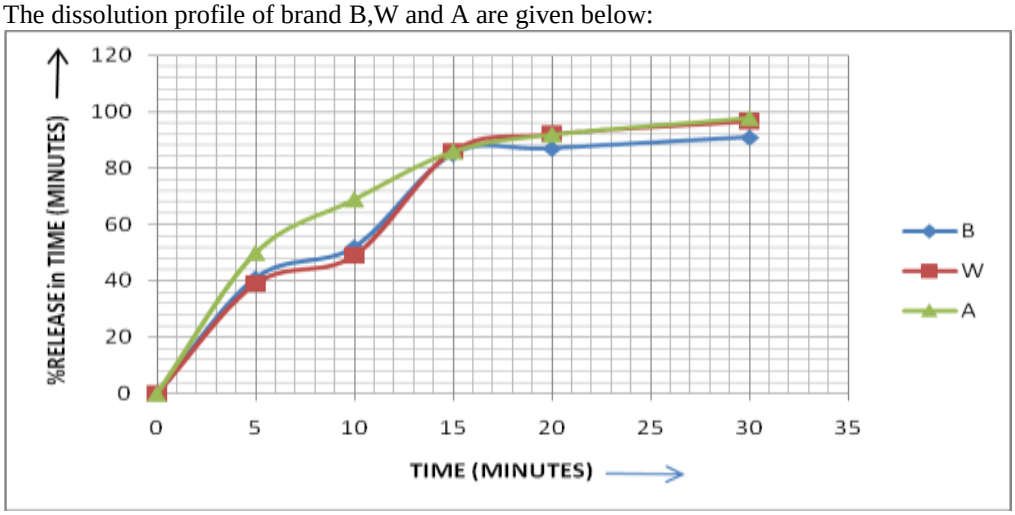
Friability test

Friability (% loss) of brand A=0.06
Friability (% loss) of brand B=0.10
Friability (% loss) of brand W=0.29

Dissolution test

DRUG	% RELEASE (minutes)				
Paracetamol	5	10	15	20	30
B	41	52	85	87	90.9
W	39	49	86	92	96.6
A	50	69	86	92	97.9

Thus all the product showed the bioavailability more than 80 % in 15 minutes and therefore passes the test.
The dissolution profile of brand B,W and A are given below:



CAPSULES

Moisture contents of the tablets

Moisture content of the tab of brand B-
The moisture content of the brand B was found to be 0.073%

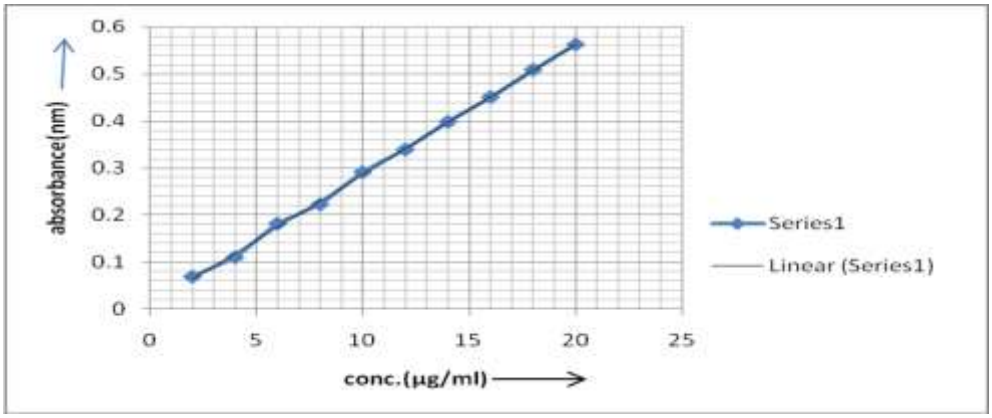
Moisture content of the tab of brand C-

The moisture content of the brand C was found to be 0.059%

Moisture content of the tab of brand X-
The moisture content of the brand X was found to be 0.067%

Assay of active ingredients
Std. calibration curve of pure amoxycilllin trihydrate drug.

Conc (µg/ml)	2	4	6	8	10	12	14	16	18	20
Abs (nm)	.0691	.1098	.1817	.2225	.2914	.3390	.3979	.4505	.5086	.5623



Weight variation of capsules

Weight variation of brand C= 16.9%
Weight variation of brand D= 19.2%
Weight variation of brand X= 18.56%
Thus the capsule passes the weight variation test.

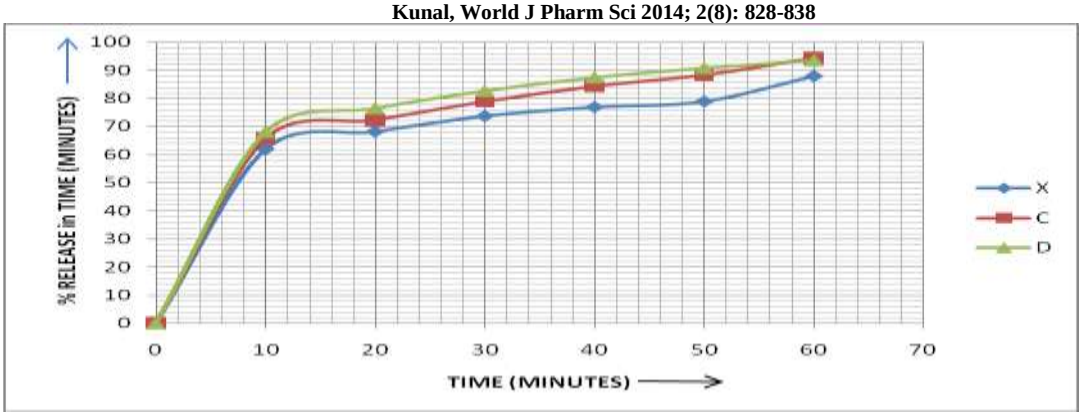
Size of capsules
Size of brand C=16.10mm
Size of brand D=15.90mm
Size of brand X=15.90mm
All the capsules after measuring fall into the size 3 category of capsule shell and also capsule capacity(mg).

Disintegration test
Disintegration time of brand C= 5minutes 25sec
Disintegration time of brand D= 4minutes 10 sec
Disintegration time of brand X= 3minutes 86 sec

Dissolution test

DRUG	% RELEASE (minutes)					
Amoxicillin	10	20	30	40	50	60
X	61.93	68.17	73.70	76.87	78.90	87.88
C	65.83	72.30	78.90	84.33	88.33	94.37
D	68.10	76.50	82.73	87.50	90.83	93.60

The dissolution profile of drugs of brand X,C and D are given below:



SUSPENSION

Ph
The Ph of the brand of suspension P is-8.08
The Ph of the brand of suspension Q is-8.32
The Ph of the brand of suspension S is-8.47

Viscosity
The viscosity of the brand P is-1250cp
The viscosity of the brand Q is-2400cp
The viscosity of the brand S is-2300cp

Sedimentation ratio
The sedimentation ratio of suspension of brand P-F=0.9
The sedimentation ratio of suspension of brand Q-F=0.9
The sedimentation ratio of suspension of brand S-F=0.8

Weight per ml
The weight per ml of brand P-5gm/5ml
The weight per ml of brand Q-250mg/5ml
The weight per ml of brand S-2.5gm/5ml

SYRUP

Ph
The Ph of the brand of suspension M is-3.17
The Ph of the brand of suspension N is-4.20
The Ph of the brand of suspension O is-5.70

Viscosity
The viscosity of the brand M is-45.7cp
The viscosity of the brand N is-127.8cp
The viscosity of the brand O is-724cp

Sugar conc.
The sugar conc. of brand M is-59%
The sugar conc. of brand M is-65.8%
The sugar conc. of brand M is-75.6%

Weight per ml
The weight per ml of brand M-5mg/5ml
The weight per ml of brand N-5mg/5ml
The weight per ml of brand O-20mg/5m

DISCUSSION

The present cross-sectional survey of availability and public procurement or private retail prices in West Bengal is perhaps the only one of its kind in recent times. The methodology utilized has already been field-tested in some of the developed countries and may be considered to be standardized, although it is still undergoing refinement. The availability situation in the public sector was found to be dismal, with few medicines (29.4%) not being available at all. The unsatisfactory public availability of essential medicines in West Bengal is common knowledge but the extent has not been documented prior to this survey. This study is therefore expected to provide valuable baseline data against which the situation in future maybe compared and the effectiveness of rectification measures assessed. The reason for the poor availability can only be speculated on at the moment, but is likely to be multifactorial with reference to the following list:

1. Inadequate selection of essential medicines.
2. Inability to attract enough suppliers to participate in the CMS open tender bidding.
3. Channelization of supplies to particular types of facilities and negligency of proper management of medicines in local shops.
4. Failure of the distribution system and proper regulation of drugs quality and availability.
5. Budgetary constraints limiting the extent of public procurement.

When it comes to pricing in the private sector, it was seen that price of same product could vary to some extent because of procurement of different batches, differences in retail margins, or rounding off of tax components. Medicines in the private sector are definitely costlier in comparison to government procurement prices.

Besides all these factors and data of information gathered randomly from different retail stores and information obtained from different patients it was concluded that people don't have clear idea of drugs, quality, policies, price, strength and information which should be conveyed to them. The poor availability in the public sector also may indirectly push up prices in the private sector by forcing patients, who would have otherwise procured their medicines from public health facilities, to depend on private prescriptions.

The quality test and few specifications done and developed for these medicines indicate that quality, price, distribution and management system and other factor's may be the reasons for drug storage, availability in terms of price and strength and also for recall and complaints may be the reason for factor's such as temp, composition, quality, physiochemical factor's etc. The survey obtained some results on supply and quality of drugs and also to obtain adequate information to ascertain the cost component of medicines apart from verification of retail margins.

Following recommendations can be made:

1. Urgent steps are needed to assess the functioning of the public distribution system for medicines in West Bengal for rectification of shortcomings.
2. Enhancing the efficiency of Central Medical Stores public procurement mechanisms. This could include broadening the base of bulk purchasing and/or wider use of regional and national alternatives.
3. Developing and promoting the concept of state level essential medicines list, based on evidence-based selection, to be used in conjunction with national and/or hospital clinical guidelines. This will help to focus procurement and increase efficiency of the supply system.
4. Public education to increase awareness of the interchangeability of generic and brand products so as to improve affordability. This would need to be preceded by research into medical practitioner and consumer attitudes towards generic medicines so as to appropriately design educational interventions to address concerns.
5. Monitoring quality along with availability and price. Samples can be collected following randomization schemes and submitted to a government approved drug testing laboratory. Results of testing may be provided as feedback to the concerned facilities.

CONCLUSION

The present survey on the availability, pricing and affordability of medicines in West Bengal has attempted to obtain reliable data on these aspects, limiting itself to a select basket of essential medicines. It has shown that medicines that are obtained from public hospitals free of cost by patients are procured economically, but the overall availability in the public sector is disheartening and needs immediate redress. Medicines are readily available from private retail counters but this comes at a price higher than international reference prices, with some brand premium for many items but quality is also an important factor that determines the safety and good quality medicines to the patients which are available in the market. Standard treatments are mostly affordable, provided that the earning member of a family draws minimum daily wages at rates specified by the government. The study has not covered all therapeutic categories or all sectors that distribute medicines to the people. Nevertheless, the results that have been obtained can serve as baseline for future studies and point to issues that need further investigation or rectification.

REFERENCES

1. Timothy Powell-Jackson, et al. An Assessment of the Quality of Primary Health Care in India
2. Ayyaz Kiani &Alia Qadeer Prices, availability and affordability of medicines in Egypt..
3. Roger Bate, et al.Pilot Study of Essential Drug Quality in Two Major Cities in India.
4. WHO: Measuring medicine prices, availability, affordability and price components 2nd edition
5. Nirmalya Manna, et al. A study on client satisfaction as per standard treatment guidelines in a rural hospital of West Bengal, India.
7. Generic Medicines: Essential contributors to the long-term health of society sector sustainability challenges in Europe.
8. Prabal Vikram Singh, et al.Understanding public drug procurement in India: a comparative qualitative study of five Indian states
9. Anita Kotwani,Where are we now: assessing the price, availability and affordability of essential medicines in Delhi as India plans free medicine for all.
10. WHO: Sources, quality & prices of API of antiretroviral drugs Results of a 2012 survey.
11. Tigray, et al.Quality Assessment of the Co mmonly Prescribed Antimicrobial Drug,amoxicillin capsules.
12. Palash Karmakar, Md. Golam Kibria. In-vitro comparative evaluation of quality control parameters between paracetamol tablets available in Bangladesh.
13. Insights for policymakers from a medicine price survey in Rajasthan: a correspondence by kotwani.
14. Creese A, et al. Evaluating pharmaceuticals for health policy in low-and middle-income country settings.
15. Government of India, National Pharmaceutical Pricing Authority homepages. Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers. http://www.nppaindia. nic.in/index1.html, accessed on February 6, 2013.
16. Management Sciences for Health. 2002. International drug price indicator guide . Available at: http://erc.msh.org, accessed on August 28, 2013.
17. Habbe Kabid Naushadari. Assessment of Different Quality Control Parameters of Marketed Brands.