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Production Capacity of the Pharmaceutical Manufacturing Industry in Kenya

S. K. VUGIGI*[1,2], G. N. THOITHI[3], J. I. OGAJI[4] and S. O. ONUONGA[5]

[1]*Elys Chemical Industries Ltd., P.O. Box 40411–00100, Nairobi, Kenya.*
[2]*Department of Pharmacy and Complementary/Alternative Medicine, Kenyatta University, P.O. Box 43844-00100, Nairobi, Kenya.*
[3]*Department of Pharmaceutical Chemistry, University of Nairobi, P.O. Box 19676-00202, Nairobi, Kenya.*
[4]*Department of Pharmaceutics and Pharmaceutical Technology, University of Jos, P M B 2084-930001, Jos, Plateau State, Nigeria.*
[5]*Department of Econometrics and Statistics, Kenyatta University, P.O. Box 43844-00100, Nairobi, Kenya.*

This study aimed to determine the production capacity in the Kenyan pharmaceutical industry and to forecast the year for full capacity utilization. Data was collected on installed, available and utilized capacities in this industry for the period 2010–2014, using a structured questionnaire. Six dosage forms namely tablets, capsules, oral liquids, external preparations, dry powders and oral rehydration salts were evaluated. Projection of capacity utilization was performed using time series forecasting method. The available capacity in billions was 29.3 tablets, 2.3 capsules, 0.4 bottles of oral liquids, 0.1 tubes of external preparations, 0.1 bottles of dry powders and 0.1 sachets of oral rehydration salts. In 2014, the overall utilized capacity was 27.4 %. The study showed that production capacity was underutilized. However, overall utilized capacity increased steadily during the five years. The forecasted year for achieving full capacity utilization for the manufactured dosage forms was 2043.

KEY WORDS: Pharmaceutical manufacturing, production capacity, installed, utilized.

INTRODUCTION

The government of Kenya, through 'Vision 2030' aims to develop a robust and competitive manufacturing sector by strengthening local production [1]. The Kenya National Pharmaceutical Policy (KNPP) is an integral part of this Vision and intends to encourage self-sufficiency in essential medicines by promotion of local production [2]. In 2014, the local pharmaceutical industry comprised 30 firms licensed by Pharmacy and Poisons Board of Kenya. This industry is engaged in secondary and tertiary production of human and veterinary medicines (24 and 6 facilities, respectively). The products which are manufactured are mainly non-sterile (97.3 %). Three companies make sterile dosage forms, mainly ophthalmic and parenteral preparations. The non-sterile products include tablets, capsules, oral liquids, external preparations and oral rehydration salts (ORS). The pharmaceutical market share from local production is estimated as 25.0 %, leaving ample room for expansion through improved production capacity utilization [3].

Production capacity is defined in terms of installed, available and utilized capacities obtained annually [4, 5]. Installed capacity

*Author to whom correspondence may be addressed.

of a production machine is the maximum output capability according to the manufacturers' specifications, allowing no adjustments for preventive maintenance, unplanned downtime, breakdowns and facility shutdown [6]. Available capacity is what is practically feasible, i.e., the highest level of operation with an acceptable degree of efficiency, taking into consideration unavoidable losses of productive time. Automated high capacity machinery, optimized processes and fast change procedures ensure that each operation is running at the maximum validated speed that yields the desired quality attributes [7]. Utilized capacity refers to the relationship between actual output produced and potential output that could be produced with installed equipment if the available capacity was fully utilized [8, 9]. High capacity utilization may not always be economically desirable, and as the output increases most firms might experience an increase in the average cost of production because of the need to operate extra shifts or to undertake additional plant maintenance. Economic utilization rate is therefore a measure of the ratio of actual output to the level of output beyond which the average cost of production begins to rise.

Production capacity utilization is one way of measuring the performance of an industry [10, 11]. Official estimates of capacity utilization have not been released by many countries probably due to variance in results arising from the different methods of computation [12]. A prerequisite of self-sufficiency through local production is sufficient production capacity. The realization of self-sufficiency in essential medicines in Kenya as envisaged by the KNPP and Vision 2030 will require strategic plans for their implementation based on accurate situational data on available and utilized capacities in the local pharmaceutical industry. Review of literature indicates that no comprehensive study has been carried out on production capacity and the trend in capacity utilization in the Kenyan pharmaceutical industry. Utilized capacity in this industry was reported by United Nations Industrial Development Organization (UNIDO) to vary between 53.0 % and 67.0 % based on responses of what various manufacturers estimated for a one shift operation [13].

In view of the unsynchronized unit operations in production for the majority of the companies, and the complexity in capacity determination, a follow-up survey was necessary in order to obtain extensive data on installed, available and utilized capacities from actual production processes on the manufacturing floor. In this study, installed, available and utilized production capacities were evaluated for two shift operations in the Kenyan pharmaceutical industry for the years 2010–2014, and the projected capacity utilization computed in order to gain understanding on the level of readiness of Kenya to be self-sufficient in essential medicines through local production. This study, to our knowledge, provides the first comprehensive data on production capacity in the Kenyan pharmaceutical industry that is based on actual computation of the output of installed machinery on a production line.

EXPERIMENTAL

Data collection

A survey was conducted on production capacity in the pharmaceutical industry in Kenya. Data on production capacity based on two shift operations was collected from all manufacturers of human pharmaceutical products using a standard structured questionnaire in hard and soft copies. The

process entailed making telephone calls, sending electronic mails and visits to the facilities. The contact person at each facility was the quality assurance manager who coordinated collection of data by personnel who had been at the facility for at least three years and were familiar with the activity in question. Information on capacities was collected from actual production processes on the manufacturing floor. The number of production machines that were installed, designed maximum output capability, machine performance, maintenance period, changeover time, facility shut down and actual available operation time for each machine were established and recorded. Production output for each unit operation in the production process was obtained from machine log books and from quality control finished product release records from 2010 to 2014.

Data analysis and computation

Production capacity for tablets, capsules, oral liquids, external preparations, dry powders for reconstitution and ORS was evaluated from the data provided in the questionnaire based on the overall equipment effectiveness model [14]. The installed capacity was taken as the designed output capability of the production machine. Available capacity (AC) was determined by making adjustments to installed capacity to cater for product changeover time, preventive maintenance, unplanned downtime and facility shut down. Utilized capacity (UC) was derived from the actual and potential output of production machines. The AC and UC were calculated using Equations 1 and 2, respectively.

$$AC = Equipment\ availability \times Equipment\ performance \times Quality \qquad Equation\ 1$$

$$UC = \frac{Number\ of\ units\ (i.e.\ Number\ of\ batches\ x\ batch\ size)}{AC} \qquad Equation\ 2$$

Forecasting of production capacity utilization was evaluated using the time series forecasting method. Utilized capacity/time series plots were drawn for the dosage forms that were assessed for the study period to establish the underlying pattern in production capacity utilization, upon which the forecasting method was based. A trend-based time series method was applied in the forecasting since the overall capacity utilization demonstrated linearity. Assuming a linear upward trend between utilized capacity and time, projection of capacity utilization was determined using the linear trend Equation 3.

$$T_t = b_1 t + b_0 \qquad Equation\ 3$$

Where: T_t is capacity forecast at time t, b_0 is intercept of the linear trend line and b_1 is the slope of the linear trend line [15].

The Microsoft Excel® function of forecasting was used in the projection of future capacity utilization since it uses a linear regression to predict Y by extrapolation when historical values of X and Y are known. Projections were performed till 2050 to avoid errors associated with long term forecasting.

RESULTS

Demography of respondent local manufacturers

Sixteen (66.7 %) out of 24 manufacturers of medicines for human use responded to the

questionnaire on production capacity in the Kenya pharmaceutical industry. All the large and established manufacturers responded to the questionnaire. One respondent was licensed to produce rapid diagnostic kits for detection of infectious diseases, one facility manufactured sterile products and 14 were engaged in manufacturing of non-sterile dosage forms. The dry powders manufactured were mainly β-lactam products, which require proof of containment during production. Four companies had closed their β-lactam department due to Good Manufacturing Practices (GMP) non-compliance. Dry powders for reconstitution and ORS require stringent humidity control and were produced by few manufacturers. The established manufacturers produced all the dosage forms that were assessed and two small start-up facilities manufactured liquid preparations only.

Overall installed production capacity

Table 1 presents the annual installed and available production capacities based on two shift operations for the six dosage forms in the 14 companies (coded as A to N) in 2014. Production of tablets, capsules, oral liquids, external preparations, dry powders and ORS was carried out in 12, 9, 13, 9, 4 and 4 respondent facilities, respectively.

Table 1: Installed and available annual production capacity at respondent manufacturers in 2014

Company	Dosage form					
	Tablets	Capsules	Oral liquids (bottles)	External preparations (tubes)	Dry powders (bottles)	Oral rehydration salts (sachets)
A	1,342,500,000	NP	30,000,000	NP	NP	NP
B	2,000,000,000	104,000,000	29,000,000	12,000,000	NP	NP
C	NP	NP	10,000,000	NP	NP	NP
D	3,000,000,000	170,000,000	30,000,000	9,240,000	NP	20,000,000
E	2,130,000,000	83,600,000	48,000,000	4,840,000	6,600,000	NP
F	2,400,000,000	800,000,000	24,000,000	20,000,000	40,000,000	20,000,000
G	1,000,000,000	NP	NP	NP	NP	NP
H	7,000,000,000	400,000,000	44,000,000	18,000,000	NP	30,000,000
I	1,000,000,000	NP	6,600,000	NP	NP	NP
J	NP	NP	18,000,000	NP	NP	NP
K	1,552,500,000	143,750, 000	16,000,000	15,750,000	NP	NP
L	2,400,000,000	336,000,000	160,000,000	16,000,000	35,200,000	NP
M	1,500,000,000	60,000,000	20,000,000	10,000,000	10,000,000	NP
N	4,000,000,000	220,000,000	7,680,000	8,800,000	NP	20,000,000
TA Capacity	29,325,000,000	2,317,350,000	443,280,000	114,630,000	91,800,000	90,000,000
TI Capacity	37,946,250,000	2, 834,900,000	535,875,000	141,650,000	119,200,000	111, 500,000

TA: Total Available (calculated); TI: Total Installed; NP: The dosage form was not produced by the manufacturer.

Tablet compression and the filling operation in production of capsules, oral liquids, external preparations, dry powders and ORS were used to compute production capacity.

Data on installed production capacities was provided by all 14 facilities. The industry had large installed capacity for tablets, capsules and oral liquids compared to the other dosage forms that were produced. The established companies had invested in automated high capacity tablet compactors and large capacity (≥4000L) liquid manufacturing tanks and the unit operations were synchronized to avoid holdups during production process. The installed capacity for capsules was less than 10.0 % that of tablets while the capacity of external preparations was 26.4 % of oral liquids. The available capacity as a percentage of installed capacity for tablets, capsules, oral liquids, external preparations, dry powders and ORS in this industry was 77.3, 81.7, 82.7, 80.9, 77.0 and 80.7 %, respectively. The overall available capacity was 80.1 %. The available capacity for the respondent companies ranged from 66.7-80.0 % for tablets, 80.0-90.5 % for capsules, 60.5-90.9 % for oral liquids, 77.8-90.0 % for external preparations, 57.1-85.7 % for dry powders and 80.0-83.3 % for ORS. The downtime was mainly due to scheduled preventive maintenance, machine breakdown, machine setting, product changeover activities, cleaning up procedures, quality audits and scheduled breaks.

Utilized production capacity

The mean utilized capacity for the years 2010 to 2014 is shown in Table 2. Utilized capacity demonstrated linear increase for tablets, liquids and dry powders. Utilized capacities for capsules, external preparations and ORS fluctuated. In 2014, the mean of utilized capacity (two shifts) for the six dosage forms was 27.4 %, up from 16.1 % in 2010, an increase of 11.3 % during the 5 years. However, the available capacity for all dosage forms was underutilized by more than 70 % for tablets, oral liquids, external preparations and dry syrups, and by 50 % for ORS.

Table 2: Mean utilized production capacity in the Kenyan pharmaceutical industry (2010–2014)

Year	Percentage utilized capacity (%)						
	Tablets	Capsules	Oral liquids	External preparations	Dry powders	ORS	Mean
2010	22.8	11.4	22.3	14.3	12.1	13.6	16.1
2011	21.3	11.7	22.9	17.9	16.1	28.8	19.8
2012	24.8	15.7	24.4	30.1	20.9	9.1	20.8
2013	24.9	12.2	28.3	25.6	28.9	19.8	23.3
2014	26.8	13.0	28.4	21.0	28.6	46.7	27.4
Mean % (2010–2014)	24.1	12.8	25.3	21.8	21.3	23.6	21.5

ORS: Oral rehydration salts.

Figure 1 shows the trend for utilized capacity for the respondent manufacturers over the years 2010–2014. Some companies did not provide data on utilized production capacity due to poor record keeping or upgrading of the documentation system.

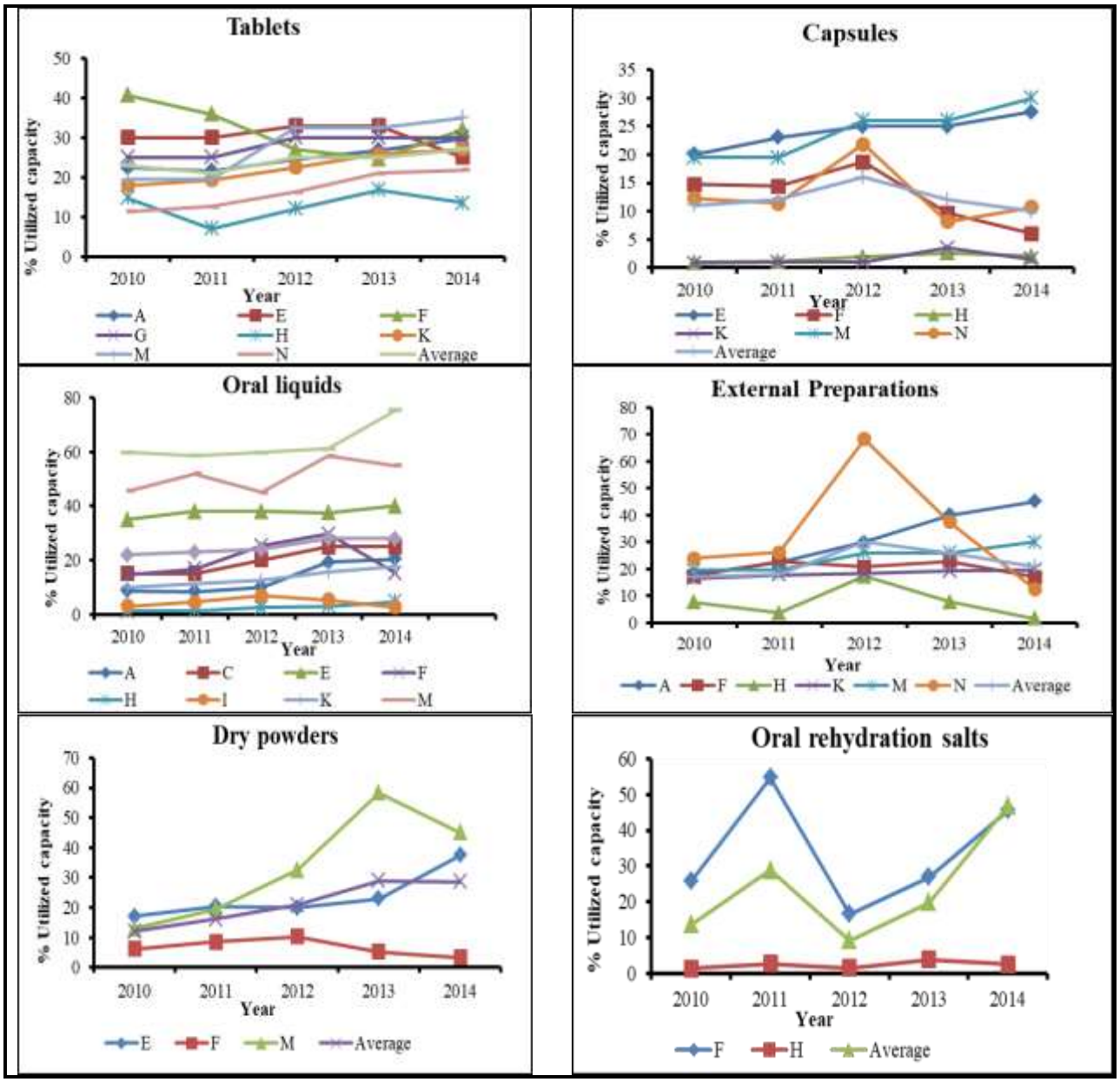

Figure 1: Utilized capacity at respondent manufacturers over the 2010-2014 period.

Utilized production capacity for tablets

Out of the 12 companies that manufactured tablets, three companies did not provide data for calculation of utilized capacity, and one provided data for only 2 years. The trend in capacity utilization varied among the manufacturers, with most showing a slight increase. Capacity utilization increased by 4.0 % during the 5 years. Tablets lines had idle capacity of over 70.0 %.

Utilized production capacity for capsules

The capsules filling line was the most underutilized, with an average utilized capacity of 12.8 % during the 5 years. Six out of the 9 manufacturers of capsules provided data on utilized capacity. Two companies utilized less than 3.5 % of the available capacity during this period. Two manufacturers, depicted an increase in utilized capacity, one showed a decrease

while the utilized capacity for three fluctuated.

Utilized production capacity for oral liquids

The average utilized capacity for liquid filling line was 25.3 %, but it varied significantly among individual manufacturers across the industry with one facility utilizing more than 50.0 %. Two facilities utilized less than 7.0 % of the available capacity during the 5 year period. Two facilities, in addition to manufacturing, also operated a chain of wholesale outlets for pharmaceutical products and these facilities demonstrated an increase in utilized capacity during this period. The average utilized capacity for the liquids line increased by 6.1 % over the study period.

Utilized production capacity for external preparations, dry syrups and oral rehydration salts

The mean utilized capacity for external preparations, dry syrups and ORS was 21.8, 21.3 and 23.6 %, respectively. The utilized capacity for external preparations increased by 15.8 % from 14.3 % in 2010 to 30.1 % in 2012 and thereafter declined. The utilized capacity for dry powders increased steadily till 2013 and then stagnated, while for ORS it fluctuated during this period, with a significant increase in 2014. This was attributed to elevated utilized capacity of 92.0 % by one facility in 2014.

Projection of self-sufficiency in essential medicines through local production

Respondents were asked to estimate the year of self-sufficiency in essential medicines through local production. Four companies were optimistic that it would be by 2030 and two of them by 2040. One company stated 2050 and another 2065. However, six respondents reported that the year was not predictable, due to the many variables that affect demand. The respondents view was that favourable government policies and their implementation were key determinants of achieving self-sufficiency through the local pharmaceutical industry. The utilized capacity for the dosage forms for the 5 years (2010-2014) exhibited a linear trend ($y = 2.16x - 5229.8$; $r = 0.9824$). The projected utilized capacity by 2030 for tablets, capsules, oral liquids, external preparations, dry powders and oral ORS was 45.0, 19.5, 56.9, 59.8, 100 and 100 %, respectively. The overall forecasted year for achieving full capacity utilization in all the dosage forms that were assessed is 2043.

DISCUSSION

Out of the 30 licensed pharmaceutical manufacturers in Kenya in the year 2014, twenty four were engaged in production of human medicines, three being sterile manufacturers. Evaluation of production capacity of non-sterile dosage forms namely tablets, capsules, oral liquids, external preparations, dry powders and ORS in this industry depicted a vast installed capacity in all production lines assessed. Six leading and established manufacturers had upgraded their installed capacities to increase batch size in order to improve the manufacturing efficiency by reducing the number of batches and changeover times. This was probably a strategic step in readiness for public tender supply, since the government is the major procurer of local pharmaceutical products and installed capacity is an important criterion since it determines the production time for a bid. The large installed capacity for tablets may be attributed to the higher demand for this dosage form by procurement agencies as many pharmaceutical products are designed as tablets for excellent patient compliance since the route of administration is

convenient. Tablets also confer good stability and therefore a long shelf life to the product [16, 17].

The overall utilized capacity increased by 11.3 % during the 5 years but the growth trend fluctuated amongst the dosage forms assessed and this may have been caused by factors such as the uncertainty of public procurement, closure of some production lines for renovation and facility upgrading. The capsules filling line was the most underutilized, with an average utilized capacity of 12.8 % during the 5 years. This may have been as a result of stiff competition from imported pharmaceutical equivalents. Two of the 14 manufacturers assessed had opted to import doxycycline and indomethacin capsules for participation in public tenders instead of local production. The underutilized capacity across the industry may be attributed to production of similar products, lack of technology to develop substantial products that are listed as essential medicines and non-participation in donor funded international tenders for antiretroviral and some anti-malarial products due to the prequalification prerequisite which disqualifies majority of local manufacturers. All respondents were of the opinion that capacity underutilization was due to low demand for the products caused by competition from cheaper imported pharmaceutical equivalents in the market, insufficient government incentives to pharmaceutical industry investors, poor transportation infrastructure and costly electricity and production inputs which have contributed to the high price of locally manufactured products.

Capacity underutilization in the pharmaceutical industry is not peculiar to Kenya but is common to other African countries. The Tanzanian pharmaceutical industry is also faced with low capacity utilization as a result of prevalence of competitive imports [18]. In Nigeria, capacity utilization in the production of liquid preparations and tablets was in the range 33.0-55.0 % and 36.0-50.0 %, respectively [19]. The pharmaceutical industry in Uganda operated at an average capacity utilization of between 30.0 % and 55.0 % [20], while in Ghana and Zimbabwe, it was 55.0 % and 20.0 %, respectively [21, 22]. Capacity utilization is mostly driven by market demand, investment capital, government policies, marketing strategies, cost of production and technical capacity. The pharmaceutical industry in India meets approximately 70.0 % of the country's demand [23] and utilizes 60.0-70.0 % of the installed capacity [24], whereas that in Germany utilizes 84.0-88.0 % of its installed capacity [25]. Bangladesh is nearly self-sufficient in essential medicines and the local pharmaceutical industry meets 97.0 % of domestic demand of essential medicines, with an estimated production capacity utilization of 70.0 % [26, 27]. The success of pharmaceutical production in Bangladesh is credited to the application of the exemption from the obligation to implement patent protection, favourable government policies such as the National Drug Policy which promotes local production to ensure availability, affordability and safety of essential drugs and also access to qualified technical personnel [28].

This study shows that the pharmaceutical manufacturing industry in Kenya has ample idle production capacity since the mean utilized capacity in 2014 was 27.4 %. It is the responsibility of the Kenyan pharmaceutical industry in collaboration with the government to design strategies that will consistently promote demand for local products in the midst of competition from imported pharmaceutical equivalents in order to utilize the available production

capacity. These may include aggressive marketing of products by the local industry, pursuit of international accreditation in order to target the international market, development of new products with guaranteed markets, review of the prescribed margin of preference in public procurement for locally manufactured products and designation of some public tenders to locally manufactured products. Although the overall forecasted year for achieving full capacity utilization in the non-sterile products assessed is 2043, this may change since trend projections are affected by factors such as disease patterns, government policies, donor requirements, economic performance and political status of a country.

CONCLUSION

In 2014, the available production capacity in billions was 29.3 tablets, 2.3 capsules, 0.4 bottles of oral liquids, 0.1 tubes of external preparations, 0.1 bottles of dry powders and 0.1 sachets of ORS and the mean of utilized production capacity (two shifts) for the assessed dosage forms was 27.4 %. The available production capacity was underutilized. However, the overall utilized capacity increased by 11.3 % during the period 2010–2014. The predicted utilized capacity in 2030 for tablets, capsules, oral liquids, external preparations, dry powders and ORS was 45.0, 19.5, 56.9, 59.8, 100 and 100 %, respectively. The forecasted year for achieving full capacity utilization for the manufactured dosage forms was 2043.

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