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A Review on Saviryta Avadhi w.s.r. to Shelf Life of Ayurvedic Formulations

Dr. Pritika Devi
Lecturer in Ras Shastra & Bhaishjya Kalpana, Babe ke Duadhar College, Moga (Punjab)
Dr. Keshav Rana
Lecturer in Kayachikitsa, Babe ke Duadhar College, Moga (Punjab)

Abstract

The notion of *Saviryata Avadhi* for different *Ayurvedic* dosage forms are not properly explained in the brihtriya like Charak, Sushruta, Vagbhatta although some of references of usage time of various kalpana like panchvidha kashaya kalpana are found. In old times, our traditional vaidyas were used fresh drugs or drie drugs for the preparation of various medicines. These were not preserved some to them due to their spoiling of taste, colour, potency, odor etc. all their physical or chemical properties with the passage of time with some exceptions like Asava i.e. alcoholic preparations and sneh preparations. The whole time in which medicines are fit to use and can treat diseases can be correlate with sarviyta avdhi. So, without the knowledge of its Savriyta Avadhi i.e. if the medicine is not good in their potency then the prescription is incomplete and results may not found satisfactory. After 13th century, *Various Ayurveda texts*, put a glimpse on the *Saviryta Avadhi*. And with the advancement of time, in the present scenario many technologies have developed to maintain the potency and stability of drugs. This present article is about a brief review that how *saviryata avadhi* in *Ayurveda* classics will be revised as the name of Shelf life by contemporary science.

INTRODUCTION:

In Ayurvedic Literature, *Saviryta Avdhi*[2] term is mentioned in context of time period during in which virya of any drug remains same under any internal or external environmental conditions whereas in contemporary system, shelf life is indicate the time period during in which finished pharmaceutical product is remain same within approved stability, specification, provided that it is stored under the conditions explained on the label of container. Now a days, due to development and advancement of packaging and storage technology, it is todays need to restudy and re- establish a new criteria for all ayurvedic medicines. Govt. of India has regularly issued a Gazette notification for the Shelf life of Ayurvedic Formulations and they are revised with time to time.

These Ayurvedic formulations are of various types in different dosage forms which particularly depend upon the consistency.

The Solid dosage: *this is hard in consistency Vati*

The Liquid dosage: these are used in the form of *Sawrasa, Asava, Arishta, Kwatha, Him, Phanta*

The Semisolid dosage: these are used as *Kalka, Avleha*

The powder dosage: Churan, Bhasma

The Panchvidha kashaya kalpana like Sawrasa,Kalka,Kwatha,Him,Phanta are the basic kalpana for the preparation of all the medicines and it is strictly mentioned by all the acharyas that it should be used in fresh conditions. The saviryta avadhi of various other upkalpana which are also included in panchvidha kashaya depends upon the method their preparation and use. For example Kalka kalapana should be used fresh but Churan are used within 2 months as explained by Acharya Sharangdhara.

Sharangdhara Samhita Prathama Khanda[2]:

Formulations	vanga sena	Sarviryta Avdhi	yog ratnakar
Sawrasa	-	-	*03 hours*
Kwatha	-	-	*03 hours*
Kalka	-	-	*03 hours*
Anjana	-	-	*03 months*

Churan	-	*2 Months*	*03 months*
Gutika	-	*12 Months*	*06 months*
Avleha	-	*12months*	*12 Months*
Taila	*06 months*	*16 Months*	*12 months*
Laghupaka	-	*01 Year*	-
Asava	-	*No Expiry*	-
Bhasma/ Rasa Formulations	-	*No Expiry*	-

Ancient versus Modern views prospective need:

Saviryta Avadhi as defined above, is an indicative of that specific period during which the virya (potency) of drugs remains same up to certain threshold provided that it isstored in mentioned conditions. It is believed beyond that time, the drugs may lose its potency up to some extent. Till date no specific guidelines are explained regarding the stability of shelf life of any Ayurvedic Formulations from any Govt. Organisation, except Gazette notification issued by Govt. of India on 20^{th} October 2009 with slight modifications in the earlier draft notification issued on 26^{th} November 2005, which is again revised on 12 August 2016 with slight amendment. In this notification, Deptt. Of Ayush, Ministry Of Health and Family welfare, has implemented the Drug and Cosmetic Act 1940, rule 1945 under rule namely 161B to display the date of expiry of ASU drugs and proposed shelf life of Ayurvedic formulations like Churan, Kwatha etc and Asava, Arishta, Rasaushadhis, Parpati became more efficacious with the passage of time. Here it is specified that the bhasma start solidifying after 5years and they need 1or 2 puta again, before using in the dosage form.

As per official gazette in drug and cosmetic rules, 1945, New amendment on August 12, 2016[3]:

Formulations	Shelf life
Anjan –kashthaushdhi	1 year
Anjan - Rasa+ Uprasa+Bhasma+ Kashthaushdhi	2 year
Anjan- only with Rasa+Uprasa + Bhasma	3 year
Arka	1 year
Asava – Arishta	10 year
Aveleha,khand,paak,guda	3 year
Churna, kwatha churna, lepa churna, Danta manjana	2 year
Dhupana	2 year
Dravaka,lavana, kashara	5 year
Ghrita	2 year
Guggul	5 year
Vati/Gutika-	
Rasa/uparsa/bhasma/guggul+ kashthaushadhi	5 year
Only kashthaushadhi	3 year
Only rasa/uprasa/bhasma (except tamra & naag bhasma)	10 year
Droplets (nose/ear)	2 year
Kupipakpwa	10 year
Malhara	3 year
Mandur loha	10 year
Naag , Vang, Tamra Bhasma	5 year
Eye droplets	1 year
Parpati	10 year
Pishti & Bhasma (except, Naag, vang,tamra)	10 years
Pravahi kwatha	3 years
Rasa yoga same as the bhasma	10 years, 5 years

Satva	2years
Sharkara/panak/sharbata	3years
Shawet parpati	2years
Taila	3years
Varti	2years

Discussion[4]:

The shelf life of all these formulations depends upon the stabilization of their potency for the certain period of threshold. These stabilities can be maintained by modern technologies by various methods like use of preservatives, maintenance of proper packaging, storage and stabilisers used.

Concept of Packing: According to Charak Samhita, a drug or medicine should packed in such type of vessels which do not interfere with packaging material with the physical, chemical or biological property of drug. The packing material must have the quality of giving primary protection against temperature, light, moisture, exposure to air. Modern pharmaceutical industries, suitably packed the products so that they should retain their potency from the time of packaging till they are used.

Concept of Stabilisers: These are the substances which are used to maintain the stability of formulations or any finished products. In ancient no any stabilisers were used by the Acharya, they prepared and processed in different way which may leads to potency and shelf life of medicines. Nowadays, so many problems are faced by doctor and patient for the availability of particular medicine. This can be overcome by using some stabilisers which can help to avoid any deterioration of medicine and can be used at any time. The shelf life of these pharmaceutical products can be increased by using proper stabilisers. At present most of stabilisers are antioxidants and preservatives.

Conclusion

The main aim behind the development of different formulations that they should be used anytime with good palatability and best potency. The five basic kalpana i.e. panchvidha kalpana should be used in freshly prepared form. The availability of drugs, appliances used for preparation, their stability may be major problem for the patients. To overcome these problems various formulations like Churan, Vati, Aveleha, Taila, Asava, Arishta are developed by time to time. They are prepared in well-established pharmacies with modern technology which are keep trying to maintain their stability, shelf life, prevention from environmental factors like, temperature, humidity etc. There is still need to maintain the quality of drugs as per Ayurvedic Pharmacopoeia of India, so that with all these qualities, people will get good results of Ayurvedic formulation anytime anywhere.

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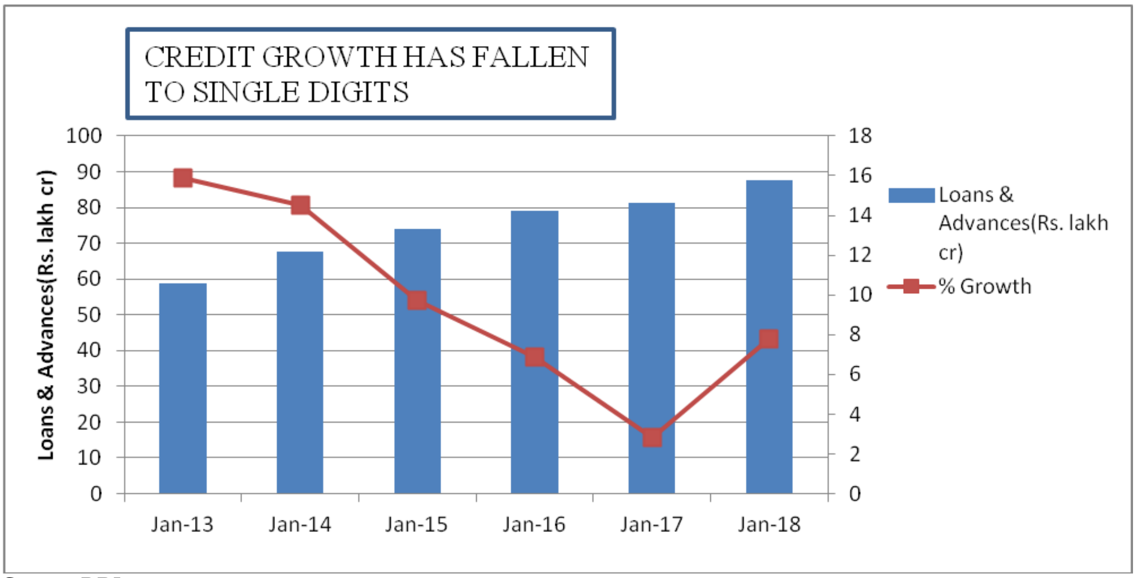
Indian Banking – Clean Up Balance Sheets

Dr. Rajmani Ram Patel
Professor, Government P.G. College, Doiwala, Dehradun

In the next five years, the Indian banking system will probably have fewer public sector banks (PSBs) from the current two dozen as the consolidation drive accelerates to create a few large banks. There would also be some serious effort to delink the government, or most specifically the finance ministry, from PSBs by making the existing Bank Board Bureau (BBB) more autonomous, and also to push for Bank Investment Company (BIC) to house government stake in PSBs. There would also be less burden of recapitalisation on the government exchequer as the surplus capital of the Reserve Bank of India (RBI), estimated to be in the region of Rs. 1-3 lakh crore, is deployed. Last but not the least, the fine tuning of the Insolvency and Bankruptcy Code (IBC) with additional infrastructure, especially in National Company Law Tribunal (NCLT) benches, would result in faster resolution of lakhs of crores stuck in stressed assets. But there is a big if before the script can play out in the fashion we have described, and that is the new government's seriousness to first admit that there is indeed a problem.

While no bank has failed, the situation is alarming. Recently, the CEOs of three large private banks were shunted out on performance, governance and compliance issues. A mid-sized private bank is saddled with large loans given to troubled IL&FS, Jet Airways, Dewan Housing and a few other companies. Banking as a whole is running on single-digit credit growth, profitability is declining while bad loans are increasing (they increased by 30 per cent-plus in 2017-18).



Source: RBI

The reality is that India's banking system is clogged. Banks' capital is locked in over Rs. 14 lakh crore of stressed assets where the resolution mechanism is still slow. There are capital shortages, especially in PSBs, which control two-thirds of the banking sector. Close to a dozen banks are classified as potentially weak, though some are being pushed ahead with the blessings of the regulator in order to support economic growth. There is also complete risk aversion among bankers who are moving away from long-term project financing. In fact, there are also new pockets of risk building up in areas like unsecured loans (personal loans and credit card), MSMEs, MUDRA loans and the agricultural sector. Given the overall economic slowdown and the decline in high frequency indicators like Index of Industrial Production (IIP), exports, auto sales and credit growth, the problems for banks are only going to compound if the regulator and the government do not fix the banking system.

Policy Side Solution

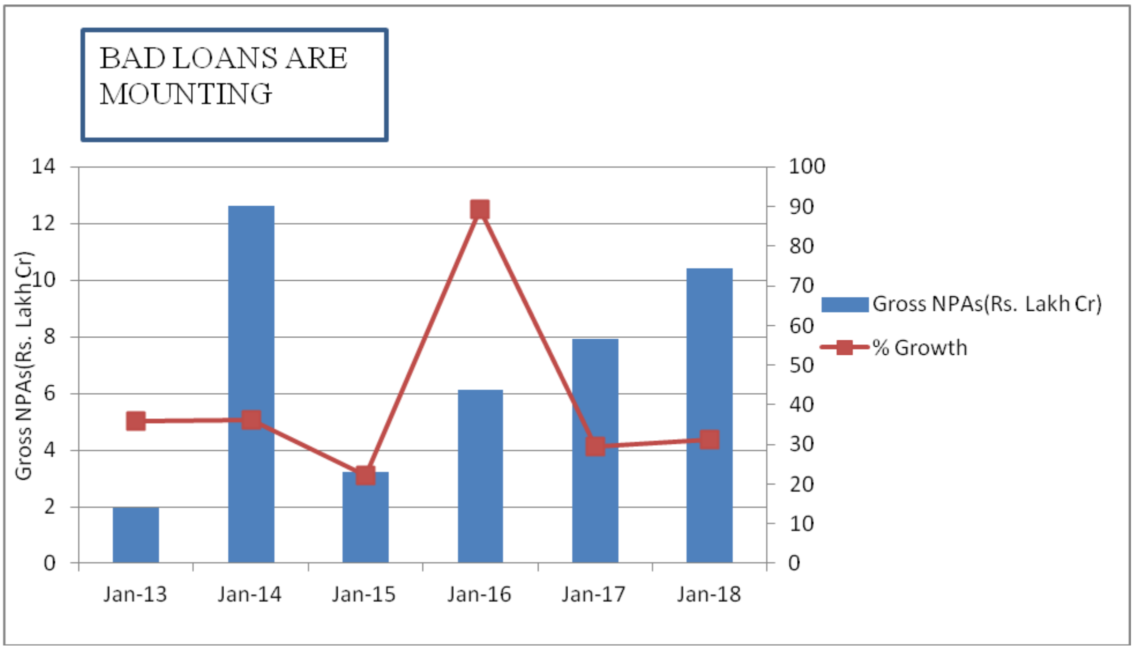
In its previous term, the current BJP-led NDA government pursued an agenda of creating a few large banks from among the PSB pack. The largest, the State Bank of India (SBI), merged five of its associates with itself. A three-way merger of Bank of Baroda, Vijaya Bank and Dena Bank was also announced. IDBI Bank was handed over to LIC as promoter. Clearly, the government plans to take forward the model of merging three PSBs with at least one lead bank with a size like Punjab National Bank or Canara Bank. The idea is to merge mid-sized or weak banks so that they have better management bandwidth, a bigger platform to exploit business opportunities and also use capital efficiently. But many experts suggest that the issues with PSBs are more fundamental.

PSBs currently mirror each other in terms of portfolio mix with large exposure to corporate banking, a high-cost structure, look and feel of branches, work culture and also lack of digitisation, risk management practices and performance management. It is felt that he merger will create more of the same. Size is important but so is profitability and efficiency. Create more small banks. The control will be far higher in smaller entities. Today, it is very difficult for the senior management to have an oversight of a large bank, our supervisor Prof. Ansari has felt.

What is missing in the government's current merger strategy is the right fit in terms of product, geography, management, etc. While the merger exercise and integration would take two to three years, the government has to think of how to better govern PSBs since a merged entity will carry a much higher systemic risk. Any failure of a large bank could bring down the entire system, public sector banks.

In its previous term, the government came out with the path breaking BBB for selecting the right candidates to head PSBs. It, however, remained an advisory body for appointments with no other role. BBB can play a role in risk management, human resource and asset resolution. Similarly, the next logical step after BBB, as recommended by the P.J. Nayak Committee on Governance, was to set up a Bank Investment Company (BIC) to hold the government's stake in PSBs.

BIC was modelled as a sovereign wealth fund for PSBs to raise funds from the market. Even as the government pursues its agenda of merger, reforming BBB and setting up BIC, the immediate priority is to recapitalise banks. Many have suggested the RBI's surplus capital, if any, should be specifically utilised to make PSBs stronger in terms of capital.



Source: RBI

Weak Banks Systemic Risk

A merger of PSBs is likely to lead to creation of a few large PSBs, or too-big-to-fail institutions, which are more vulnerable to failure because of legacy issues and the fundamental nature of their business mix. SBI, with a balance sheet size of Rs 37 lakh crore post-merger, controls a quarter of the deposits and advances in the banking system. Bank of Baroda's merger will create a large entity with over Rs 11 lakh crore balance sheet size, close to the second largest bank, HDFC Bank. Similarly, other PSB mergers will create a few large entities of Rs 10 lakh-plus asset size. The banking regulator will have to closely monitor their functioning, otherwise an IL&FS kind of an incident could create more trouble for the banking industry. Currently, half a dozen potentially weak PSBs are out of the prompt corrective action (PCA) zone, thanks to the government and the RBI, and have resumed normal lending. These weak banks pose a risk to the system. Take for example, Corporation Bank, which has recently come out of PCA. It has seen a 120 per cent-plus jump in exposure to NBFCs when other banks have turned cautious after IL&FS and Dewan Housing defaults. Similarly, another PCA-released bank, Allahabad Bank, has seen its corporate exposure growing, especially in the infrastructure sector (roads and ports, cement, gems and jewellery). Delhi-based Oriental Bank of Commerce has seen robust growth in its retail book, but a close examination shows rise in unsecured loans, especially personal loans.

It is question of the entire PCA mechanism. Probably it hasn't been constructive; there has been no deep introspection on the reasons for the weakness. The focus of the regulator should be on drastic changes in the business model, building in more checks and balances, better credit evaluation and risk management framework. It is suggested for creating a new layer of risk management for PSBs for validating and using surrogates to verify information provided by loan seekers.

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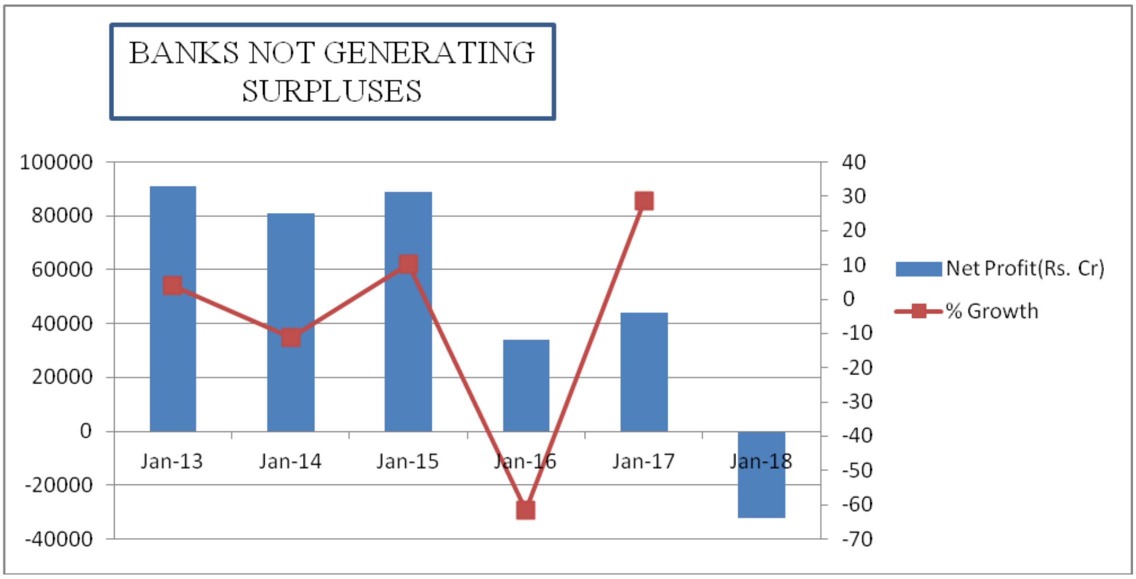

Source: RBI

New Pockets of Risk

Between 2000 and 2010, risk was building up in corporate loans as banks blindly funded expansion and diversification plans of India Inc. The economic slowdown and policy paralysis in India and China downslide also put companies and banks in a fix. The result was excess capacity, over-leveraged companies and defaults in bank loans. Many experts suggest that risk is again building up in the system, especially in retail banking due to unsecured loans like personal loans and credit cards, the MSME and business banking segment (loans against property), and in government directed MUDRA and agricultural loans.

MSME loans have got an RBI breather by way of restructuring so the real picture of NPAs (non-performing assets) will emerge only after the scheme ends. Similarly, banks are going after retail banking, where there is a tough competition. Margins and yields are low in mortgages, so banks are chasing unsecured loans, where margins are high. "For how long can this lone engine support growth?" says a consultant.

A bigger concern is risk aversion among bankers which is taking them away from project loans. The days of taking aggressive calls on project loans and infra financing are gone. The banks have realised that their ALM (asset liability management) is not suited for long gestation loans. Even in the past, the majority of banks would not evaluate a large project loan on a standalone basis. Instead they went by the judgment of lead banks like SBI, ICICI Bank or PNB. Today, the government has big plans for infrastructure investment while the framework of development financial institutions (DFI) is missing. ICICI, IDBI and IDFC have all converted into retail banks. Federal Bank's top officials suggest creating new instruments to fund infra needs. Globally, banks get in when the project is either completed or nearing completion.

There are already plans to create new entities or funds to pool in resources from pension funds, insurance companies and other long-term investors. But that's easier said than done as the requirement of funds is more immediate. Therefore, the burden of supporting project financing and the infrastructure sector is likely to fall on PSBs. All the more reason for the government and the RBI to tread cautiously to not only fix the banking system, but also protect it from threats.

The Solutions:

-Merger of public sector banks.

-More freedom to banks to take commercial lending decision.
-Discouraging MUDRA, farm loan waiver.
-Privatisation of banks, bringing in strategic inverstors.
-Banks under PCA need monitoring as a bank failure could pose a systemic risk.
-Strengthening the Bankruptcy code.
-RBI-monitored restructuring framework for banks to handle pre-IBC issues.
-The government should step in to clear land acquisition hurdle for new projects, reduce payment delays and speed up arbitration for infra companies.
-Loan waiver must be avoided.
-More power to the Bank Board Bureau.
-Hiring of outside professionals in PSBs.
-More Stringent compensation norms for CEOs and seniors management.
-Use of the RBI's surplus capital for capitalization of PSBs
-Creation of a Bank Investment Company for housing government stake in PSBs; it can raise money from the market.

Abbreviations:

PSB- Public Sector Bank
BBB-Bank Board Bureau
BIC- Banking Investment Company
RBI- Reserve Bank of India
IBC- Insolvency and Bankruptcy Code
NCLT- National Company Law Tribunal
IL&FS- Infrastructure Leasing & Financial Services
MSME- Micro, Small & Medium Enterprises
MUDRA- Micro Units Development and Refinance Agency Bank
ALM- Asset Liability Management

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