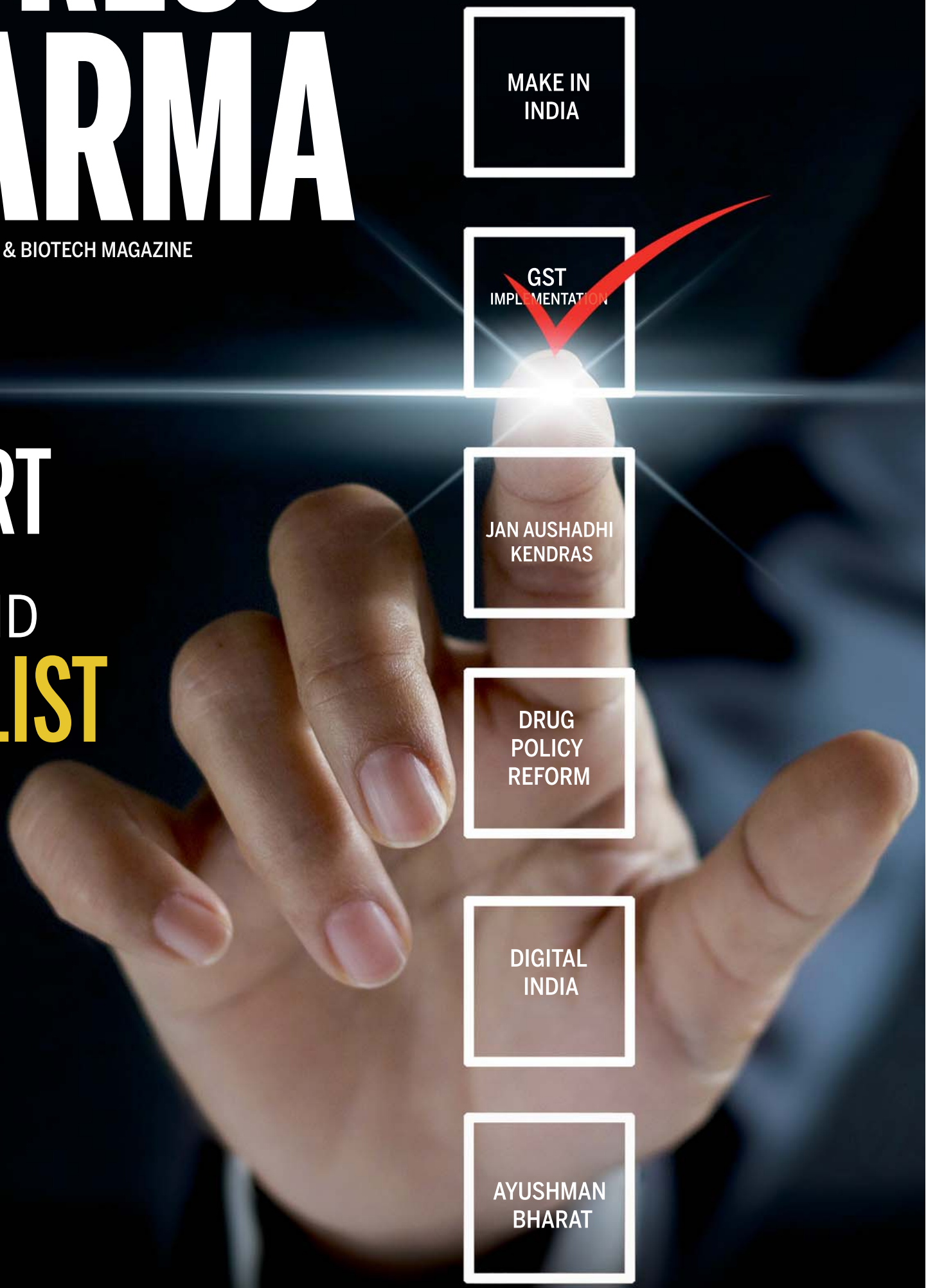
VOL. 14 NO. 14 PAGES 60 www.expresspharmaonline.com

EXPRESS PHARMA

INDIA'S FOREMOST PHARMA & BIOTECH MAGAZINE
16-31 MAY 2019, ₹40

A REPORT CARD AND A WISHLIST

Pharma experts review some of the major industry-related policies framed by the current government



VALUE ADD

BioWise: The next best thing to human gut

Dr Abhijit Gothoskar, Technical Head, BioWise Science and **Padmanabh Mukhedkar**, Product Specialist, Electrolab, provide insights on applications of biorelevant media in dissolution testing

DISSOLUTION of drugs from solid dosage forms is a key parameter in assessing the product quality and uniformity at the formulation stage as well as throughout the shelf life of the product. The dissolution method should be discriminative, reproducible, scientifically justifiable and more importantly biorelevant.

Surfactant solutions are often proposed as dissolution media for drugs characterised by low water solubility. Generally, aqueous solutions of such surfactants may simulate the physiological environment more accurately. However, it was shown that for a low solubility drug, increase in solubility by addition of surfactants to meet sink conditions (based on bulk drug solubility data) may not always produce biorelevant results. *(AAPS PharmSciTech. 2006; 7 (2): E1-E6)*

Aqueous buffers can be used to reflect typical pH conditions in the stomach or small intestine, but do not represent other key aspects of the composition of the GI contents (e.g., Osmolality, ionic strength, viscosity, surface tension) that can be relevant to drug release from the dosage form to be tested. In particular, they cannot be used to simulate the influence of food ingestion on drug release.

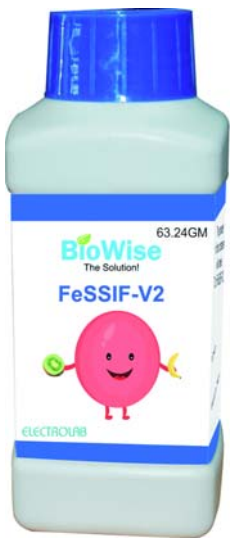
Normal adult diet contains about 150gm of lipids, 95 per cent of which are long-chain triglycerides and 4-8gm of phospholipids mainly composed of lecithin. *(Int J Pharm. 1996; 140: 69-76)*

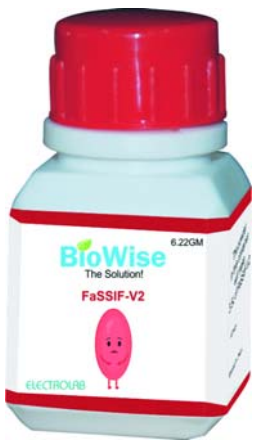
In fed state bioavailability of drug can be increased when there will be change in GIT environment such as:

- Prolonged gastric emptying and decrease in intestinal motility increasing the time available for solubilisation.
- Increased dissolution rate and solubilisation of drug substances in mixed micelles due to simulation of pancreatic secretion of bile salts and lipase.
- Protection from gastric/luminal degradation, due to protection in lipids.
- Increased lymphatic transport, thus avoiding first pass metabolism. *(Eur J Pharm Sci. 2007; 31: 8-15)*

To bridge the gap between the pharmacopoeial media and human GI tract, simulated media were developed such as Simulated Gastic Fluid (SGF) and Simulated Intestinal Fluid (SIF). However, these are still far from real conditions and pose problems such as low surface tension, high pepsin content, high surfactant concentration (in case of SGF); high bile salt concentration (in case of SIF).

To overcome these issues, the concept of Biorelevant Dissolution Media was developed.





These media are developed taking into consideration the physiological aspects of human GI tract. Bio-relevant media are broadly classified into Fasted state simulated intestinal fluid (FaSSIF) and Fed state simulated intestinal fluid (FeSSIF). These media closely mimic the composition of upper GI tract where majority drugs are absorbed. These media were first described by Prof Jennifer Dressman in 1998. *(Dressman J B et al, Evaluation of various dissolution media for predicting in vivo performance of class I and class II drugs, Pharm Res, 15, 698-705, 1998)*

The conventional methods of preparing these media are not user friendly as they are

- Multi-ingredient
- Solvent based and its subsequent removal
- Giving variable results owing to variability in preparation process
- Difficult to produce on large scale
- Difficult to replicate
- Time consuming to prepare

Biowise Science has developed BioWise, a ready to use blend of biorelevant media powder concentrate. The powder concentrate has been manufactured with high quality raw materials in a cGMP facility. The preparation is simple, quick and user friendly. The pack size of one bottle is good for one dissolution test, which completely avoids problems surrounding the storage of leftover powder concentrate.

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