



Communication Address

Site No. Special 3, Property No. 482, KSSIDC Industrial Estate, Kasaba Hobli, Hebbal, Mysore-570 016, Karnataka State, India
 Tel: Operations.+91-821-4191022I info@triphasepharma.com www.triphasepharma.com

PRODUCT REGULATORY DATASHEET

Section 1 - PRODUCT INFORMATION	
PRODUCT NAME & CODE	PROVASIC™ (TPPL-PB-21B)
COMMON OR USUAL NAME OF PRODUCT	<i>Lactobacillus plantarum</i> (TSP-Lp1)
SCOPE OF DOCUMENT	This document provides information specific to <i>Lactobacillus plantarum</i>
GENERAL PRODUCT INFORMATION	<i>Lactobacillus plantarum</i> is Isolated from Dairy

Section 2 - MANUFACTURING INFORMATION	
NAME & ADDRESS OF MANUFACTURING SITE	Triphase Pharmaceuticals Pvt Ltd
MODE OF MANUFACTURING	Fermentation
MANUFACTURING PROCESS	Process Flow Chart Attached
GMP COMPLIANCE	Follow GMP guidelines but no certification as yet. Will be applied for new plant (Under Construction)
SEWAGE SLUDGE USED	Sewage sludge statement attached
STERILIZATION or FUMIGATION METHOD(S)	GRAMICID
KNOWN OR POTENTIAL SOURCES OF IMPURITIES AND/OR CONTAMINANTS:	Yeast & Mold. <i>Lactobacillus plantarum</i> conforms to USP methods and standards for above mentioned contaminants.

Section 3 - PHYSICAL/CHEMICAL PROPERTIES				
INGREDIENTS				
COMMON or USUAL NAME	SYNONYM	ORIGIN	CAS NUMBER	WEIGHT PERCENT
<i>Lactobacillus plantarum</i>	<i>Lactobacillus plantarum</i> 6/15/50 Billion cfu/g	INDIA	-----	6 Billion – 10 – 20% 15 Billion – 30 - 40%
Water	-----	-----	-----	-----
Maltodextrin	-----	ROQUETTE	-----	65% - 90%
CURRENT PRODUCT SPECIFICATION SHEET ATTACHED				

Section 4 - LABELING INFORMATION	
REQUIRED FINISHED PRODUCT LABEL STATEMENTS	Labeling per DSHEA
RECOMMENDED RESTRICTIONS of USE	Consult a physician if you are using any prescription medication, or if pregnant or nursing
OTHER	None



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Section 5 - REGULATORY INFORMATION	
PATENT COVERAGE	YES
COMPENDIAL GRADE	UNITED STATES PHARMACOPIEA (USP)
REGULATORY STATUS AND SUPPORTING DOCUMENTS	<i>Lactobacillus plantarum</i> is considered as Food Product
BSE/ TSE INFORMATION	BSE/TSE - Refer to attached
VEGAN OR VEGETARIAN STATUS	Suitable for Vegan and Vegetarian
ALLERGENS/ HYPERSENSITIVITIES	Allergen statement is enclosed
PRESERVATIVES (or PROCESSING AIDS)	None
KOSHER/ HALAL/ORGANIC STATUS	None

Section 6 - MISCELLANEOUS PRODUCT INFORMATION	
BATCH/ LOT NUMBERING SYSTEM	Manufacturing facility/Year/Finished product/Sequential number
BATCH SIZE/DEFINITION	TPPL/17-18/Lp - 004; TPPL – Triphase Pharmaceuticals Pvt Ltd; 17-18 – Financial Year; Lp – <i>Lactobacillus plantarum</i> ; 004 – Sequential Number.
EXPIRATION DATING	18 Months
RECOMMENDED STORAGE CONDITIONS	Storage condition: 25 ± 2° C, RH 65% ± 2% is preferred
OTHER OPTIONAL INFORMATION	None
PACKAGE SIZE(S)	5 kg packed in double polypropylene cover & sealed in Fibre Drums & 20 kg packed in double polypropylene cover & sealed in HDPE Blue Drums
MSDS	16 Point MSDS attached
OTHER PRODUCT SAFETY INFORMATION	Not Applicable

Section 7 - REVISION			
REVISION DATE	10/03/2018	REVISION No	0

Section 8 - CONTACT INFORMATION			
COMPANY NAME	Triphase Pharmaceuticals Pvt Ltd		
CONTACT NAME	Irfanulla Sharieff	TITLE	GENERAL MANAGER
CONTACT PHONE	+91 821 4191022	EMAIL	isharieff@triphasepharma.com