



Communication Address

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

PRODUCT REGULATORY DATASHEET

| Section 1 - PRODUCT INFORMATION | |
|--|---|
| PRODUCT NAME & CODE | (TPPL-PB-21C) |
| COMMON OR USUAL NAME OF PRODUCT | <i>Lactobacillus rhamnosus</i> (TSP-LRh1) |
| SCOPE OF DOCUMENT | This document provides information specific to <i>Lactobacillus rhamnosus</i> |

| 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: | Other organisms, Yeast & Mold. <i>Lactobacillus rhamnosus</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 rhamnosus</i> | <i>Lactobacillus rhamnosus</i> 6/15/100 Billion cfu/g | INDIA | ----- | 6 Billion – 10 – 20% 15 Billion – 30 - 40% 100 Billion - 60 – 70% |
| 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 | |
|--|--|
| COMPENDIAL GRADE | UNITED STATES PHARMACOPIEA (USP) |
| REGULATORY STATUS AND SUPPORTING DOCUMENTS | <i>Lactobacillus rhamnosus</i> is considered as Food Product |
| BSE/ TSE INFORMATION | BSE/TSE-Refer to attached |
| VEGAN OR VEGETARIAN STATUS | Suitable for Vegetarian |
| PRESERVATIVES (or PROCESSING AIDS) | None |
| KOSHER/ HALAL/ORGANIC STATUS | None |
| GM STATUS (for each dietary ingredient) | Non-GMO statement attached |

| Section 6 - MISCELLANEOUS PRODUCT INFORMATION | |
|---|--|
| BATCH/ LOT NUMBERING SYSTEM | Manufacturing facility/Year/Finished product/Sequential number |
| BATCH SIZE/DEFINITION | TPPL/17-18/LRh - 001; TPPL – Triphase Pharmaceuticals Pvt Ltd; 17-18 – Financial Year; LRh – <i>Lactobacillus rhamnosus</i> ; 001 – Sequential Number. |
| EXPIRATION DATING | 12 Months (Further stability under test) |
| RECOMMENDED STORAGE CONDITIONS | Storage condition: 25 ± 2° C, 65% ± 2% is preferred |
| OTHER OPTIONAL INFORMATION | None |
| PACKAGE SIZE(S) | 5 kg packed in double polypropylene cover & sealed in Fibre Drums & 25 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 | 10/12/2017 | 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 |