



To: Medpace Clinical Pharmacology Unit

From: Zachary Prenskey, CEO - LB Pharmaceuticals

Date: May 07, 2020

RE: Clarification Memo #7

LB-102-001: A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

The intent of this protocol clarification memo is to provide clarification for the LB-102-001 protocol (Protocol Version 4, 08 April 2020). All items listed below will be incorporated into the next amendment. The protocol amendment will be sent after it is filed with FDA.

**Section 14.1 – Appendix 1: Clinical Pharmacology Summary Table**

**Original Wording**

General Information					
Chemical Structure and Major Physical and Chemical Properties					
	Molecular Weight: 383.51				
	Description	White to off-white powder			
	pKa	9.36			
	Partition Coefficient (LogP)	1.72 (pH 7)			
Aqueous Solubility	Vehicle	HPLC Area of Sample (225 nm)	Sample Concentration (mg/mL)	Calculated Solution Concentration (mg/mL)	Comment
	30% DMF 70% pH 4.7 MES	2769	0.44	44.0	100:1 dilution, pH of buffer is unchanged
	pH 4.7 MES Buffer	3770	0.614	61.4	100:1 dilution, pH of buffer is unchanged

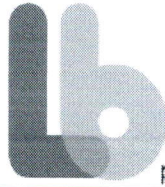


pharmaceuticals

		pH 5 HCl	4990	0.839	83.9	100:1 dilution, pH of buffer is unchanged
		pH 6 phosphate buffer	3827	0.625	625	1000:1 dilution, pH of buffer is unchanged
		pH 5 acetate buffer	Not Determined	>800	>800	pH of solution becomes 6.5
Indication (for this IND)	For the Treatment of Schizophrenia.					
Route and Formulation Type (for this IND)	Oral Capsule.					
Planned Strengths (for this IND)	LB-102 consists of API in a Size 2 white opaque/white opaque hard gelatin capsule in dosage strengths of 25 mg and 100 mg.					

**Revised Wording**

General Information																										
Chemical Structure and Major Physical and Chemical Properties																										
	Molecular Weight: 383.51																									
	Description White to off-white powder																									
	pKa 9.36																									
	Partition Coefficient (LogP) 1.72 (pH 7)																									
	Aqueous Solubility																									
	<table border="1"> <thead> <tr> <th>Vehicle</th> <th>HPLC Area of Sample (225 nm)</th> <th>Sample Concentration (mg/mL)</th> <th>Calculated Solution Concentration (mg/mL)</th> <th>Comment</th> </tr> </thead> <tbody> <tr> <td>30% DMF 70% pH 4.7 MES</td> <td>2769</td> <td>0.44</td> <td>44.0</td> <td>100:1 dilution, pH of buffer is unchanged</td> </tr> <tr> <td>pH 4.7 MES Buffer</td> <td>3770</td> <td>0.614</td> <td>61.4</td> <td>100:1 dilution, pH of buffer is unchanged</td> </tr> <tr> <td>pH 5 HCl</td> <td>4990</td> <td>0.839</td> <td>83.9</td> <td>100:1 dilution, pH of buffer is unchanged</td> </tr> <tr> <td>pH 6 phosphate buffer</td> <td>3827</td> <td>0.625</td> <td>625</td> <td>1000:1 dilution, pH of buffer is unchanged</td> </tr> </tbody> </table>	Vehicle	HPLC Area of Sample (225 nm)	Sample Concentration (mg/mL)	Calculated Solution Concentration (mg/mL)	Comment	30% DMF 70% pH 4.7 MES	2769	0.44	44.0	100:1 dilution, pH of buffer is unchanged	pH 4.7 MES Buffer	3770	0.614	61.4	100:1 dilution, pH of buffer is unchanged	pH 5 HCl	4990	0.839	83.9	100:1 dilution, pH of buffer is unchanged	pH 6 phosphate buffer	3827	0.625	625	1000:1 dilution, pH of buffer is unchanged
Vehicle	HPLC Area of Sample (225 nm)	Sample Concentration (mg/mL)	Calculated Solution Concentration (mg/mL)	Comment																						
30% DMF 70% pH 4.7 MES	2769	0.44	44.0	100:1 dilution, pH of buffer is unchanged																						
pH 4.7 MES Buffer	3770	0.614	61.4	100:1 dilution, pH of buffer is unchanged																						
pH 5 HCl	4990	0.839	83.9	100:1 dilution, pH of buffer is unchanged																						
pH 6 phosphate buffer	3827	0.625	625	1000:1 dilution, pH of buffer is unchanged																						



pharmaceuticals

		pH 5 acetate buffer	Not Determined	>800	>800	pH of solution becomes 6.5
Indication (for this IND)	For the Treatment of Schizophrenia.					
Route and Formulation Type (for this IND)	Oral Capsule.					
Planned Strengths (for this IND)	LB-102 consists of API in a Size 2 white opaque/white opaque hard gelatin capsule in dosage strengths of 25 mg, <b>50 mg</b> , <b>75 mg</b> , and 100 mg.					

Z. PRENSKI

Zachary Prensky, CEO

Signature

5.7.20

Date