CLINICAL STUDY PROTOCOL

PROTOCOL TITLE

Evaluating the Safety and Effectiveness of Deriphyllin in Respiratory Disorders: A Real-World Multicentric Study

Protocol Number	PN/DERI0612/06
Version	1.0
Date	04 May 2025
Sponsor	Zydus Healthcare Limited
Principal Investigator	Dr. Kunal Jhaveri
Number of Study Sites	200
This study will be conducted in compliance with the Protocol, Good Clinical Practice (GCP) as set forth in the International Council on Harmonization (ICH) guidelines on GCP (ICH E6-R2) and applicable local regulatory requirements.	

Protocol Approval – Sponsor Signatory

TITLE: Evaluating the Safety and Effectiveness of Deriphyllin in Respiratory Disorders: A Real-World Multicentric Study

PROTOCOL VERSION No.: 1.0 **PROTOCOL DATE: 04/05/2025**

Protocol accepted and approved by:

Name:

Designation:

Address:

_____ _____

Signature Date

Protocol Approval - Statistical Signatory

TITLE: Evaluating the Safety and Effectiveness of Deriphyllin in Respiratory Disorders: A Real-World Multicentric Study

PROTOCOL VERSION No.: 1.0 **PROTOCOL DATE: 04/05/2025**

I, the undersigned, declare that I have thoroughly reviewed the statistical analysis/evaluation of this protocol for completeness, accuracy, and compliance with applicable regulatory expectations and have found no deficiency.

Head Statistician	Signature	Date

Protocol Approval – Principal Investigator Signatory

TITLE: Evaluating the Safety and Effectiveness of Deriphyllin in Respiratory Disorders: A Real-World Multicentric Study

PROTOCOL VERSION NO.: 1.0 **PROTOCOL DATE: 04/05/2025**

I have carefully read and understood the foregoing protocol and agree that it contains all the necessary information for conducting this study safely. I will conduct this study in strict accordance with this protocol, ICH guidelines for Good Clinical Practice and local regulatory guidelines. I will attempt to complete the study within the time designated.

I will ensure that the rights, safety, and welfare of subjects under my care are protected.

I will provide copies of the protocol and all other study-related information supplied by the sponsor to all personnel responsible for me who participate in the study. I will discuss this information with them to ensure that they are adequately informed regarding conduct of the study.

I agree to keep records on all subjects' information (case report forms and all other information collected during the study) in accordance with applicable regulations.

I will not enroll any subjects into this study until ethics committee approval, and sponsor approval are obtained.

_____

PI Signature and Date

Abbreviations

6MWT	6-Minute Walk Test
ACT	Asthma Control Test
ALT	Alanine Aminotransferase
AST	Aspartate Aminotransferase
AE	Adverse Event
CAT	COPD Assessment Test
COPD	Chronic Obstructive Pulmonary Disease
CTRI	Clinical Trials Registry - India
ECG	Electrocardiogram
EF	Ejection fraction
FEV_1	Forced Expiratory Volume in 1 s
FEV_1/FVC	Forced Expiratory Volume in 1 s / Forced Vital Capacity
GGT	Gamma-Glutamyl Transferase
LVH	Left Ventricular Hypertrophy
mMRC	Modified Medical Research Council
PEFR	Peak Expiratory Flow Rate
PR	Pulse Rate
SAE	Severe Adverse Event
SpO_2	Oxygen Saturation
SR	Sustained Release

Contents

1. Protocol Synopsis

Title:	Evaluating the Safety and Effectiveness of Deriphyllin in Respiratory Disorders: A Real-World Multicentric Study
Objectives:	**Primary Objective:** • To assess the safety of Deriphyllin by monitoring adverse events and serious adverse events throughout the study duration. **Secondary Objective:** • To assess the effectiveness of Deriphyllin on respiratory function by evaluating changes in spirometry parameters (FEV_1, FEV_1/FVC ratio, PEFR), pulse rate, 6MWT, and SpO_2 from baseline to follow-up visits within three months of baseline (at available study sites). • To evaluate the relief in severity of symptoms through the mMRC questionnaire for COPD from baseline to follow-up visits within three months of baseline. (Annexure 1) • To assess symptom control in COPD patients using COPD Assessment Test (CAT) scores from baseline to follow-up visits within three months of baseline. (Annexure 2) • To assess symptom control in asthma patients using Asthma Control Test (ACT) scores from baseline to follow-up visits within three months of baseline. (Annexure 3) • To assess the effectiveness of the Deriphyllin through Subject Satisfaction Assessment at the end of the study. (Annexure 5) • To evaluate the effect of Deriphyllin on ECG parameters from baseline to follow-up visits within three months of baseline. • To assess hematological parameters including CBC, Liver enzyme (ALT, AST, and GGT), serum bilirubin, and serum creatinine from baseline to follow-up visits within three months of baseline. • To assess the overall tolerability of Deriphyllin through Global Physician Assessment at the end of the study. (Annexure 4)

Design	Prospective, Observational, Multi-centric study

Study Type	Real World Evidence study
Study Population:	Adults aged 18 years and above with Chronic respiratory conditions (Asthma, COPD, and others)
Eligibility Criteria	***Inclusion Criteria:*** 1. All the patients >18 years of either gender 2. All Patients with respiratory conditions such as Asthma, COPD, and other conditions who are receiving Deriphyllin treatment at the discretion of the treating physician. 3. Patients for whom Deriphyllin is being newly initiated as an add-on to ongoing therapy and who have not received Deriphyllin treatment prior to study enrollment. ***Exclusion Criteria:*** 1. Patients under 18 years of age. 2. Patients with known hypersensitivity to theophylline, etofylline, or any other components of Deriphyllin, or those using other methylxanthines (e.g., aminophylline). 3. Patients with significant cardiovascular conditions like Arrhythmia, LVH with EF < 30%, and Severe heart failure 4. Patients diagnosed with active peptic ulcers due to the potential exacerbation of gastrointestinal symptoms. 5. Patients having a history of epilepsy or other seizure disorders. 6. Patients with severe liver dysfunction. 7. Pregnant and lactating females. 8. Any other conditions which are not suitable for Deriphyllin treatment at the discretion of treating physician

Enrolment Period	3 months
Study Duration:	6 months (Enrollment + Treatment)
No. of subjects targeted	4,000 patients
Investigational product	• Tab. Deriphyllin 300mg SR • Tab. Deriphyllin 450mg SR • Tab. Deriphyllin Retard 150mg • Tab. Deriphyllin Retard 300mg

Study Schedules:	**Duration:** 12 weeks post enrolment **Follow-up visits:** Visit 1(Within 3 months) and Visit 2 (Within 3 months) (if any) **Baseline:** • The Case Report Form (CRF) will document informed consent, demographic details, and baseline clinical parameters, including vital signs (SpO_2, blood pressure, pulse rate). • Baseline pulmonary assessments including spirometry parameters (FEV_1, FEV_1/FVC ratio, PEFR) and the 6-Minute Walk Test (6MWT) will be conducted and recorded in the CRF. • Disease-specific symptom evaluation will include the mMRC Questionnaire for COPD, COPD Assessment Test (CAT), and Asthma Control Test (ACT), as applicable, and will be captured in the CRF. • Baseline laboratory assessments will include complete blood count (CBC), liver enzymes (ALT, AST, and GGT), serum bilirubin, and serum creatinine, which will be collected and recorded in the CRF. • ECG monitoring will be performed, and findings will be entered in the CRF. • Baseline adverse event (AE) assessment will be conducted and recorded. **Visit 1 (Within 3 Months):** • Vital signs (SpO_2, blood pressure, pulse rate) will be reassessed and entered in the CRF. • Pulmonary function tests including FEV_1, FEV_1/FVC ratio, PEFR, and the 6MWT will be repeated and results will be documented. • Symptom assessment tools (mMRC Questionnaire, CAT, and ACT) will be re-administered and documented. • Laboratory investigations including CBC, liver enzymes (ALT, AST, and GGT), serum bilirubin, and serum creatinine will be reassessed and documented in the CRF. • Global physician assessment of tolerability and effectiveness expectations will be conducted using a standardized tool and recorded. • Subject satisfaction assessment will be conducted to gauge patient

	experience and comfort with treatment and follow-up procedures. • ECG monitoring will be performed, and findings will be entered in the CRF. • AEs and serious adverse events (SAEs) will be evaluated and reported as per study protocol. **Visit 2 (Within 3 Months, if applicable):** • Vital signs (SpO_2, blood pressure, pulse rate) will be reassessed and recorded. • Spirometry parameters (FEV_1, FEV_1/FVC ratio, PEFR) and the 6MWT will be repeated to monitor respiratory function over time. • Symptom severity and disease control will be reassessed using the mMRC Questionnaire for COPD, CAT, and ACT, and documented in the CRF. • Follow-up laboratory assessments will include CBC, liver enzymes (ALT, AST, GGT), serum bilirubin, and serum creatinine, and will be recorded in the CRF. • The global physician assessment for effectiveness and tolerability will be repeated using a standardized tool. • The subject satisfaction assessment will be repeated to evaluate patient-reported outcomes regarding the treatment experience. • ECG monitoring will be conducted to assess cardiac function and any changes during the course of treatment. • Any ongoing or new AEs and SAEs will be assessed and documented in accordance with protocol guidelines.
Statistical Methods:	All quantitative variables will be summarized using Mean ± Standard Deviation (SD) for parametric data and Median with Interquartile Range (IQR) for non-parametric data. Qualitative variables will be presented as frequencies and percentages. For comparisons over time within groups, the paired t-test will be applied to parametric variables, while the Wilcoxon Signed-Rank Test will be used for non-parametric continuous variables. Repeated measures across multiple time points will be analyzed using ANOVA for parametric data and the Kruskal-Wallis test for non-parametric data. Categorical variables, such as the incidence of AE, will be compared using the Chi-Square Test or Fisher's Exact Test, as appropriate. All statistical analyses will be performed using SPSS Version 27.0. A p-value of less than 0.05 will be considered statistically significant.

2. Introduction

2.1 Background

Chronic respiratory diseases like asthma and COPD are major contributors to global illness and disability, with a significant burden in countries like India. These conditions require long-term management to control symptoms, reduce exacerbations, and improve patients' quality of life. Deriphyllin, a fixed-dose combination of etofylline and theophylline, is commonly used in India for treating such respiratory disorders. It acts as a bronchodilator and has anti-inflammatory properties, making it beneficial in improving respiratory function. However, limited real-world data exist on its safety and effectiveness in diverse clinical settings.

Real-world evidence (RWE) studies help bridge this gap by assessing drug performance in everyday clinical practice. This multicentric, prospective study aims to evaluate the safety and effectiveness of Deriphyllin in adult patients with chronic respiratory diseases by analyzing changes in respiratory function, symptom control, ECG and laboratory parameters, and overall treatment satisfaction.

2.2 Study Rationale

Deriphyllin (Etofylline + Theophylline) is commonly prescribed for asthma, COPD, including other respiratory disorders due to its bronchodilator and anti-inflammatory properties. However, real-world data on its effectiveness and safety in routine clinical practice remains limited. This observational study aims to evaluate the impact of Deriphyllin on respiratory function, symptom control, and safety profile in patients with chronic respiratory ailments, providing valuable evidence to optimize its clinical use.

2.3 Risk/Benefit Assessment

The use of Deriphyllin, a combination of theophylline and etofylline, may pose risks such as gastrointestinal discomfort, insomnia, palpitations, or arrhythmias, particularly in patients with pre-existing cardiovascular or neurological conditions. However, strict eligibility criteria excluding high-risk individuals and routine monitoring of vitals, ECG, lab parameters, and adverse events at each visit are in place to minimize these risks. Participants may benefit from improved respiratory function, better symptom control, and enhanced quality of life, along with close clinical follow-up throughout the study. Overall, the potential benefits of participation are expected to outweigh the minimal risks involved, especially with appropriate safety measures in place.

3. Objectives and Endpoints

3.1 Objectives

Primary Objective:

To assess the safety of Deriphyllin by monitoring adverse events and serious adverse events throughout the study duration.

Secondary Objective:

- To assess the effectiveness of Deriphyllin on respiratory function by evaluating changes in spirometry parameters (FEV_1, FEV_1/FVC ratio, PEFR), pulse rate, 6MWT, and SpO_2 from baseline to follow-up visits within three months of baseline (at available study sites).
- To evaluate the relief in severity of symptoms through the mMRC questionnaire for COPD from baseline to follow-up visits within three months of baseline. (Annexure 1)
- To assess symptom control in COPD patients using COPD Assessment Test (CAT) scores from baseline to follow-up visits within three months of baseline. (Annexure 2)
- To assess symptom control in asthma patients using Asthma Control Test (ACT) scores from baseline to follow-up visits within three months of baseline. (Annexure 3)
- To assess the effectiveness of the Deriphyllin through Subject Satisfaction Assessment at the end of the study. (Annexure 5)
- To evaluate the effect of Deriphyllin on ECG parameters from baseline to follow-up visits within three months of baseline.
- To assess hematological parameters including CBC, Liver enzyme (ALT, AST, and GGT), serum bilirubin, and serum creatinine from baseline to follow-up visits within three months of baseline.
- To assess the overall tolerability of Deriphyllin through Global Physician Assessment at the end of the study. (Annexure 4)

4. Study Design

4.1 Study Design

Prospective, Observational, Multi-centric study

4.2 Study type

A real-world evidence study.

5. Study Population

Inclusion Criteria:

An individual who meets any of the following criteria will be excluded from participation in this study:

1. All the patients >18 years of either gender
2. All Patients with respiratory conditions such as Asthma, COPD, and other conditions who are receiving Deriphyllin treatment at the discretion of the treating physician.
3. Patients for whom Deriphyllin is being newly initiated as an add-on to ongoing therapy and who have not received Deriphyllin treatment prior to study enrollment.

Exclusion Criteria:

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Patients under 18 years of age.

2. Patients with known hypersensitivity to theophylline, etofylline, or any other components of Deriphyllin, or those using other methylxanthines (e.g., aminophylline).
3. Patients with significant cardiovascular conditions like Arrhythmia, LVH with EF < 30%, and Severe heart failure
4. Patients diagnosed with active peptic ulcers due to the potential exacerbation of gastrointestinal symptoms.
5. Patients having a history of epilepsy or other seizure disorders.
6. Patients with severe liver dysfunction.
7. Pregnant and lactating females.
8. Any other conditions which are not suitable for Deriphyllin treatment at the discretion of treating physician.

5.1 Sample size

This is a prospective, observational, real-world evidence study with an anticipated enrollment of approximately 400 patients across multiple clinical sites in India. The sample size is based on feasibility considerations and aims to ensure sufficient representation of patients with Chronic respiratory conditions (Asthma, COPD, and others) receiving Deriphyllin in routine clinical practice.

5.2 Study Duration

The study duration will be 12 weeks from enrolment.

6. Study Visit and Assessment Schedule

This real-world evidence study is structured with three scheduled visits: Baseline (enrolment), Visit 1 (within 3 months), and Visit 2 (within 3 months, if applicable). These visits are designed to evaluate the safety and effectiveness of Deriphyllin (various sustained-release formulations) in Indian adults with chronic respiratory conditions such as asthma, COPD, and related disorders under routine clinical practice. The total study duration for each participant will be approximately 3 months from enrolment. Data will be collected through the CRF based on standard clinical evaluations and investigations, including spirometry, 6-minute walk test (6MWT), symptom scores (mMRC, CAT, ACT), ECG, laboratory parameters (CBC, liver enzymes, serum bilirubin, creatinine), and adverse event monitoring.

7. Adverse Event Monitoring

All AEs, whether spontaneously reported by the participant or observed by the investigator, will be documented at every visit. The PI will assess the severity, duration, seriousness, and causality of each AE. Any clinically significant AE will be managed as per standard medical practice and recorded in the study documents. SAEs, if any, will be reported promptly to the sponsor and ethics committee as per regulatory guidelines.

Any adverse event will be reported to Zydus Lifesciences Limited, Pharmacovigilance Dept, Ahmedabad

8. Statistical Considerations

8.1 General Considerations

Standard summary statistics will be calculated for quantitative and qualitative variables. Quantitative variables will be presented with the Number of subjects, mean, median, standard deviation (SD), minimum, and maximum. Qualitative variables will be presented using the number of subjects and percentages.

8.2 Data Analysis

All statistical analyses will be conducted using IBM SPSS Statistics, Version 27.

- Quantitative variables (e.g., spirometry parameters such as FEV_1, FEV_1/FVC ratio, PEFR; 6MWT distance; vital signs; and laboratory parameters including CBC, liver enzymes, serum bilirubin, and creatinine) will be summarized as mean ± standard deviation (SD) for normally distributed data or median with interquartile range (IQR) for non-normally distributed data.
- Qualitative variables (e.g., AEs, SAEs, global physician assessments, and subject satisfaction scores) will be presented as frequencies and percentages.
- Within-group comparisons (e.g., baseline vs. Visit 1 and/or Visit 2) will be performed using the paired t-test for parametric data and the Wilcoxon Signed-Rank Test for non-parametric data.
- Repeated measures across time points (Baseline, Visit 1, Visit 2) will be assessed using repeated-measures ANOVA for parametric data or the Kruskal-Wallis test for non-parametric variables.
- Categorical variables (e.g., changes in symptom severity, mMRC, CAT, ACT scores) will be compared using the Chi-square test or Fisher's Exact Test, as appropriate.

All statistical tests will be two-tailed, and a p-value of < 0.05 will be considered statistically significant.

9. Supporting Documentation and Operational Considerations

9.1 Regulatory, Ethical, And Study Oversight Considerations

The sponsor and the PI must comply with all instructions, regulations and agreements in this protocol and applicable ICH guidelines for Good Clinical Practice and conduct the study according to local regulations.

9.1.1 Informed Consent Process

Written informed consent will be obtained from each participant prior to any study-related procedures, in accordance with ICH-GCP guidelines and applicable regulatory requirements. The study purpose, procedures, potential risks, and benefits will be explained, and participants will have the opportunity to ask questions before signing an EC-approved informed consent form (ICF). Participation is voluntary, and subjects may withdraw at any time without penalty. The consent process will be documented in the medical record. A signed copy of the ICF will

be provided to the participant; the original will be retained at the investigational site. Any new information that may affect participation will be promptly communicated. Upon consent, each participant will receive a patient identification and emergency card with site contact details for use in case of emergencies.

9.1.2 Premature Termination of Study in a Study Center

The sponsor reserves the right to terminate the study or a study site at any time, with reasons discussed with the PI. Termination may occur due to protocol non-compliance, recruitment challenges, false or careless data entry, lack of cooperation, or at the PI's request.
In case of early termination, subjects will be informed and provided appropriate follow-up care. The Ethics Committee will be notified in accordance with applicable regulations.

9.1.3 Termination of the Study

Premature termination of this study may occur because of a change in opinion of the IRB/IEC, or at the discretion of Zydus Healthcare Limited, India. In addition, Zydus Healthcare Limited, India retains the right to discontinue study at any time.
If a study is prematurely terminated or discontinued, Zydus Healthcare Limited, India will promptly notify the PI. After notification, the PI shall contact all participating subjects. As directed by Zydus Healthcare Limited, India, all study materials must be collected and all CRFs completed to the greatest extent possible.

9.1.4 Confidentiality and Privacy

Participant confidentiality will be strictly maintained by the Principal Investigator (PI), study staff, and sponsor in accordance with applicable regulations. This includes protection of both clinical data and biological samples. Study-related data and documentation will be kept confidential and will not be disclosed to unauthorized third parties without the sponsor's prior written approval.

9.1.5 Clinical Monitoring

The study will be monitored by authorized representatives of the sponsor throughout its duration by means of personal visits to the PI's facilities and through other communications (e.g., telephone calls, written correspondence). Monitoring visits will be scheduled at mutually agreeable times periodically throughout the study and at frequency deemed appropriate for the study.

9.1.7 Data Handling and Record Keeping

9.1.7.1 Essential Study Documents

The PI is tasked with preparing and keeping crucial study documents up to date. These documents, both individually and collectively, enable the assessment of how the study is conducted and the quality of the resulting data. They also show that the PI and the sponsor (or an authorized representative) adhere to GCP standards and comply with all relevant national regulatory requirements.
Essential study documents will encompass source documents, which consist of original

materials, data, and records of clinical findings, observations, and other activities crucial for reconstructing and evaluating the study. These source documents include hospital records, clinical and office charts, laboratory notes, subject diaries, evaluation checklists, data recorded from automated instruments, and files maintained at laboratories and medical/technical departments involved in the clinical study. The Principal Investigator (PI) agrees to provide direct access to all essential clinical study documents for monitoring and/or auditing by the sponsor (or an authorized representative) and for inspection by relevant national and foreign regulatory authorities.

9.1.7.2 Case Report Form (CRF) Completion

All case report form (CRF) data will be entered by site personnel authorized and trained by the Principal Investigator (PI). Data entry will begin only after appropriate training and system access setup.

9.1.7.3 Study Records Retention

The PI should maintain the essential clinical study documents (including CRFs, source documents, signed subject informed consent forms, AE reports and other regulatory documents) as per the sponsor requirements. The PI is to take adequate measures to prevent accidental or premature destruction of these documents. In the event of accidental destruction, the PI should notify the sponsor (or an authorized representative) immediately.

9.1.8 Publication Policy

The data generated by this study are confidential information of the sponsor. The sponsor will publicly disclose the results of all applicable clinical trials following legal and regulatory requirements. The publication policy with respect to the PI and study centre will be set forth in the Clinical Trial Agreement.

9.2 Ethics Committee

The study and the subject informed consent form must be approved in writing by an appropriate IEC/ IRB prior to enrolment of any study subjects.

10. Schedule of Assessment

Laboratory and other diagnostic assessments list:

Parameters	**Baseline**	**Visit 1 (Within 3 months)**	**Visit 2 (Within 3 months) (if any)**
Informed Consent	X		
Vitals: SpO_2, BP, PR	X	X	X
Spirometry Parameters: FEV1, FEV1/FVC ratio, PEFR*	X	X	X
6MWT*	X	X	X
Symptom severity (mMRC Questionnaire) For COPD	X	X	X
COPD assessment test (CAT)	X	X	X
ACT for Asthma	X	X	X
Lab parameters: • CBC • Liver enzyme (ALT, AST, and GGT) • Serum Bilirubin • Serum creatinine	X	X	X
Global Physician Assessment		X	X
Subject Satisfaction Assessment		X	X
ECG Monitoring *	X	X	X
Adverse events/SAEs		X	X

**wherever available*

Commented [PP1]: Add ECG monitoring at baseline too

ANNEXURES

Annexure 1

Modified Medical Research Council (mMRC) Dyspnea Scale

Grade	Description
0	"I only get breathless with strenuous exercise"
1	"I get short of breath when hurrying on the level or walking up a slight hill"
2	"I walk slower than people of the same age on the level because of breathlessness or have to stop for breath when walking at my own pace on the level"
3	"I stop for breath after walking about 100 yards or after a few minutes on the level"
4	"I am too breathless to leave the house" or "I am breathless when dressing"

Doherty DE et al. COPD: Consensus Recommendations for early diagnosis and treatment. Journal of Family Practice, Nov 2006.

Annexure 2

How is your COPD? Take the COPD Assessment Test™ (CAT)

This questionnaire will help you and your healthcare professional to measure the impact that COPD (Chronic Obstructive Pulmonary Disease) is having on your wellbeing and daily life. Your answers and test score can be used by you and your healthcare professional to help improve the management of your COPD and gain the greatest benefit from the treatment.

If you wish to complete the questionnaire by hand on paper, **please click here** and then print the questionnaire.

For each item below, place a mark (X) in the box that best describes your current situation. Please ensure that you only select one response for each question.

Example: I am very happy 0 X 2 3 4 5 I am very sad

								SCORE
I never cough	0	1	2	3	4	5	I cough all the time	
I have no phlegm (mucus) on my chest at all	0	1	2	3	4	5	My chest is full of phlegm (mucus)	
My chest does not feel tight at all	0	1	2	3	4	5	My chest feels very tight	
When I walk up a hill or a flight of stairs I am not out of breath	0	1	2	3	4	5	When I walk up a hill or a flight of stairs I am completely out of breath	
I am not limited to doing any activities at home	0	1	2	3	4	5	I am completely limited to doing all activities at home	
I am confident leaving my home despite my lung condition	0	1	2	3	4	5	I am not confident leaving my home at all because of my lung condition	
I sleep soundly	0	1	2	3	4	5	I do not sleep soundly because of my lung condition	
I have lots of energy	0	1	2	3	4	5	I have no energy at all	
							TOTAL SCORE	

DA4247000

Annexure 3

ASTHMA CONTROL TEST™

Know your score

The Asthma Control Test™ provides a numerical score to help you and your healthcare provider determine if your asthma symptoms are well controlled.

Take this test if you are 12 years or older. Share the score with your healthcare provider.

Step 1: Write the number of each answer in the score box provided.

Step 2: Add up each score box for the total.

Step 3: Take the completed test to your healthcare provider to talk about your score.

If your score is 19 or less, your asthma symptoms may not be as well controlled as they could be. No matter what the score, bring this test to your healthcare provider to talk about the results.

					SCORE
1. In the past 4 weeks, how much of the time did your asthma keep you from getting as much done at work, school or at home?	All of the time **[1]**	Most of the time **[2]**	Some of the time **[3]**	A little of the time **[4]**	None of the time **[5]**	.....
2. During the past 4 weeks, how often have you had shortness of breath?	More than Once a day **[1]**	Once a day **[2]**	3 to 6 times a week **[3]**	Once or twice a week **[4]**	Not at all **[5]**	.....
3. During the past 4 weeks, how often did your asthma symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?	4 or more nights a week **[1]**	2 to 3 nights a week **[2]**	Once a week **[3]**	Once or twice **[4]**	Not at all **[5]**	.....
4. During the past 4 weeks, how often have you used your rescue inhaler or nebulizer medication (such as albuterol)?	3 or more times per day **[1]**	1 or 2 times per day **[2]**	2 or 3 times per week **[3]**	Once a week or less **[4]**	Not at all **[5]**	.....
5. How would you rate your asthma control during the past 4 weeks?	Not Controlled at All **[1]**	Poorly Controlled **[2]**	Somewhat Controlled **[3]**	Well Controlled **[4]**	Completely Controlled **[5]**	.....

If your score is 19 or less, your asthma symptoms may not be as well controlled as they could be. No matter what your score is, share the results with your healthcare provider.

TOTAL: .....

Annexure 4

Global Physician Assessment

☐ Excellent

☐ Very Good

☐ Good

☐ Fair

☐ Poor

Annexure 5

Subject Satisfaction Assessment

☐ Excellent

☐ Very Good

☐ Good

☐ Fair

☐ Poor