1.6.1.1 Name of the medicinal Product

Diphenhydramine HCL, Ammonium Chloride, Sodium Citrate And Menthol Syrup 100 Ml-ABACOFF

1.6.1.1.1 Strength

Diphenhydramine HCL-14.08 MG + Ammonium Chloride-138.00 MG + Sodium Citrate 57.03 MG + Menthol-0.90 MG Per 5 ML Contains

1.6.1.1.2 Pharmaceutical Form

Oral Solution

1.6.1.2 Qualitative and Quantitative Composition

1.6.1.2.1 Qualitative declaration

Diphenhydramine HCL BP

Ammonium Chloride BP

Sodium Citrate BP

Menthol USP

1.6.1.2.2 Quantitative declaration

Name of active ingredient(s)*	Quantity / Unit	Unit of measure/Unit	Reference/ monograph standard
Diphenhydramine Hydrochloride	14.08*	MG	BP
Ammonium Chloride	138.0	MG	BP
Sodium Citrate	57.03	MG	BP
Menthol	0.900**	MG	USP
Citric Acid Monohydrate	10.00	MG	BP
Saccharin Sodium	5.00	MG	BP
Sucrose	2500	MG	BP
Liquid glucose	1165.0	MG	USP-NF
Glycerol	390.75	MG	BP

Propylene Glycol	283.75	MG	BP
Methyl HydroxyBenzoate	10.00	MG	BP
Propyl HydroxyBenzoate	2.500	MG	BP
Disodium Edetate	5.000	MG	BP
Essence Cherry Sweet	15.00	MG	In-House
Colour Ponceau 4R (supra)	0.400	MG	In-House
Purified Water	Q.S.	MG	BP

*= 4% Overages are taken

**=25% Overages are taken

Note: ** Only one name for each substance should be given in the following order of priority: INN**, Pharmacopoeia, common name, scientific name*

*** The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant.*

Details of overages *should not be included in the formulation columns but should be stated below:*

- Active substance(s): NA
- Excipient(s): NA

Details of overages *should not be included in the formulation columns but should be stated below:*

- Active substance(s): NA
- Excipient(s): NA

1.6.1.3 Pharmaceutical Form

Oral Solution

Red coloured liquid filled in 100 ml amber bottle.

1.6.1.4 Clinical Particulars

1.6.1.4.1 Therapeutic Indications

For the symptomatic relief of troublesome cough associated with upper respiratory tract congestion.

1.6.1.4.2 Posology and Method of Administration

Children 1 To 5 Years : Half of one 5 ml spoonful every 4 hours Children 6 to 12 years : One 5 ml spoonful every 4 hours Adult and Elderly : One or Two 5 ml spoonful every 4 hours.

1.6.1.4.3 Contraindications

Hypersensitivity to any ofthe ingredients. Children below one year of age.

Patients on monomine oxidase inhibitor therapy within previous 14 days. The drug is contraindicated in epileptics.

1.6.1.4.4 Special Warnings and Special Precautions for Use

Raised intra-ocular pressure, stenosing peptic ulcer, pyloro-duodenal obstruction, prostatic hypertrophy, asthma, hypertension, hyperthyroidism, severe artery disease and hepatic or renal dysfunctions.

Use in pregnancy and Lactation : In view of the potential risks versus small benefits, it is recommended that Abacoff Syrup should not be used during pregnancy and lactation, particularly as the safety ofAbacoffSyrup in human pregnancy is not established.

Effect on ability to drive and use machines : Abacoff Syrup may cause drowsiness and the patients so affected should not drive or operate machinery

1.6.1.4.5 Interaction with other medicinal products and other forms of interaction

Additive CNS depressant effects with alcohol and other CNS depressants. Additive anticholinergic effects with other drugs of similar properties.

Monomine oxidase inhibitors prolong and intensifY the anti-cholinergic effects of antihistamines.

Diphenhydramine may mask the response of the skin to allergenic skin tests and also the ototoxic symptoms associated with certain antibiotics.

1.6.1.4.6 Fertility, Pregnancy and Lactation

In pregnancy and Lactation : In view of the potential risks versus small benefits, it is recommended that Abacoff Syrup should not be used during pregnancy and lactation, particularly as the safety ofAbacoffSyrup in human pregnancy is not established.

Effect on ability to drive and use machines : Abacoff Syrup may cause drowsiness and the patients so affected should not drive or operate machinery

1.6.1.4.7 Effects on ability to Drive and use Machines

Not Applicable.

1.6.1.4.8 Undesirable Effects

Sedation, incoordination, confusion, occasional allergic or anaphylactic reactions, anticholinergic effects such as blurred vision, dry mouth, tachycardia, urinary hesitancy, constipation, photosensitivity, paradoxical excitability (particularly in children) and tremors.

1.6.1.4.9 Overdose

Symptoms of overdosage include those due to diphenhydramine or menthol (drowsiness, dizziness, ataxia, anti-cholinergic effects, pyrexia, headache, convulsions, hallucinations, excitement and respiratory depression).

Treatment should be symptomatic & supportive. Treatment consists of gastric lavage and aspiration. Administration of activated charcoal may help.

1.6.1.5 Pharmacological Properties

1.6.1.5.1 Pharmacodynamics Properties

Diphenhydramine Hydrochloride -It has central sedative, local anaesthetic, spasmolytic and anti- cholinergic (diminishes upper respiratory tract secretions) properties, in addition to its main antihistaminic actions. Ammonium Chloride - Reflexly acting expectorant which reduces viscosity of sputum, making it easierto expectorate. Sodium citrate- Directly acting expectorant. Menthol- Soothing agent.

1.6.1.5.2 Pharmacokinetic Properties

On oral administration, the components are well absorbed and produce its effect, 30-45 minutes after ingestion. Duration of action is 4-6 hours

1.6.1.5.3 Preclinical Safety Data

Not Applicable.

1.6.1.6 Pharmaceutical Particulars

1.6.1.6.1 List of Excipients

Citric Acid Monohydrate

Saccharin Sodium

Sucrose

Liquid glucose

Glycerol

Propylene Glycol

Methyl HydroxyBenzoate

Propyl HydroxyBenzoate

Disodium Edetate

Essence Cherry Sweet

Colour Ponceau 4R (supra)

Purified Water

1.6.1.6.2 Incompatibilities

Not applicable.

1.6.1.6.3 Shelf Life

36 months

1.6.1.6.4 Special Precautions for Storage

Store below 30°C. Protect from light.

1.6.1.6.5 Nature and Contents of Container

Red coloured liquid filled in 100 ml amber bottle having 25 mm "LPL" logo Printed Aluminium P.P. Cap & 10 ml measuring cup. Such one labeled bottle is packed in a printed carton with Packing Insert.

1.6.1.6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

1.6.1.7 Marketing Authorization Holder And Manufacturing Site Addresses

1.6.1.7.1 Name and Address of Marketing Authorization Holder

Name : **LINCOLN PHARMACEUTICALS LTD.**

Address : Trimul Estate, Khatraj, Tal. Kalol,

Dist. Gandhinagar,

Gujarat, India.

Phone : +91-2764-665000

Fax : +91-2764-281809

E-mail : info@lincolnpharma.com

Website : www.lincolnpharma.com

1.6.1.7.2 Name and Address of manufacturing site(s)

Name : **LINCOLN PHARMACEUTICALS LTD.**

Address : Trimul Estate, Khatraj, Tal. Kalol,

Dist. Gandhinagar,

Gujarat, India.

Phone : +91-2764-665000

Fax : +91-2764-281809

E-mail : info@lincolnpharma.com

Website : www.lincolnpharma.com

1.6.1.8 Marketing Authorization Number

To be included after obtaining first registration.

1.6.1.9 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

1.6.1.10 Date of Revision of the Text

1.6.1.11 Dosimetry (If Applicable)

Not Applicable

1.6.1.12 Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable