HEATHCARE Ltd. 1802 - 1805, GIDC, Phase III, Vapi - 396 195 (Gujarat), India



CERTIFICATE OF ANALYSIS FOR WORKING STANDARD

Nme of WS

: Ambroxol HCL IP/BP

Btch No.

: AMX/40240813

W Code No

: WS/14/004

Ref. Std & Lot No.: EP-3.1

Mg. Date

: Aug.2013

Exp. Date

: Jul.2017

Anlysis Date

: 08.01.2014

Sample Qty. : 100.0 gm

Dte of Preparation: 09.01.2014

Valid up to : 08.01.2016

: AMI LIFESCIENCES PVT LTD

Sr.	Test	Specification	Observation
No			
1	Appearance	A white or yellowish crystalline Powder.	A yellowish crystalline Powder.
2	Identification: By IR	The infra red absorption spectrum is concordant with the spectrum obtained from Ambroxol RS.	The infra red absorption spectrum is concordant with the spectrum obtained from Ambroxol EP RS.
3, .	Loss on Drying	Not more than: 0.5 %	0.25 %
4,	Related substance: By HPLC 1.Unspecified Impurity	Not more than 0.1 %	Not Detected
٠	2.Total Impurity	Not more than 0.3 %	Not Detected
5.	Assay: by Potentiometrically	Between: 99.0 % to 101.0 % (on Dried basis)	100.2 % (on such basis) 100.5 % (on dried basis)

Remarks: The above sample is complies as per the IP/BP and in house specification w.r.t above test only.

Prepared by: H.N-181el

Date: 09.01-2014

Name: Hemil Patel Designation: Q.C Chemist Checked by:

Date:

Name: Hitesh Gheewala

Designation: Q.C Asst. Manager

Head - Quality Control:

Name: Mahendra. P

Designation: Manager

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