CERTIFICATE OF ANALYSIS

Name of the Product & Grade: Allopurinol BP/Ph.Eur.

Batch No.	ALP-16015/01	**Manufacturing Date**	February 2016
A. R. No.	QC/05/16/0084	**Date of Release**	24/02/16
Batch Quantity	1000.90 Kg	**Expiry Date**	January 2021

Sr. No.	Tests	Results	Specifications
CHARACTERS			
1.0	Appearance	Almost white powder.	White or almost white powder.
2.0	Solubility	Complies	Very slightly soluble in water and in ethanol (96 percent). It dissolves in dilute solutions of alkali hydroxides.
IDENTIFICATION			
3.0	Identification		
	Infrared absorption spectrophotometry	Conforms	IR spectrum of test sample should be concordant with the IR spectrum of Allopurinol WS.
TESTS			
4.0	Related substances By HPLC		
I	Impurity A	Below Disregard Limit	Not more than 0.20 %
	Impurity B	Below Disregard Limit	Not more than 0.10 %
	Impurity C	Not Detected	Not more than 0.10 %
	Unspecified impurities	Not Detected	Not more than 0.10 %
	Sum of Impurities (Other than A, B and C)	Not Detected	Not more than 0.30%
II	Impurity F	Below Detection Limit	Not more than 2.5 ppm

PREPARED BY	CHECKED BY	APPROVED BY
24/2/2016	24/02/16	24/2/16
Sr. Executive QC	Sr. Executive QC	Sr. Manager QC

24/02/16

INDOCO REMEDIES LIMITED

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CIN: L85190MH1947PLC005913

LOTE INCOFARMA: J70733

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CERTIFICATE OF ANALYSIS			
Name of the Product & Grade: Allopurinol BP/Ph.Eur.			
Batch No.	ALP-16015/01	**Manufacturing Date**	February 2016
A. R. No.	QC/05/16/0084	**Date of Release**	24/02/16
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Sr. No.	Tests	Results	Specifications
5.0	Heavy Metals	Complies	Maximum 20 ppm
6.0	Loss on drying	0.23 %	Maximum 0.5%
7.0	Sulphated ash	0.04 %	Maximum 0.1%
8.0	Assay (On dried basis)	99.3 %	97.0 – 102.0 %
9.0	Residual solvents		
	Isopropyl Alcohol	Not Detected	Not more than 250 ppm
	Ethyl Alcohol	Not Detected	Not more than 100 ppm
	Formamide	6 ppm	Not more than 200 ppm

Remark: The above batch **complies** with the prescribed standards of quality with respect to above tests as per BP/ Ph.Eur. grade by referring to specification No.FP/SPC/051-00 and COA is compiled as per specification No.FP/SPC/051-01.

CEP No.: R1-CEP 2008-017- Rev 01

Note: Test for determination of Impurity D & E are excessive, as these impurities are not possible in our Route of Synthesis (ROS) and never observed in our API till date. Hence through a change control which is approved by EDQM, these impurities were removed from the specification.

PREPARED BY	CHECKED BY	APPROVED BY
24/02/16	24/02/16	25/02/16
Sr. Executive QC	Sr. Executive QC	Sr. Manager QC

REVIEWED BY QA 25/02/16

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