QUANTUM PHARMACEUTICALS PVT LTD

Rajvant, 797/3 Bhandarkar Road.,, Mumbai, Maharashtra - 400093 Tel. No. 022 - 28202932

WORK-SHEET FOR

Raw Material

Material Name	:	Allopurinol IP	Material Code	:	RAI007
Batch No.	:	SE0100284	AR No.	:	RM2526/009
GRN No.	:	00006	Mfg. Date	:	Feb,2025
Received Date	:	09/04/2025	Exp. Date	:	Jan,2030
Manufacturer's Name	:	HARMAN FINOCHEM LTD.	Received Qty.	:	25.000 Kg
Supplier's Name	:	HARMAN FINOCHEM LTD.	Sampling Date	:	09/04/2025
Specification No.	:	RM/RAI007/IP/05	Sampled Qty.	:	0.014 Kg
Sampled By	:	Gadekar Siddhi D	Control Sample	:	0.007 Kg
Challan No. & Date	:	91403077 Dt. 01/04/2025	Retest Date	:	NA

Description (Complies / Does not complies) ✔

Specification: A white or almost white, crystalline powder.

Analysed By/Date : ABC update 23/09/2025

Solublity (Complies / Does not complies) ☐

Specification: Very slightly soluble in water and in ethanol (95%); practically insoluble in chloroform and in ether. It is soluble in dilute solutions of alkali hydroxides.

Analysed By/Date :

Identification ☐

Identification A (Complies / Does not complies)

Specification: By IR absorption, identical with std.

IR ID : IL/QC/85

Analysed By/Date :

Identification B (Complies / Does not complies) ☐

Specification: By UV absorption: when solution examined in the range 220nm to 360nm shows an absorption maximum at about 250nm & minimum at about 231nm; ratio of the absorbance at the minimum at about 231nm to that at the maximum at about 250nm, 0.52 to 0.62

UV ID : IL/QC/84

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Analysed By/Date :

Identification C (Complies / Does not complies) ☐

Specification: A flocculent yellow ppt is produced

BALANCE ID : IL/QC/74, IL/QC/01

Sample :_____ gm

Analysed By/Date :

Identification D (Complies / Does not complies) ☐

Specification: A grey-blue colour is produced.

BALANCE ID: IL/QC/74, IL/QC/01

Sample :_____ gm

Analysed By/Date :

Appearence Of Solution (Complies / Does not complies) ☐

Specification: The solution is clear and not more intensely coloured than reference solution YS6 or GYS4.

Balance ID. IL/QC/74, IL/QC/01

Mol. Reg. No._____ Ref. IL/QC/ML/_____

Appearance Ref. IL/QC/CC/_____ Pg. no._____

Sample taken :_____ gm------->_____ml

Observation:

Analysed By/Date :

Related Substances

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Impurity A (Complies / Does not complies) ☐

Specification: NMT 0.2%

Balance ID : IL/QC/01, IL/QC/108, IL/QC/74

HPLC ID : IL/QC/_____

Mobile phase : _____g Potassium dihydrogen orthophosphate dissolved in _____ml water.

0.4% w/v NaOH solution : _____g NaOH dissolved in_____ml water.

Test solution :_____mg Test sample +_____ml 0.4% w/v NaOH solution ----> _____ml MP.

Ref. soln. (a) :_____ml Test solution ----> _____ml ---->_____ml------->_____ml MP.

Ref. soln. (b): _____mg Impurity A +_____mg Impurity B +_____mg Impurity C +_____ml 0.4% w/v NaOH solution ---->_____ml MP.

(Separate stock solution) --->_____ml Impurity A stock solution +_____ml each of Impurity B & Impurity C stock solution -->

_____ ml MP.

HPLC Condition: Column ID: _____, Flow rate: _____ml/min; Wavelength: _____nm; RT;_____min; Inj. Vol: _____µl

Value : _____ Unit : _____

Analysed By/Date :

Impurity B (Complies / Does not complies)

Specification: NMT 0.1%

Value: _____ Unit: _____

Analysed By/Date :

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Impurity C (Complies / Does not complies)

Specification: NMT 0.1%

Value: _____ Unit: _____

Analysed By/Date :

Any Other Impurity (Complies / Does not complies)

Specification: NMT 0.1%

Value: _____ Unit: _____

Analysed By/Date :

Total Other Impurities (Complies / Does not complies)

Specification: NMT 0.3%

Value: _____ Unit: _____

Analysed By/Date :

Disregard Limit (Complies / Does not complies)

Specification: NMT 0.05%

Analysed By/Date :

Heavy metals (Complies / Does not complies)

Specification: Not more than 20 ppm

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Balance ID.IL/QC/74,IL/QC/01

LT ref. IL/QC/LT/_____ , Pg.No._____

Sample :

Std :

Analysed By/Date :

Sulfated Ash (Complies / Does not complies)

Specification: NMT 0.1% w/w

BALANCE ID NO.:IL/QC/01\IL/QC/74

MUFFLE ID NO.:IL/QC/60

Wt. of container(A) _____ g

Wt. of Sample (B) _____ g

Wt. of container + sample(C) _____ g

Wt. of container + residue(D) _____ g

Wt. of residue(C-A) _____ g

$$\frac{\text{Wt. of residue(C-A)}}{\text{Wt. of Sample (B)}} \times 100$$

Analysed By/Date :

Loss On Drying (Complies / Does not complies)

Specification: NMT 0.5% w/w

BALANCE ID NO.:IL/QC/01, IL/QC/74, IL/QC/108

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Sampled By	:	Gadekar Siddhi D	Control Sample	:	0.007 Kg
Challan No. & Date	:	91403077 Dt. 01/04/2025	Retest Date	:	NA

OVEN ID NO.IL/QC/48, IL/QC/11, IL/QC/98

Wt. of bottle(A) _____ g

Wt. of bottle+sample (B) _____ g

Wt. of sample(C) (B-A) _____ g

Wt. of bottle+sample(after drying)(D) _____ g

Wt. of sample(after drying) (D-A) _____ g

Loss in Weight (B-D) _____ g

Loss in Weight(B-D)
---------- X 100
Wt. of Sample(C)

Analysed By/Date :

Assay

Allopurinol (Complies / Does not complies)

Specification: 98 to 101 %w/w (odb)

BALANCE ID NO.:IL/QC/01, IL/QC/74, IL/QC/108

MOLARITY REF.NO.IL/QC/ML/_____

REG.NO._____Pg.NO._____

Wt. or Vol. of sample _____ g/ml

Diluted to ml; ml-> ml; ml-> ml;

Volume of _____N consumed -> Test _____

Titration factor _____ g Stated normality _____N

B.R - T.R) x Normality x Titration factor x 100

Wt. of sample x Stated Normality

Method:

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Sampled By	:	Gadekar Siddhi D	Control Sample	:	0.007 Kg
Challan No. & Date	:	91403077 Dt. 01/04/2025	Retest Date	:	NA

Analysed By/Date :

Residual Solvents (Complies / Does not complies)

Specification: By GC.

BALANCE ID NO. IL/QC/_____

GC ID NO.: IL/QC/_____

Blank solution :- _____

Standard solution :- _____microlitre Formamide ---> _____ml ---> ____ml ---> _____ml ---> _____ml ---> _____ml DMSO

Test solution :- _____g Test sample ------> _____ml DMSO, shake for 10 min. & filter

GC condition: Column ID: _____; Flow rate: _____cm/s; Injector Temp.: _____ ; Detector Temp.:_____ ;

Inj. Vol. : _____ml; Column oven temp.:_____

Result:- Residual solvent name Result in ppm

1)

Analysed By/Date :

Reported By / Analysed By	Approved By
Q.C. Chemist / Date:	Q.C. Manager / Date: