

**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 :

**Solubility** (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 :

**Appearance 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-----&gt; \_\_\_\_\_ 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 ----&gt; \_\_\_\_\_ml MP.

Ref. soln. (a) : \_\_\_\_\_ml Test solution ----&gt; \_\_\_\_\_ml ----&gt; \_\_\_\_\_ml-----&gt; \_\_\_\_\_ml MP.

Ref. soln. (b): \_\_\_\_\_mg Impurity A + \_\_\_\_\_mg Impurity B + \_\_\_\_\_mg Impurity C + \_\_\_\_\_ml 0.4% w/v NaOH solution ----&gt; \_\_\_\_\_ml MP.

(Separate stock solution) ---&gt; \_\_\_\_\_ml Impurity A stock solution + \_\_\_\_\_ml each of Impurity B &amp; Impurity C stock solution --&gt;

\_\_\_\_\_ 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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| Challan No. & Date  | : 91403077 Dt. 01/04/2025 | Retest Date    | : NA         |

**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

Wt. of residue(C-A)

----- x 100

Wt. of Sample (B)

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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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-&gt; ml; ml-&gt; ml;

Volume of \_\_\_\_\_N consumed -&gt; 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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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 ---&gt; \_\_\_\_\_ml ---&gt; \_\_\_\_\_ml ---&gt; \_\_\_\_\_ml ---&gt; \_\_\_\_\_ml ---&gt; \_\_\_\_\_ml DMSO

Test solution :- \_\_\_\_\_g Test sample -----&gt; \_\_\_\_\_ml DMSO, shake for 10 min. &amp; 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: