ISO 9001-2008
Reg. No. RQ91/1030

AMSAL CHEM
PRIVATE LIMITED

A-1, 401, 402 & 403,
G.I.D.C. Industrial Estate,
Ankleshwar-393 002.
District : Bharuch, Gujarat, India.
CIN : U24231GJ1992PTC018289

## QUALITY CONTROL LABORATORY

**The Drugs & Cosmetic Act 1940 & the rules thereunder**

Format No.STP/QC/71/FM02

## CERTIFICATE OF ANALYSIS

Name of Product: ISONIAZID
Batch No : 14207/INH
Mfg. Date : ~~05/08/2014~~
Exp. Date : 04/08/2018
Sample quantity : 50 gm

A.R. No : AC/INH/207/2014
Batch size : 1050 kgs
Date of Receipt : 09/08/2014
Date of Completion : 16/11/2014
Analysed as per : ~~B.P/EP8/USP/IP~~/IN HOUSE

| *Sr. No.* | *TESTS* | *PHARMACOPOEIAL SPECIFICATION & RESULTS* | | |
|---|---|---|---|---|
| | | **EP / BP** | **USP** | **IP** |
| 1. | Description / Characters | A white or almost white crystalline powder or colour less crystals. | Colorless or white crystals or white, crystalline powder. Odorless and is slowly affected by exposure to air and light. | Colourless crystals or a white, crystalline powder. |
| | *Result* | Complies | N. A. | N. A. |
| 2. | Solubility | Freely soluble in water, sparingly soluble in Alcohol. | Freely soluble in water, sparingly soluble in alcohol, slightly soluble in chloroform, and very slightly soluble in ether. | Freely soluble in water, sparingly soluble in ethanol (95%), slightly soluble in chloroform, very slightly soluble in ether. |
| | *Result* | Complies | N. A. | N.A |
| 3. | Identification: | (Perform Tests A&B or A&C) | (Perform Tests B&D) | (Perform Tests A & B or A&C ) |
| | A. Melting Point/ Melting Range: | 170 °C to 174 °C. | 170 °C to 173 °C | 170 °C to 174 °C |
| | *Result* | 171° C | N. A. | N.A |
| | B. Infrared Absorption Spectrum | Should be concordant with IR spectrum of Isoniazid CRS / RS. | Should be concordant with IR spectrum of Isoniazid CRS / RS. | Should be concordant with IR spectrum of Isoniazid CRS / RS. |
| | *Result* | Complies | N. A. | N.A |
| | C. Melting Point of Derivative | 226 °C to 231°C. | N. A. | 226 °C to 231°C. |
| | *Result* | N.A | N.A | N.A |

16/11/14
**Analysed by**
**(Q.C. Chemist)**

16/11/14
**Checked by**
**(Q.C. Incharge)**

17/11/2014
**Approved by**
**(Q.A. Manager)**

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Name of Product: **ISONIAZID** A.R. No : **AC/INH/207/2014**

| *Sr. No.* | *TESTS* | *PHARMACOPOEIAL SPECIFICATION & RESULTS* | | |
|---|---|---|---|---|
| | | **EP / BP** | **USP** | **IP** |
| | D. Ultraviolet Absorption Spectrum | N. A. | Should be concordant with UV spectrum of Isoniazid USP RS. | N. A. |
| | *Result* | N. A. | N. A. | N. A. |
| 4. | Appearance of Solution: | A 5% w/v solution is clear and not more intensely colored than reference Solution $BY_7$ | N. A. | A 5% w/v solution is clear and not more intensely colored than reference Solution $BYS_7$. |
| | *Result* | Complies | N. A. | N.A |
| 5. | pH: | The pH of a 5% w/v solution is 6.0 to 8.0 | The pH of a 10% w/v solution is 6.0 to 7.5 | The pH of a 5% w/v solution is 6.0 to 8.0 |
| | *Result* | 7.2 | N. A. | N.A |
| 6. | Hydrazine and Related Substances (by TLC) | | | |
| | Hydrazine | 0.05% | N. A. | 0.05% |
| | *Result* | Complies | N. A. | N.A |
| | Total Related Substances (Except Hydrazine) | 0.20% | N. A. | N. A. |
| | *Result* | Complies | N. A. | N. A. |
| 7. | Related Substances As per IP (HPLC Method) | N. A. | N. A. | Any individual impurity is not more than 0.20%. Sum of all impurities found is not more than 1.0 %. |
| | *Result* | N. A. | N. A. | N.A |

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**CERTIFICATE OF ANALYSIS**

Format No.STP/QC/71/FM02

Name of Product: **ISONIAZID** A.R. No : **AC/INH/207/2014**

| *Sr. No.* | *TESTS* | *PHARMACOPOEIAL SPECIFICATION & RESULTS* | | |
|---|---|---|---|---|
| | | **EP / BP** | **USP** | **IP** |
| 8. | Heavy Metals | Not more than 10 ppm Pb | Not more than 0.002% Pb | Not more than 20 ppm Pb |
| | *Result* | Complies | N. A. | N.A |
| 9. | Loss on Drying | Not more than 0.50% | Not more than 1.0%. | Not more than 0.50% |
| | *Result* | 0.28 % | N. A. | N.A |
| 10. | Sulphated Ash | Not more than 0.10%. | N. A. | Not more than 0.10%. |
| | *Result* | 0.02 % | N.A | N.A |
| 11. | Residue on Ignition | N. A. | Not more than 0.20% | N. A. |
| | *Result* | N. A. | N. A. | N. A. |
| 12. | Assay | Not less than 99.0 % and not more than 101.0 % of $C_6H_7N_3O$. (By Titrimetry) | Not less than 98.0 % and not more than 102.0 % of $C_6H_7N_3O$. (By HPLC) | Not less than 98.0 % and not more than 101.0% of $C_6H_7N_3O$. (By HPLC) |
| | *Result* | 99. 8 % | N. A. | N.A |

| *Sr. No.* | *ADDITIONAL TESTS* | | |
|---|---|---|---|
| | *TESTS* | *SPECIFICATION* | *Results* |
| 13. | Related Substances (In-House HPLC Method): | | |
| | Isonicotinic Acid | Not more than 0.05% | 0.008 % |
| | Isonicotinamide | Not more than 0.10% | N.D |
| | Nicotinoyl Hydrazide | Not more than 0.10% | N.D |
| | Diisonicotinoyl Hydrazine | Not more than 0.10% | N.D |
| | 2-Isoniazid | Not more than 0.10% | N.D |
| | 4-Cyanopyridine | Not more than 0.10% | N.D |
| | Benzoyl Hydrazine | Not more than 0.10% | 0.028 % |
| | Any Other Single Impurity | Not more than 0.10% | 0.017 % |
| | Total Impurities | Not more than 0.50% | 0.056 % |

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Name of Product: **ISONIAZID** A.R. No : **AC/INH/207/2014**

| *Sr. No.* | *ADDITIONAL TESTS* | | |
|---|---|---|---|
| | *TESTS* | *SPECIFICATION* | *Results* |
| 14. | Residual Solvents (In-House GC Method): | | |
| | Benzene: | Not more than 2 ppm. | N.D |
| | Pyridine: | Not more than 200 ppm. | N.D. |
| | Methyl Alcohol: | Not more than 3000 ppm. | 161 ppm |
| 15. | Particle Size N.A | N.A | N.A |
| 16. | Microbiological Analysis | | |
| | Total Viable Aerobic Count: | | |
| | Total Bacterial Count: | Not More Than 1000 CFU/gm | -- |
| | Total Fungal Count (Yeasts + Moulds): | Not More Than 100 CFU/gm | -- |
| | Pathogens: | | |
| | *Escherichia coli* | Should be absent. | -- |
| | *Salmonella abony* | Should be absent. | -- |
| | *Staphylococcus aureus* | Should be absent. | -- |
| | *Pseudomonas aeruginosa* | Should be absent. | -- |
| | *Candida albicans* | Should be absent. | -- |
| | *Aspergillus brasilinesis* | Should be absent. | -- |
| | *Clostridium sporogenes* | Should be absent. | -- |

**Conclusion:**

**In the opinion of the undersigned the sample referred to above complies / ~~does not comply~~ with the requirement as per EP8/~~BP/USP/IP~~ and the In-House specification.**

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