

CERTIFICATE OF ANALYSIS

Name of Product : **THIOPROPERAZINE MESYLATE**

Batch No.: **9DTPN002**

Date of Mfg. : **April 2009**

Retest date : **09.04.2010**

TESTS	OBSERVATIONS	STANDARDS
Charecteristic	White colour fine odorless powder	White with slight shade of yellow to yellowish green colour fine odorless or very faint odour powder
Solubility	Freely soluble in water, sparingly soluble in methanol ,dimethyl formamide ,slightly soluble in chloroform ,very slightly soluble in ethanol	Freely soluble in water, sparingly soluble in methanol ,dimethyl formamide ,slightly soluble in chloroform ,very slightly soluble in ethanol
Melting point	227- 228°C	225-230°C
Identification		
A. I.R.Spectrum	Complies	Must comply
B. TLC	Complies	Must comply
Appearance of solution	Clear	Must be clear or very faintly opalescent
pH	2.23	2.0-4.0 2% aqueous solution
Loss on drying	0.64 %	Not more than 1.0 % at 120 ° C for 3 hours
Contained impurities	Complies	Must comply
Sulphated ash	0.06 %	Not more than 0.1 %
Heavy metals	Less than 10 ppm	Not more than 10 ppm
Assay Thiopropazine mesylate	99.54 %	98.0 – 101.0 % on dry basis
Conclusion : The sample complies with In house Specifications		
Final Disposition: APPROVED	Disposition by: <i>SPD/aly</i>	Date : 09.04.2009

CHECKED BY: Christophe P. Cordier

NOTES:

- This Certificate of Analysis is issued using results supplied by manufacturing location
- Manufactured in India



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CERTIFICATE OF ANALYSIS

Name of Product : **THIOPROPERAZINE MESYLATE**

Batch No.: **9DTPN001**

Date of Mfg. : **April 2009**

Retest date : **06.04.2010**

TESTS	OBSERVATIONS	STANDARDS
Charecteristic	White colour fine odorless powder	White with slight shade of yellow to yellowish green colour fine odorless or very faint odour powder
Solubility	Freely soluble in water, sparingly soluble in methanol ,dimethyl formamide ,slightly soluble in chloroform ,very slightly soluble in ethanol	Freely soluble in water, sparingly soluble in methanol ,dimethyl formamide ,slightly soluble in chloroform ,very slightly soluble in ethanol
Melting point	228°C	225-230°C
Identification		
A. I.R.Spectrum	Complies	Must comply
B. TLC	Complies	Must comply
Appearance of solution	Clear	Must be clear or very faintly opalescent
pH	2.26	2.0-4.0 2% aqueous solution
Loss on drying	0.69 %	Not more than 1.0 % at 120 ° C for 3 hours
Contained impurities	Complies	Must comply
Sulphated ash	0.06 %	Not more than 0.1 %
Heavy metals	Less than 10 ppm	Not more than 10 ppm
Assay Thiopropazine mesylate	99.50 %	98.0 – 101.0 % on dry basis
Conclusion : The sample complies with In house Specifications		
Final Disposition: APPROVED	Disposition by: <i>SDDAWY</i>	Date : 06.04.2009

CHECKED BY: Christophe P. Cordier

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CERTIFICATE OF ANALYSIS

Name of Product : **THIOPROPERAZINE MESYLATE**

Batch No.: **9CTPN001**

Date of Mfg. : **Mar 2009**

Retest date : **31.03.2010**

TESTS	OBSERVATIONS	STANDARDS
Charecteristic	White colour fine odorless powder	White with slight shade of yellow to yellowish green colour fine odorless or very faint odour powder
Solubility	Freely soluble in water, sparingly soluble in methanol ,dimethyl formamide ,slightly soluble in chloroform ,very slightly soluble in ethanol	Freely soluble in water, sparingly soluble in methanol ,dimethyl formamide ,slightly soluble in chloroform ,very slightly soluble in ethanol
Melting point	227°C	225-230°C
Identification		
A. I.R.Spectrum	Complies	Must comply
B. TLC	Complies	Must comply
Appearance of solution	Clear	Must be clear or very faintly opalescent
pH	2.19	2.0-4.0 2% aqueous solution
Loss on drying	0.59 %	Not more than 1.0 % at 120 ° C for 3 hours
Contained impurities	Complies	Must comply
Sulphated ash	0.06 %	Not more than 0.1 %
Heavy metals	Less than 10 ppm	Not more than 10 ppm
Assay Thiopropazine mesylate	99.57 %	98.0 – 101.0 % on dry basis
Conclusion : The sample complies with In house Specifications		
Final Disposition: APPROVED	Disposition by: <i>SPD</i>	Date : 31.03.2009

CHECKED BY: Christophe P. Cordier

NOTES:

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