



ALIVIRA

**ALIVIRA ANIMAL HEALTH LIMITED**  
**CERTIFICATE OF ANALYSIS**

**TOLTRAZURIL**

Batch No.	ASA003147A	Batch Size	100.00 Kg
Manufacturing Date	May-2022	Retest / Expiry Date	April-2025
A.R.NO.	ALIV-FP-220244	Lot No.	40000059902
Storage Condition	Preserve in well closed containers, store at 25°C, excursions permitted between 15-30°C		
Customer Name/Vendor Name	SUAN FARMA INC		
S.No.	TEST PARAMETERS	SPECIFICATIONS	RESULTS
1	Description	White or almost white crystalline powder.	White crystalline powder
2	Solubility	Sparingly soluble in chloroform, slightly soluble in methanol, insoluble in water.	Complies
3	Identification by IR	The infrared absorption spectrum of sample should matches with spectrum obtained from standard	Complies
4	Identification by HPLC	The retention time of major peak of sample solution should correspond to that of standard solution as obtained in assay by HPLC test.	Complies
5	Appearance of solution	Solution is clear and not more intense than B7	Complies
6	Loss on drying	Not more than 1.0%	0.35% w/w
7	Sulphated ash	Not more than 0.20%	0.18% w/w
8	Heavy metals	Not more than 20 ppm	Less than 20 ppm
9	Related Substances by HPLC		
	Impurity- A	Not more than 0.50%	Not detected
	Impurity- B	Not more than 0.50%	0.11%
	Impurity- C	Not more than 0.50%	Not detected
	Impurity- E	Not more than 0.50%	0.03%
	Impurity- G	Not more than 0.50%	Not detected
	Impurity- H	Not more than 0.50%	0.02%

	PREPARED BY	REVIEWED BY	APPROVED BY
DESIGNATION	Sr.Analyst-L-1-QC	Head-QC/Designee	Head-QA/Designee
SIGNATURE	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
DATE	12/01/2023	12/01/2023	12/01/2023

Format No.: QC/116/FMT-001/R1

**Alivira Animal Health Ltd.**

Regd. Off : 301, 3rd Floor, Dosti Plinnacle, Plot No. E7, Road No. 22, Wagle Indl. Estate, Thane (W), Mumbai-400 604, India. T+91 22 41114777 F+91 22 41114754

Factory : Plot No. 104 to 109, Part of 112 & 113, Ramky Pharma City India Limited - SEZ, JNPC, Parawada Mandal,

Visakhapatnam - 531 019, A.P., India. Tel. : +91 08924 - 660888

Web : www.alivira.co Email : info@alivira.in CIN : U74120MH2013PLC248708



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### TOLTRAZURIL

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Customer Name/Vender Name	SUAN FARMA INC		
S.No.	TEST PARAMETERS	SPECIFICATIONS	RESULTS
	Impurity- I	Not more than 0.50%	Not detected
	Unspecified impurity	Not more than 0.20%	0.19%
	Total impurities	Not more than 1.0%	0.43%
10	Toltra ester content by HPLC	Not more than 0.50%	0.02%
11	Assay by HPLC (on dried basis)	98.0% - 102.0%	99.3%
12	Residual solvents by GC		
	Isopropyl alcohol	Not more than 5000 ppm	Not detected
	Methanol	Not more than 3000 ppm	175 ppm
	Dimethyl carbonate	Not more than 1000 ppm	Not detected
	Dimethyl sulphoxide	Not more than 5000 ppm	Not detected
	Toluene	Not more than 890 ppm	4 ppm
	Benzene	Not more than 2 ppm	Not detected
	Pyridine	Not more than 200 ppm	Not detected
	Dimethyl acetamide	Not more than 1090 ppm	Not detected
13	Nickel content by AAS	Not more than 10 ppm	BDL(LOD:1.0 ppm)
14	Bulk density	For information	0.362 g/ml
15	Tapped density	For information	0.5656 g/ml

**Remarks : The above batch complies as per IH Specifications.**

	PREPARED BY	REVIEWED BY	APPROVED BY
DESIGNATION	Sr.Analyst-L-1-QC	Head-QC/Designee	Head-QA/Designee
SIGNATURE			
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