ALIVIRA ANIMAL HEALTH LIMITED
CERTIFICATE OF ANALYSIS

TOLTRAZURIL

Batch No.	ASA002935A	Batch Size	250.00Kg
Manufacturing Date	Nov-2021	Retest / ~~Expiry~~ Date	Oct-2024
A.R.NO.	ALIV-FP-210676	Lot No.	40000055293
Storage Condition	Preserve in well closed containers,store at 25°C,excursions permitted between 15-30°C		
Customer Name	LGM PHARMA,LLC		

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%	0.27% w/w
7	Sulphated ash	Not more than 0.20%	0.12% w/w
8	Heavy metals	Not more than 20 ppm	Less than 20 ppm
9	Related Substances by HPLC Impurity- A Impurity- B Impurity- C Impurity- E Impurity- G Impurity- H	 Not more than 0.50% Not more than 0.50% Not more than 0.50% Not more than 0.50% Not more than 0.50% Not more than 0.50%	 Not detected 0.16% Not detected 0.14% Not detected Not detected

	PREPARED BY	REVIEWED BY	APPROVED BY
DESIGNATION	Sr.Analyst L-1-QC	Head-QC	Head-QA
SIGNATURE			
DATE	06/12/2021	06/12/2021.	06/12/2021

Format No.: QA/039/FMT-002-R2

Alivira Animal Health Ltd.
Corporate Office: 301, Dosti Pinnacle, Plot No.22, Wagle Indl. Area, Thane (W)-400 604, India. T +912241114777
Factory Address: Plot No.104 to 109, Part of 112 & 113, Ramky Pharma City India Limited –SEZ, JNPC, Parawada Mandal, Visakhapatnam – 531 019,Andhra Pradesh, India. Email: info@alivira.in Web: www.alivira.co
CIN: U74120MH2013PLC248708

ALIVIRA ANIMAL HEALTH LIMITED
CERTIFICATE OF ANALYSIS

TOLTRAZURIL

Batch No.	ASA002935A	Batch Size	250.00Kg
Manufacturing Date	Nov-2021	Retest / ~~Expiry~~ Date	Oct-2024
A.R.NO.	ALIV-FP-210676	Lot No.	40000055293
Storage Condition	Preserve in well closed containers,store at 25°C,excursions permitted between 15-30°C		
Customer Name	LGM PHARMA,LLC		

S.No.	TEST PARAMETERS	SPECIFICATIONS	RESULTS
	Impurity- I Unspecified impurity Total impurities	Not more than 0.50% Not more than 0.20% Not more than 1.0%	Not detected 0.18% 0.68%
10	Assay by HPLC (on dried basis)	98.0% - 102.0%	99.6%
11	Toltra ester content by HPLC	Not more than 0.50%	Not detected
12	Residual solvents by GC Methanol Isopropyl alcohol Dimethyl carbonate Benzene Pyridine Toluene Dimethyl sulfoxide Dimethyl acetamide	 Not more than 3000 ppm Not more than 5000 ppm Not more than 1000 ppm Not more than 2 ppm Not more than 200 ppm Not more than 890 ppm Not more than 5000 ppm Not more than 1090 ppm	 227 ppm Not detected Not detected Not detected Not detected Not detected Not detected Not detected
12	Nickel content by AAS	Not more than 10 ppm	BDL(LOD: 0.7 ppm)
13	Bulk density	For information	0.362 g/ml
14	Tapped density	For information	0.7240 g/ml

Remarks : The above batch complies as per IH Specifications. (specification No.TTZF/01C/FP/R1)

	PREPARED BY	REVIEWED BY	APPROVED BY
DESIGNATION	Sr.Analyst L-1-QC	Head-QC	Head-QA
SIGNATURE			
DATE	06/12/2021	06/12/2021	06/12/2021

ALIVIRA ANIMAL HEALTH LIMITED QA

Format No.: QA/039/FMT-002-R2

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