Eltroxin Tablets: ESR Test Results

Independent testing on batches of Eltroxin tablets supplied in New Zealand was conducted by the Institute of Environmental Science and Research Limited (ESR).

Test results are detailed below; the acceptance criteria that Eltroxin tablets must meet are also included in the table. All test results met the acceptance criteria.

Sample	ESR Lab #	Results	Acceptance Criteria
Eltroxin 100 Lot 7C002	PHA0920/1	Assay Levothyroxine sodium 91.9% Related Substances Liothyronine 0.13% Largest impurity 0.26% Tetrac <DL HDPhDB acid <DL Total impurities 1.11% Dissolution 1 82% 2 81% 3 74% 4 74% 5 73% 6 70% S_1 = 76%	Assay Levothyroxine sodium 90.0 – 105.0 % of label claim Related Substances Liothyronine NMT 1.0% Largest impurity NMT 1.0% Tetrac NMT 1.0% HDPhDB acid NMT 2.5% Total impurities NMT 5.0% Dissolution Complies with USP where Q=70% at 45 minutes
Eltroxin 100 Lot 7F004	PHA0920/2	Assay Levothyroxine sodium 95.7% Related Substances Liothyronine 0.11% Largest impurity 0.17% Tetrac <DL HDPhDB acid <DL Total impurities 1.32% Dissolution Stage 1 / Stage 2 1 77% / 1 85% 2 74% / 2 92% 3 77% / 3 87% 4 75% / 4 93% 5 66% / 5 88% 6 72% / 6 80% Avg 87% S_1 73% / S_2 80%	Assay Levothyroxine sodium 90.0 – 105.0 % of label claim Related Substances Liothyronine NMT 1.0% Largest impurity NMT 1.0% Tetrac NMT 1.0% HDPhDB acid NMT 2.5% Total impurities NMT 5.0% Dissolution Complies with USP where Q=70% at 45 minutes

Sample	ESR Lab #	Results	Acceptance Criteria
Eltroxin 100 Lot 8A002	PHA0920/3	Assay Levothyroxine sodium 100.2% Related Substances Liothyronine 0.09% Largest impurity 0.18% Tetrac <DL HDPhDB acid <DL Total impurities 1.45% Dissolution 1 76% 2 83% 3 79% 4 83% 5 82% 6 81% S_1 81%	Assay Levothyroxine sodium 90.0 – 105.0 % of label claim Related Substances Liothyronine NMT 1.0% Largest impurity NMT 1.0% Tetrac NMT 1.0% HDPhDB acid NMT 2.5% Total impurities NMT 5.0% Dissolution Complies with USP where Q=70% at 45 minutes
Eltroxin 100 Lot 7F006	PHA0920/4	Assay Levothyroxine sodium 97.1% Related Substances Liothyronine 0.08% Largest impurity 0.13% Tetrac <DL HDPhDB acid <DL Total impurities 1.41% Dissolution 1 85% 2 76% 3 83% 4 83% 5 78% 6 74% S_1 80%	Assay Levothyroxine sodium 90.0 – 105.0 % of label claim Related Substances Liothyronine NMT 1.0% Largest impurity NMT 1.0% Tetrac NMT 1.0% HDPhDB acid NMT 2.5% Total impurities NMT 5.0% Dissolution Complies with USP where Q=70% at 45 minutes

Sample	ESR Lab #	Results		Acceptance Criteria	
Eltroxin 100 Lot 7F004	PHA0920/5	Assay Levothyroxine sodium	99.9%	Assay Levothyroxine sodium 90.0 – 105.0 % of label claim	
		Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 0.12% 0.21% <DL <DL 1.29%	Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 NMT 1.0% NMT 1.0% NMT 1.0% NMT 2.5% NMT 5.0%
		Dissolution 1 94% 2 92% 3 95% 4 93% 5 87% 6 91% S_1 = 92%		Dissolution Complies with USP where Q=70% at 45 minutes	
Eltroxin 100 Lot 8A001	PHA0920/6	Assay Levothyroxine sodium	99.3%	Assay Levothyroxine sodium 90.0 – 105.0 % of label claim	
		Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 0.09% 0.17% <DL <DL 1.24%	Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 NMT 1.0% NMT 1.0% NMT 1.0% NMT 2.5% NMT 5.0%
		Dissolution 1 104% 2 94% 3 97% 4 98% 5 100% 6 92% S_1 = 98%		Dissolution Complies with USP where Q=70% at 45 minutes	

Sample	ESR Lab #	Results		Acceptance Criteria	
Eltroxin 100 Lot 7H005	PHA0920/7	Assay Levothyroxine sodium	99.4%	Assay Levothyroxine sodium 90.0 – 105.0 % of label claim	
		Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 0.10% 0.16% <DL 0.14% 1.45%	Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 NMT 1.0% NMT 1.0% NMT 1.0% NMT 2.5% NMT 5.0%
		Dissolution 1 97% 2 84% 3 85% 4 89% 5 88% 6 87% S_1 88%		Dissolution Complies with USP where Q=70% at 45 minutes	
Eltroxin 100 Lot 8A003	PHA0920/8	Assay Levothyroxine sodium	99.3%	Assay Levothyroxine sodium 90.0 – 105.0 % of label claim	
		Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 0.11% 0.15% <DL 0.06% 1.42%	Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 NMT 1.0% NMT 1.0% NMT 1.0% NMT 2.5% NMT 5.0%
		Dissolution 1 72% 2 77% 3 81% 4 80% 5 77% 6 78% S_1 77%		Dissolution Complies with USP where Q=70% at 45 minutes	

Sample	ESR Lab #	Results		Acceptance Criteria	
Eltroxin 100 Lot 7H006 Complaint Batch	PHA0919/2	Assay Levothyroxine sodium	98.6%	Assay Levothyroxine sodium 90.0 – 105.0 % of label claim	
		Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 0.09% 0.38% <DL <DL 1.65%	Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 NMT 1.0% NMT 1.0% NMT 1.0% NMT 2.5% NMT 5.0%
		Dissolution Not performed – insufficient sample available		Dissolution Complies with USP where Q=70% at 45 minutes	
Eltroxin 50 Lot 7M002	PHA0920/9	Assay Levothyroxine sodium	93.6%	Assay Levothyroxine sodium 90.0 – 105.0 % of label claim	
		Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 0.07% 0.15% <DL 0.13% 1.02%	Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 NMT 1.0% NMT 1.0% NMT 1.0% NMT 2.5% NMT 5.0%
		Dissolution 1 77% 2 88% 3 62% 4 77% 5 85% 6 66% S_1 76%		Dissolution Complies with USP where Q=70% at 45 minutes	

Sample	ESR Lab #	Results		Acceptance Criteria	
Eltroxin 50 Lot 7M002	PHA0920/1 0	Assay Levothyroxine sodium	95.5%	Assay Levothyroxine sodium 90.0 – 105.0 % of label claim	
		Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	0.08% 0.17% <DL 0.13% 1.01%	Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	NMT 1.0% NMT 1.0% NMT 1.0% NMT 2.5% NMT 5.0%
		Dissolution 1 81% 2 68% 3 83% 4 88% 5 61% 6 85% S_1 78%		Dissolution Complies with USP where Q=70% at 45 minutes	
Eltroxin 50 Lot 7M009	PHA0920/1 1	Assay Levothyroxine sodium	98.0%	Assay Levothyroxine sodium 90.0 – 105.0 % of label claim	
		Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	0.08% 0.23% <DL 0.18% 1.31%	Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	NMT 1.0% NMT 1.0% NMT 1.0% NMT 2.5% NMT 5.0%
		Dissolution 1 84% 2 91% 3 81% 4 85% 5 85% 6 72% S_1 83%		Dissolution Complies with USP where Q=70% at 45 minutes	

Sample	ESR Lab #	Results		Acceptance Criteria	
Eltroxin 50 Lot 7G008	PHA0920/1 2	Assay Levothyroxine sodium	92.9%	Assay Levothyroxine sodium 90.0 – 105.0 % of label claim	
		Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 0.10% 0.58% <DL <DL 2.49%	Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 NMT 1.0% NMT 1.0% NMT 1.0% NMT 2.5% NMT 5.0%
		Dissolution 1 85% 2 89% 3 81% 4 87% 5 87% 6 89% S_1 87%		Dissolution Complies with USP where Q=70% at 45 minutes	
Eltroxin 50 Lot 8B002	PHA0920/1 3	Assay Levothyroxine sodium	94.3%	Assay Levothyroxine sodium 90.0 – 105.0 % of label claim	
		Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 0.15% 0.24% <DL 0.07% 1.15%	Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 NMT 1.0% NMT 1.0% NMT 1.0% NMT 2.5% NMT 5.0%
		Dissolution 1 85% 2 62% 3 78% 4 93% 5 70% 6 67% S_1 76%		Dissolution Complies with USP where Q=70% at 45 minutes	

Sample	ESR Lab #	Results		Acceptance Criteria	
Eltroxin 50 Lot 7A003	PHA0920/14	Assay Levothyroxine sodium	95.7%	Assay Levothyroxine sodium 90.0 – 105.0 % of label claim	
		Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 0.08% 0.46% <DL 0.36% 2.54%	Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 NMT 1.0% NMT 1.0% NMT 1.0% NMT 2.5% NMT 5.0%
		Dissolution 1 96% 2 88% 3 86% 4 86% 5 67% 6 74% S_1 82%		Dissolution Complies with USP where Q=70% at 45 minutes	
Eltroxin 50 Lot 8B001	PHA0920/15	Assay Levothyroxine sodium	99.3%	Assay Levothyroxine sodium 90.0 – 105.0 % of label claim	
		Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 0.13% 0.42% <DL 0.08% 2.04%	Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 NMT 1.0% NMT 1.0% NMT 1.0% NMT 2.5% NMT 5.0%
		Dissolution 1 85% 2 69% 3 83% 4 55% 5 93% 6 82% S_1 78%		Dissolution Complies with USP where Q=70% at 45 minutes	

Sample	ESR Lab #	Results	Acceptance Criteria
Eltroxin 50 Lot 7A003	PHA0920/16	Assay Levothyroxine sodium 92.2% Related Substances Liothyronine 0.06% Largest impurity 0.45% Tetrac <DL HDPhDB acid 0.34% Total impurities 2.55% Dissolution Stage 1 / Stage 2 1 79% / 1 73% 2 60% / 2 81% 3 91% / 3 80% 4 62% / 4 79% 5 63% / 5 83% 6 94% / 6 59% Avg 76% S_1 75% / S_2 = 76%	Assay Levothyroxine sodium 90.0 – 105.0 % of label claim Related Substances Liothyronine NMT 1.0% Largest impurity NMT 1.0% Tetrac NMT 1.0% HDPhDB acid NMT 2.5% Total impurities NMT 5.0% Dissolution Complies with USP where Q=70% at 45 minutes
Eltroxin 50 Lot 7D004	PHA0920/17	Assay Levothyroxine sodium 99.8% Related Substances Liothyronine 0.13% Largest impurity 0.35% Tetrac <DL HDPhDB acid 0.20% Total impurities 1.70% Dissolution Stage 1 / Stage 2 1 76% / 1 92% 2 72% / 2 77% 3 71% / 3 64% 4 71% / 4 78% 5 62% / 5 86% 6 76% / 6 83% Avg 80% S_1 = 71% / S_2 = 76%	Assay Levothyroxine sodium 90.0 – 105.0 % of label claim Related Substances Liothyronine NMT 1.0% Largest impurity NMT 1.0% Tetrac NMT 1.0% HDPhDB acid NMT 2.5% Total impurities NMT 5.0% Dissolution Complies with USP where Q=70% at 45 minutes

Sample	ESR Lab #	Results		Acceptance Criteria	
Eltroxin 50 Lot 7D007	PHA0920/18	Assay Levothyroxine sodium	94.7%	Assay Levothyroxine sodium 90.0 – 105.0 % of label claim	
		Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 0.10% 0.54% <DL 0.34% 2.55%	Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 NMT 1.0% NMT 1.0% NMT 1.0% NMT 2.5% NMT 5.0%
		Dissolution 1 72% 2 77% 3 67% 4 80% 5 80% 6 76% S_1 75%		Dissolution Complies with USP where Q=70% at 45 minutes	
Eltroxin 50 Lot 8B001	PHA0920/15	Assay Levothyroxine sodium	92.7%	Assay Levothyroxine sodium 90.0 – 105.0 % of label claim	
		Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 0.10% 0.53% <DL 0.33% 2.40%	Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 NMT 1.0% NMT 1.0% NMT 1.0% NMT 2.5% NMT 5.0%
		Dissolution 1 60% 2 82% 3 80% 4 73% 5 78% 6 76% S_1 75%		Dissolution Complies with USP where Q=70% at 45 minutes	

Notes: *Eltroxin 50* *Eltroxin 50 microgram tablets*
Eltroxin 100 *Eltroxin 100 microgram tablets*
DL *Detection Level*
NMT *Not more than*
USP *United States Pharmacopeia*

Test Results from Eltroxin Tablets "Old" Formulation

Sample	ESR Lab #	Results		Acceptance Criteria	
Eltroxin 100 Lot 8D003	PHA0956/1	Assay Levothyroxine sodium	100.4%	Assay Levothyroxine sodium 90.0 – 110.0 % of label claim	
		Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 0.17% 0.14% <DL <DL 1.00%	Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 NMT 1.0% NMT 1.0% NMT 1.0% NMT 2.5% NMT 5.0%
		Dissolution 1 103% 2 102% 3 101% 4 102% 5 104% 6 104% S_1 102%		Dissolution Complies with USP where Q=70% at 45 minutes	
Eltroxin 50 Lot 8A003	PHA0956/2	Assay Levothyroxine sodium	100.4%	Assay Levothyroxine sodium 90.0 – 110.0 % of label claim	
		Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 0.12% 0.31% <DL <DL 1.42%	Related Substances Liothyronine Largest impurity Tetrac HDPhDB acid Total impurities	 NMT 1.0% NMT 1.0% NMT 1.0% NMT 2.5% NMT 5.0%
		Dissolution 1 96% 2 103% 3 100% 4 100% 5 98% 6 98% S_1 99%		Dissolution Complies with USP where Q=70% at 45 minutes	

Notes: *Eltroxin 50* — *Eltroxin 50 microgram tablets*
Eltroxin 100 — *Eltroxin 100 microgram tablets*
DL — *Detection Level*
NMT — *Not more than*
USP — *United States Pharmacopeia*