

BMDS 3.0 Analysis Report

GWTX1412

For

GWTX1412 – 26 Week Oral Administration in Rats

28.07.2022 10:12:25

Analysis Info

Analysis Name: GWTX1412

Analysis Description: C:\bmds3201\BMDS3201

Model Type: Dichotomous

Selected Models:

- Frequentist Dichotomous Hill (restricted)

Option Sets:

- Option Set #1
 - Risk Type: Extra Risk
 - BMR: 0.1
 - Confidence Level: 0.95
 - Background: Estimated

Data

GWTX1412 – 26 Week Oral Administration in Rats		
Source: FDA (2018)		
CBD Dose	N	Incidence
mg/kg bw/day	males + females combined	Liver (centrilobular hypertrophy)
0	29	0
15	30	0
50	29	19
150	30	28

Frequentist Dichotomous Hill Restricted Option Set #1

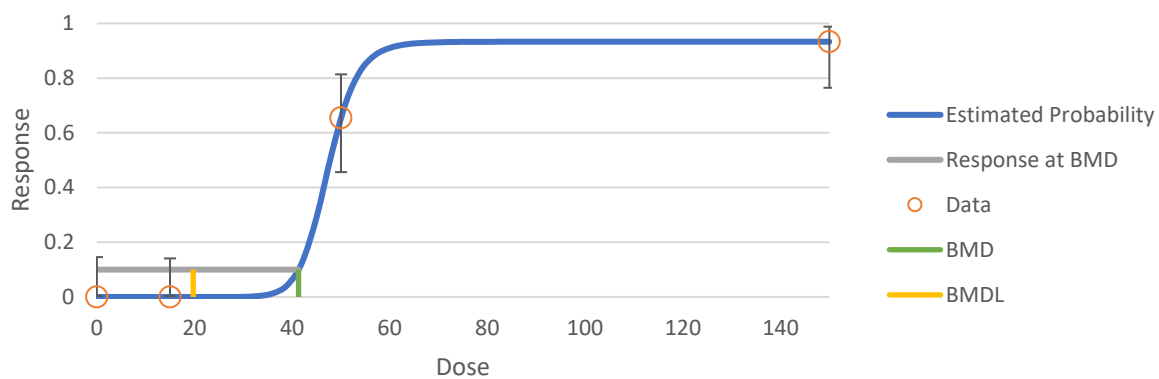
User Input					
Info		Model Options		Model Data	
Model	frequentist Dichotomous Hill v1.1	Risk Type	Extra Risk	Dependent Variable	mg/kg bw/day
Dataset Name	GWTX1412	BMR	0.1	Independent Variable	Liver (centrilobular hypertrophy)
User notes	Source: FDA (2018)	Confidence Level	0.95	Total # of Observations	4
		Background	Estimated		

Model Results																	
<table> <tr> <th colspan="2">Benchmark Dose</th></tr> <tr> <td>BMD</td><td>41.31587603</td></tr> <tr> <td>BMDL</td><td>19.73381974</td></tr> <tr> <td>BMDU</td><td>43.48675444</td></tr> <tr> <td>AIC</td><td>58.05858068</td></tr> <tr> <td>P-value</td><td>0.998871924</td></tr> <tr> <td>D.O.F.</td><td>1</td></tr> <tr> <td>Chi²</td><td>1.99893E-06</td></tr> </table>		Benchmark Dose		BMD	41.31587603	BMDL	19.73381974	BMDU	43.48675444	AIC	58.05858068	P-value	0.998871924	D.O.F.	1	Chi ²	1.99893E-06
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Goodness of Fit					
Dose	Estimated Probability	Expected	Observed	Size	Scaled Residual
0	2.61306E-08	7.57789E-07	0	29	-0.000871
15	4.13654E-08	1.24096E-06	0	30	-0.001114
50	0.655173124	19.0000206	19	29	-8.05E-06
150	0.933332854	27.99998561	28	30	1.054E-05

Analysis of Deviance					
Model	Log Likelihood	# of Parameters	Deviance	Test d.f.	P Value
Full Model	-26.02928834	4	-	-	NA
Fitted Model	-26.02929034	3	3.9975E-06	1	0.9984047
Reduced Model	-79.33357714	1	106.608578	3	<0.0001

Frequentist Dichotomous Hill Model with BMR of 10% Extra Risk for the BMD and 0.95 Lower Confidence Limit for the BMDL



Summary of Results

Option set #1 (Hover for details)											
Model	Analysis Type	Restriction	RiskType	BMD	BMDL	BMDU	P Value	AIC	Unnormalized Log Posterior Probability	BMDS Recommendation	BMDS Recommendation Notes
<u>Dichotomous Hill*</u>	frequentist	Restricted	Extra Risk	41.31588	19.73382	43.486754	0.9988719	58.05858068	-	Viable - Recommended	Lowest AIC

*Selected model in bold; scaled residuals for selected model for doses 0, 15, 50, 150 were -8.70510677218652E-04, -1.11398536497397E-03, -8.04863581109238E-06, 1.05353254517334E-05 [units], respectively.

