

European Commission



**Draft Assessment Report prepared according to the Commission
Regulation (EU) N° 1107/2009**

Napropamide-M

Volume 3 – B.2 (PPP) – D-Devrinol

Rapporteur Member State : United Kingdom

Version History

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B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT D-DEVRIOL

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.1. APPEARANCE						
Physical state and colour B.2.1/01	Visual Inspection	D-Devrinol SC Batch No: JM262 (HBW03) Nominally 450 g/L	Creamy beige coloured liquid with a faint non-descript odour	Acceptable.	Y	Bates, G. (2015), J19547
B.2.2. EXPLOSIVE AND OXIDIZING PROPERTIES						
Explosive properties B.2.2/01	EEC A14/ (Differential Scanning Calorimetry) Reasoned case	D-Devrinol SC Batch No: JM262 (HBW03) Nominally 450 g/L	<p>Based on the examination of the structure of the napropamide-M it can be conducted that the compound does not contain any groups that directly infer explosive properties e.g nitrates, chlorates. Nitrate esters, aromatic nitro, aliphatic nitro, nitramine, azide, nitroso, perchlorate, acetylides. In addition the compound does not contain groups that are able to contribute to the explosive property when present alongside groups directly associated with explosivity (e.g hydroxyl, carbonyl, ether, amino, sulphonic acid).</p> <p>The 'oxygen balance' calculated for napropamide-M, based on its structure, suggests a low risk of potential for explosivity.</p> <p>The formulation contains mainly the active substance and water, and other coformulants are present in relatively small quantities, as commonly available proprietary preparations. The formulation presents no risk of explosivity.</p> <p>In order to investigate thermal explosivity of the formulation the product was examined by the Differential Scanning Calorimetry (DSC) Over the range of 30°C to 400°C tested, no exothermic effects were observed. No evidence of a tendency to thermal explosivity was observed.</p>	<p>The applicant has provided an acceptable case that the formulation is not explosive also DSC testing for thermal explosivity – no evidence of tendency of thermal explosivity was observed.</p> <p>See also section B.2 for the active substance where it is proposed that napropamide-M is not explosive.</p>	Y	Bates, G. (2015), J19547
Oxidizing properties B.2.2/02	Reasoned case	N/A	The molecular structure of napropamide-M does not contain any oxidising groups such as peroxide, chlorate, nitrate, bromate, chromate, etc. The MSDS's submitted for each of the co-formulants do not suggest any expectation of oxidising properties.	The applicant has provided an acceptable case that the formulation has no oxidising properties.	Y	Bates, G. (2015), J19547

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference						
				See also section B.2 for the active substance where it is proposed that napropamide-M does not confer oxidising properties.								
B.2.3. FLAMMABILITY AND AUTO-FLAMMABILITY												
Flash point of the liquids formulations B.2.3/01	EEC A9 (Pensky-Martens Flashpoint Apparatus)	D-Devrinol SC Batch No: JM262 (HBW03) Nominally 450 g/L	Boiled over at 105°C. No flash observed.	Acceptable.	Y	Bates, G. (2015), J19547						
Flammability of solid formulations B.2.3/02				Not required for SC formulations								
Self-heating of formulation B.2.3/03	EEC A15	D-Devrinol SC Batch No: JM262 (HBW03) Nominally 450 g/L	<table><tr><td>Atmospheric pressure (kPa)</td><td>Temperature (°C)</td><td>Time of ignition</td></tr><tr><td>101.3</td><td>> 400</td><td>No ignition</td></tr></table>	Atmospheric pressure (kPa)	Temperature (°C)	Time of ignition	101.3	> 400	No ignition	The product does not self ignite.	Y	Bates, G. (2015), J19547
Atmospheric pressure (kPa)	Temperature (°C)	Time of ignition										
101.3	> 400	No ignition										
B.2.4. ACIDITY/ALKALINITY AND PH VALUE												
pH of the neat aqueous formulation B.2.4/01	CIPAC MT75.3	D-Devrinol SC Batch No: JM262 (HBW03) Nominally 450 g/L	pH 8.29	Noted	Y	Bates, G. (2015), J19547						
pH of a 1 % dilution of the solid or non aqueous formulation B.2.4/02	CIPAC MT75.3	D-Devrinol SC Batch No: JM262 (HBW03) Nominally 450 g/L	pH 8.24	Noted	Y	Bates, G. (2015), J19547						
Acidity / Alkalinity B.2.4/03	N/A	N/A	N/A	pH of formulation is 8.29, therefore an acidity/alkalinity test is not required (only required if the preparation has pH < 4 or pH >10)	Y	Bates, G. (2015), J19547						

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.5. VISCOSITY AND SURFACE TENSION								
Viscosity of the liquid formulation B.2.5/01	OECD 114 (Brookfield DVII viscometer)	D-Devrinol SC Batch No: JM262 (HBW03) Nominally 450 g/L	Temperature	Spindle Speed (RPM)	Viscosity (mPa.s)	With regard to aspiration hazard classification (R65) there is no indication that the material would require classification.	Y	Bates, G. (2015), J19547
			20°C	33.9	328.7			
				67.1	223.1			
				100.3	180.0			
				133.6	155.9			
				166.8	140.7			
				200.0	130.0			
			40°C	35.3	239.9			
				68.2	165.1			
				101.1	133.6			
				134.1	116.3			
				167.0	104.8			
				200.0	96.4			
			The formulation demonstrated Non-Newtonian/Pseudoplastic properties, with increased shear rate the formulation has a decreased dynamic viscosity.					
Surface tension of the formulation B.2.5/02	EEC A5 (Du-Nuoy Tensiometer)	D-Devrinol SC Batch No: JM262 (HBW03) Nominally 450 g/L	0.1% solution in water:		The determination of surface tension should be made using the highest dilution recommended for use of the preparation. According to the proposed GAPs, the highest in-use concentration is 1.7L/ha in 200L of water or 0.85% v/v and lowest is 1.7L/ha in 600L of water or 0.28 %v/v. The applicant provided data outside the proposed in- use concentration ranges but demonstrated that product is not strongly concentration dependant. The data are therefore	Y	Bates, G. (2015), J19547	
			52.3 mN/m at 20 °C					
			51.5 mN/m at 40 °C					
			3% solution in water:					
			48.0 mN/m at 20 °C					
			44.3 mN/m at 40 °C					
			The surface tension did not vary with time (the assessments were made over a 30 minute period). The surface tension of the formulation is not strongly concentration dependant.					

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference		
				considered acceptable. The formulation has surface active properties (the surface tension is lower than 60 mN/m).				
B.2.6. RELATIVE DENSITY AND BULK DENSITY								
Relative density of the liquid formulation B.2.6/01	EEC A.3, CIPAC MT 3.3.2	D-Devrinol SC Batch No: JM262 (HBW03) Nominally 450 g/L	Relative Density (D ²⁰ ₄) = 1.09	Noted	Y	Bates, G. (2015), J19547		
Bulk density (pour and tap) of powder or granules B.2.6/02				Not required for SC formulations				
B.2.7. STORAGE STABILITY AND SHELF-LIFE: EFFECTS OF TEMPERATURE ON TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT								
Stability after accelerated storage (54°C during 14 days, 8 weeks at 40°C, 12 weeks at 35°C or 18 weeks at 30°C) B.2.7/01	HPLC Method M774 and M774B (chiral analysis) CIPAC MT75.3 CIPAC MT184 CIPAC MT160 CIPACMT185 CIPAC MT148	D-Devrinol SC Batch No: JM262 (HBW03) Nominally 450 g/L	2 weeks at 54°C No change in odour or colour. No package incompatibility.		Acceptable – no significant (> 5%) change in active ingredient content or isomer ratio post storage Physical-chemical parameters (appearance, pH in a 1% w/V aqueous solution, suspensibility, spontaneity of dispersion, pourability) of the formulation did not change significantly after storage for 2 weeks at 54°C. Method M744 was satisfactorily validated in accordance with SANCO3030/99/rev.4	Y	Bates, G. (2015), J19547	
			Test	Initial				Post-storage
			% a.i	40.5 % w/w Isomer ratio (D:L) – 96.88 : 3.12				41.8% w/w Isomer ratio (D:L) – 96.85 : 3.15
			pH	pH neat – 8.29 pH 1% dilution – 8.24				pH neat – 7.64 pH 1% dilution – 7.63
			Suspensibility	Concentration 0.3% w/w - 99.1 % Concentration 3% w/w – 99.7				Concentration 0.3% w/w – 91.4 % Concentration 3% w/w – 89.3%
			Spontaneity of	96.3 %				87.6 %

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference
			dispersion					
			Wet sieve	0.032 % retained on 75µm sieve	0.058 % retained on 75µm sieve			
			Pourability	Residue – 2.29% Rinsed residue – 0.18%	Residue – 1.94% Rinsed residue – 0.18%			
Effect of low temperature on stability of liquid formulation B.2.7/02	HPLC Method M774 and M774B (chiral analysis) CIPAC MT184 CIPACMT185 CIPAC MT148	D-Devrinol SC Batch No: JM262 (HBW03) Nominally 450 g/L	1 week at 0°C			Acceptable – no significant (> 5%) change in active ingredient content or isomer ratio post storage The wet sieve test and suspensibility of the formulation remained unaffected by the cold storage period tested.	Y	Bates, G. (2015), J19547
			Test	Initial	Post-storage			
			% a.i	40.5 % w/w Isomer ratio (D:L) – 96.88 : 3.12	41.8 % w/w Isomer ratio (D:L) – 96.86 : 3.14			
			Suspensibility	Concentration 0.3% w/w - 99.1 % Concentration 3% w/w – 99.7%	Concentration 0.3% w/w - 99.9 % Concentration 3% w/w – 100.9%			
			Wet sieve	0.032 % retained on 75µm sieve	0.030 % retained on 75µm sieve			
			No separation of the formulation was observed, no changes in the formulation observed after reaching room temperature.					

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference																					
Shelf life following storage at ambient temperature B.2.7/03	HPLC Method M774 CIPAC MT75.3 CIPAC MT184 CIPAC MT160 CIPACMT185 CIPAC MT148	D-Devrinol SC Batch No: JM262 (HBW03) Nominally 450 g/L	<u>18 months at ambient temperature</u> No change in odour or colour. No package incompatibility.	Acceptable – no significant (> 5%) change in active ingredient content or isomer ratio post storage. Data provided by the applicant shows the retention of satisfactory chemical and physical properties for the product after storage in the commercial sales packs (5L HDPE-PA container) for 2 years at ambient temperature.	Y	Bates, G. (2015), J19547																					
			<table><tr><td>Test</td><td>Initial</td><td>Post-storage</td></tr><tr><td>% a.i</td><td>40.5 % w/w Isomer ratio (D:L) – 96.88 : 3.12</td><td>42.4 % w/w Isomer ratio (D:L) – 96.92 : 3.09</td></tr><tr><td>pH</td><td>pH neat – 8.29 pH 1% dilution – 8.01</td><td>pH neat – 8.01 pH 1% dilution – 7.36</td></tr><tr><td>Suspensibility</td><td>Concentration 0.3% w/w - 99.1 % Concentration 3% w/w – 99.7%</td><td>Concentration 0.3% w/w - 99.9 % Concentration 3% w/w – 99.1%</td></tr><tr><td>Spontaneity of dispersion</td><td>96.3 %</td><td>99.0 %</td></tr><tr><td>Wet sieve</td><td>0.032 % retained on 75µm sieve</td><td>0.024 % retained on 75µm sieve</td></tr><tr><td>Pourability</td><td>Residue – 2.29% Rinsed residue – 0.18%</td><td>Residue – 2.08% Rinsed residue – 0.12%</td></tr></table>				Test	Initial	Post-storage	% a.i	40.5 % w/w Isomer ratio (D:L) – 96.88 : 3.12	42.4 % w/w Isomer ratio (D:L) – 96.92 : 3.09	pH	pH neat – 8.29 pH 1% dilution – 8.01	pH neat – 8.01 pH 1% dilution – 7.36	Suspensibility	Concentration 0.3% w/w - 99.1 % Concentration 3% w/w – 99.7%	Concentration 0.3% w/w - 99.9 % Concentration 3% w/w – 99.1%	Spontaneity of dispersion	96.3 %	99.0 %	Wet sieve	0.032 % retained on 75µm sieve	0.024 % retained on 75µm sieve	Pourability	Residue – 2.29% Rinsed residue – 0.18%	Residue – 2.08% Rinsed residue – 0.12%
			Test				Initial	Post-storage																			
			% a.i				40.5 % w/w Isomer ratio (D:L) – 96.88 : 3.12	42.4 % w/w Isomer ratio (D:L) – 96.92 : 3.09																			
			pH				pH neat – 8.29 pH 1% dilution – 8.01	pH neat – 8.01 pH 1% dilution – 7.36																			
			Suspensibility				Concentration 0.3% w/w - 99.1 % Concentration 3% w/w – 99.7%	Concentration 0.3% w/w - 99.9 % Concentration 3% w/w – 99.1%																			
			Spontaneity of dispersion				96.3 %	99.0 %																			
			Wet sieve				0.032 % retained on 75µm sieve	0.024 % retained on 75µm sieve																			
			Pourability				Residue – 2.29% Rinsed residue – 0.18%	Residue – 2.08% Rinsed residue – 0.12%																			
			<u>2 years at ambient temperature</u> No change in odour or colour. No package incompatibility.																								
<table><tr><td>Test</td><td>Initial</td><td>Post-storage</td></tr><tr><td>% a.i</td><td>40.5 % w/w Isomer ratio (D:L) – 96.88 : 3.12</td><td>42.7 % w/w Isomer ratio (D:L) – 96.80 : 3.21</td></tr><tr><td>pH</td><td>pH neat – 8.29 pH 1% dilution – 8.01</td><td>pH neat – 7.96 pH 1% dilution – 7.85</td></tr><tr><td>Suspensibility</td><td>Concentration 0.3% w/w - 99.1 % Concentration 3%</td><td>Concentration 0.3% w/w - 99.7 % Concentration 3%</td></tr></table>	Test	Initial	Post-storage	% a.i	40.5 % w/w Isomer ratio (D:L) – 96.88 : 3.12	42.7 % w/w Isomer ratio (D:L) – 96.80 : 3.21	pH	pH neat – 8.29 pH 1% dilution – 8.01	pH neat – 7.96 pH 1% dilution – 7.85	Suspensibility	Concentration 0.3% w/w - 99.1 % Concentration 3%	Concentration 0.3% w/w - 99.7 % Concentration 3%															
Test	Initial	Post-storage																									
% a.i	40.5 % w/w Isomer ratio (D:L) – 96.88 : 3.12	42.7 % w/w Isomer ratio (D:L) – 96.80 : 3.21																									
pH	pH neat – 8.29 pH 1% dilution – 8.01	pH neat – 7.96 pH 1% dilution – 7.85																									
Suspensibility	Concentration 0.3% w/w - 99.1 % Concentration 3%	Concentration 0.3% w/w - 99.7 % Concentration 3%																									

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results					Comments (Acceptable / Non acceptable)	GLP	Reference		
				w/w – 99.7%		w/w – 99.6%						
			Spontaneity of dispersion	96.3 %		98.9 %						
			Wet sieve	0.032 % retained on 75µm sieve		0.220 % retained on 75µm sieve						
			Pourability	Residue – 2.29% Rinsed residue – 0.18%		Residue – 2.17% Rinsed residue – 0.18%						
			Packaging - Weight of sample:									
			Storage Period	Weight of sample and packaging		Weight loss on storage						
				Before storage	After storage	g	%					
			2 week at 54°C	4593.0	4590.6	-2.4	-0.05					
			18 months at ambient	5685.0	5683.6	-1.4	-0.03					
			2 years at ambient	5694.1	5869.7	+175.6	+3.08*					
			2 years at ambient (spare sample)	1559.7	1555.6	-4.1	-0.263					
			* - The sample for 2 years at ambient has produced a spurious weight gain. This suggests an erroneous weighing at the initial timepoint. The spare sample, which was stored under the same condition and duration was re-weighed and the results included in the table above.									

B.2.8. TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT										
B.2.8.1. Wettability										
Wettability of solid formulation B.2.8.1/01								Not required for SC formulations		

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results				Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8.2. Persistence foaming									
Persistence of foaming of the diluted formulation B.2.8.2/01	CIPAC MT 47.2	D-Devrinol SC Batch No: JM262 (HBW03) Nominally 450 g/L					The determination of persistence of foaming should be made using the highest and lowest dilution recommended for use of the preparation as any changes in surface tension will be influenced by the concentration. According to the proposed GAPs, the highest in-use concentration is 1.7L/ha in 200L of water or 0.85% v/v. The determination has been made for concentration of 3% v/v (much higher than required) and showing the amount of foaming created far below the acceptable maximum guideline limits (60 mls of foam after 1 minute) therefore acceptable. Also, see section on surface tension where the available data suggest that the surface tension for the preparation is not greatly influenced by concentration. Therefore as the amounts of foam are not too high, it is considered that the data are acceptable, even though only one concentration has been studied. [The EU Guidance on Physical and Chemical Properties indicates that the data for persistent foam should cover the highest and lowest in-use concentrations].	Y	Bates, G. (2015), J19547
			mL of Foam at time						
			10 Seconds	1 minute	3 minutes	12 minutes			
			21.5	21.5	16.5	15			
			Standard water D used for sample dilution Sample concentration – 3% v/v						

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8.3. Suspensibility						
Suspensibility of water dispersible formulation B.2.8.3/01	CIPAC MT184 (HPLC - G.C Laboratories Analytical Method M774)	D-Devrinol SC Batch No: JM262 (HBW03) Nominally 450 g/L	0.3% v/v – 99.1% 3.0% v/v – 99.7 %	<p>The determination of suspensibility should be made using the highest and lowest dilution recommended for use of the preparation.</p> <p>According to the proposed GAPs, the highest in-use concentration is 1.7L/ha in 200L of water or 0.85% v/v and lowest is 1.7L/ha in 600L of water or 0.28 %v/v.</p> <p>The determination has been made for concentrations of 0.3% v/v and 3% v/v (much higher than required) and showing suspensibility within acceptable limits therefore acceptable</p>	Y	Bates, G. (2015), J19547
Spontaneity of dispersion of water dispersible formulation B.2.8.3/02	CIPAC MT 160 (HPLC - G.C Laboratories Analytical Method M774)	D-Devrinol SC Batch No: JM262 (HBW03) Nominally 450 g/L	% spontaneity of dispersion is 96.3% Standard Hard water D was used	CIPAC MT 160 was followed, and the applicant confirmed that the sample concentration was 5% w/w. This is above the highest in-use concentration and is considered the worst case (the greater the ratio of product to water the more difficult it will be to disperse) showing spontaneity of dispersion within acceptable limits therefore acceptable.	Y	Bates, G. (2015), J19547
Dispersion stability of SE, OD or EG formulation B.2.8.3/03						
B.2.8.4. Degree of dissolution and dilution stability						
Degree of dissolution of water soluble				Not required for SC formulations		

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference		
formulation B.2.8.4/01								
Dilution stability of water soluble formulation B.2.8.4/02				Not required for SC formulations				
B.2.8.5. Particle size distribution, dust content, attrition and mechanical stability								
B.2.8.5.1. Particle size distribution								
Wet sieve test of water dispersible formulation B.2.8.5.1/01	CIPAC MT185	D-Devrinol SC Batch No: JM262 (HBW03) Nominally 450 g/L	% Retained on 75µm sieve – 0.032	The residue remaining on 75µm sieve is within acceptable limits.	Y	Bates, G. (2015), J19547		
Size distribution of particles of powder or suspension concentrate formulation B.2.8.5.1/02	CIPAC MT187 (Laser diffraction using a Malvern Mastersizer 2000)	D-Devrinol SC Batch No: JM270 (HBW03) Nominally 450 g/L	Particle size distribution		Acceptable	Y	Morgan, L. (2015) NZ/14/021/1	
			D ₁₀ (µm)	D ₅₀ (µm)				D ₉₀ (µm)
			0.7	1.7				4.3
			A further sample (of the same batch) was also stored at 40°C for 8 weeks and the particle size analysed showing there were no significant changes in particle size over this accelerated storage period.					
Nominal size range of granule B.2.8.5.1/03				Not required for SC formulations				
B.2.8.5.2. Dust content								
Dust content of granular formulation B.2.8.5.2/01				Not required for SC formulations				
B.2.8.5.3. Attrition								
Attrition characteristics of granules and tablets B.2.8.5.3/01				Not required for SC formulations				

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference																		
B.2.8.5.4. Hardness and integrity																								
Hardness of tablets B.2.8.5.4/01				Not required for SC formulations																				
Integrity of tablets B.2.8.5.4/02				Not required for SC formulations																				
B.2.8.6. Emulsifiability, re-emulsifiability, emulsion stability																								
Emulsifiability, emulsion stability and re-emulsifiability of formulation B.2.8.6/01				Not required for SC formulations																				
B.2.8.7. Flowability, pourability and dustability																								
Flowability of granular formulation B.2.8.7/01				Not required for SC formulations																				
Pourability of suspensions B.2.8.7/02	CIPAC MT148	D-Devrinol SC Batch No: JM262 (HBW03) Nominally 450 g/L	<table><tr><td colspan="3">Residue (%)</td><td colspan="3">Rinsed Residue (%)</td></tr><tr><td>a</td><td>b</td><td>Average</td><td>a</td><td>b</td><td>Average</td></tr><tr><td>2.37</td><td>2.22</td><td>2.29</td><td>0.18</td><td>0.18</td><td>0.18</td></tr></table>	Residue (%)			Rinsed Residue (%)			a	b	Average	a	b	Average	2.37	2.22	2.29	0.18	0.18	0.18	The pourability is within acceptable guideline limit (below 5%) and the rinsed residue is below maximum acceptable guideline limit (0.25%) therefore acceptable.	Y	Bates, G. (2015), J19547
Residue (%)			Rinsed Residue (%)																					
a			b	Average	a	b	Average																	
2.37	2.22	2.29	0.18	0.18	0.18																			
Dustability of dustable powders after accelerated storage B.2.8.7/03				Not required for SC formulations																				
B.2.9. PHYSICAL AND CHEMICAL COMPATIBILITY WITH OTHER PRODUCTS INCLUDING PLANT PROTECTION PRODUCTS WITH WHICH ITS USE IS TO BE AUTHORISED																								
Physical and chemical compatibility of tank mixtures	N/A	N/A	No details of compatibility provided.	The proposed label directs the user to the company website for details of compatibility however no data on	N/A	N/A																		

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.9/01				compatibility of tank mixes was provided with this submission. No tank mixes can be recommended at this time.		
B.2.10. ADHERENCE AND DISTRIBUTION TO SEEDS						
Distribution and adhesion to seeds B.2.9.10/01				Not required for SC formulations		
B.2.11. OTHER STUDIES						
Effectiveness of cleaning procedures	PSD Efficacy Guideline 305 – Triple Rinse Procedure	D-Devrinol SC Batch No: JM262 (HBW03) Nominally 450 g/L	The % of diluted product removed from the jar was reported following single, double or triple rinsing. <u>Single rinse:</u> 99.99% <u>Double rinse:</u> 99.99% <u>Triple rinse:</u> 100.00 % Analytical method M774 was used to determine active substance content.	Acceptable.	Y	Bates, G. (2015), J19547

B.2.12. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
B.2.1/01	Bates, G.	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Final Report Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
B.2.2/01	Bates, G.	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Final Report Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
B.2.2/02	Bates, G.	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Final Report Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
B.2.3/01	Bates, G.	2015	Storage stability trial for the D-	N	Y	Data protection is claimed in	UPL	

			Devrinol 450 SC (HBW03) formulation Final Report Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished			accordance with Article 59 of Regulation (EC) No 1107/2009		
B.2.3/02	Bates, G.	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Final Report Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
B.2.3/03	Bates, G.	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Final Report Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
B.2.4/01	Bates, G.	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Final Report Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
B.2.4/02	Bates, G.	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Final Report Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
B.2.5/01	Bates, G	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Final Report Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
B.2.5/02	Bates, G	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Final Report Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
B.2.7/01	Bates, G	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Final Report Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
B.2.7/02	Bates, G	2015	Storage stability trial for the D-	N	Y	Data protection is claimed in	UPL	

			Devrinol 450 SC (HBW03) formulation Final Report Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished			accordance with Article 59 of Regulation (EC) No 1107/2009		
B.2.7/03	Bates, G	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Final Report Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
B.2.8.2/01	Bates, G	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Final Report Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
B.2.8.3/01	Bates, G	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Final Report Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
B.2.8.3/02	Bates, G	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Final Report Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
B.2.8.4/02	Bates, G	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Final Report Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
B.2.8.5.1/01	Bates, G	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Final Report Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
B.2.8.5.1/02	Morgan, L.	2015	Particle size distribution of D-Devrinol before and after storage for 8 weeks at 40°C Company Report No. NZ/14/021/1 Battelle UK Ltd., UK GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

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