

EXHIBIT 2028

Cephalon Exhibit 2028
Fresenius v. Cephalon
IPR2016-00098

THISSEN Laboratories s.a.

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Nr. Of Analysis : 023303

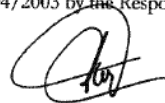
Ribomustin 100 mg Freeze-dried powder

BATCH : 03C08

Manufacture 08/03/2003 - Expiration 03/2005

TEST PARAMETER	TEST METHOD	RELEASE SPECIFICATION	RESULTS
General and specific characteristics			
Appearance	Visual examination	White, microcrystalline lyophilate	Complies
Uniformity of Dosage Units	USP <905>	Complies with USP <905>	Complies
Constituted solution	USP <1>	Complies with USP <1>	Complies
pH value after reconstitution	USP <791>	2.5 - 3.5	3.2
Identity			
Bendamustine hydrochloride	HPLC	Complies with standard	Complies
Assay			
Bendamustine hydrochloride	HPLC	100.0 mg/vial (limits : 95.0 - 105.0 mg/vial)	100.0
Purity			
Water content	USP <921> method 1	Max. 2.5 %	0.9
Related substances	HPLC		
HP1		Max 3.3 %	1.4
HP2		Max 0.5 %	ND
HP3		Max 0.1 %	ND
NP1		Max 0.5 %	<LOQ
BM1 EE		Max 0.6 %	0.2
BM1 DIMER		Max 0.7 %	0.4
BM1 DCE		Max 0.1 %	ND
HBI		Max 0.5 %	ND
Not identified single peaks		Max 0.1 %	ND
Sum of not identified peaks		Max 0.5 %	0.4
Sum of all secondary peaks		Max 5.0 %	1.9
Sterility	USP <71>	Sterile	Complies
Bacterial Endotoxins	USP <85>	Not more than 0.5 UI/mg	<0.192


Conclusion : this batch was release on 17/04/2003 by the Responsible Pharmacist, M. HUME.

 17/04/03

CERTIFICATE OF ANALYSIS		
Bendamustin 100 mg for injection, Batch no. 03C08		
Expiry Date: 03.2005		
TI no.: 3.0		
Test parameter	Specification	Result
General characteristics		
Appearance	white, microcrystalline lyophilisate	complies
Average mass	198.0 – 242.0 mg	221.8 mg
Uniformity of mass	complies with Ph. Eur. 2.9.5	complies
Solubility	soluble within 5 minutes without residues	complies
Clarity after reconstitution	clear	complies
Colour after reconstitution	≤ B 6	complies
pH-value after reconstitution	2.5 – 3.5	3.2
Identity		
- Chloride	positive	complies
- Bendamustine hydrochloride	complies with standard	complies
Purity		
Related substances		
- HP 1	max. 3.5 %	1.4 %
- HP 2	max. 0.5 %	n.d.
- NP 1	max. 0.5 %	<LOQ
- BM1EE	max. 0.5 %	0.2 %
- HBI	max. 0.5 %	n.d.
- Not identified singel peaks	max. 0.2 %	n.d.
- Sum of not identified peaks	max. 0.5 %	0.4 %
- Sum of all secondary peaks	max. 5.0 %	1.9 %
Water content	max. 2.5 %	0.9 %
Sterility	sterile, complies with Ph. Eur. 2.6.1	complies
Endotoxins	not more than 0.5 I.U. / mg	complies
Assay		
Bendamustine hydrochloride	100.0 mg / vial (limits: 95.0 – 105.0 mg / vial)	100.0 mg / vial
We herewith confirm that this batch was manufactured and tested in accordance with the relevant GMP requirements. Status: Approved for clinical trials		

Munich, May 21st, 2003


Dr. Unterlinner
 Head of Product Release/QC


Fuchs
 Product Documentation/QC

FDZe (01/02)

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