EXHIBIT 2028

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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

Fujisawa Deutschland GmbH

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 - Bendamustine hydrochloride	positive complies with standard	complies complies
Purity		
Related substances - HP 1 - HP 2 - NP 1 - BM1EE - HBI - Not identified singel peaks - Sum of not identified peaks - Sum of all secondary peaks	 max. 3.5 % max. 0.5 % max. 0.5 % max. 0.5 % max. 0.5 % max. 0.2 % max. 0.5 % max. 5.0 %	 1.4 % n.d. <LOQ 0.2 % n.d. n.d. 0.4 % 1.9 %
Water content	max. 2.5 %	0.9 %
Sterility	steriie, 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

F02e (01/02)

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