

Validation Certificate

Project Name: PreparePlus® PN	Software Version: 1.2.0.10
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PreparePlus® PN is classified as GAMP® 5 Category 5 (Custom Application)

FINAL VALIDATION APPROVAL

The validation team members have reviewed the validation documentation for the Fresenius Kabi Prepare Plus® PN software. This review included assessment of the phase reports, including details of the execution of approved test scripts, the recommended actions, conclusions and an assessment of project status derived from the outcome of each phase.

Document Title	Effective Date
Validation Plan Prepare <i>Plus</i> PN	01 June 2010
Final Validation Report	28 April 2011

STATUS

As a result, it is determined that the Prepare Plus® PN software has been validated to date in accordance with the requirements of the Validation Plan effective 01 June 2010 and can be used in the operational environment by suitably trained and authorised business personnel.

It is recognised that continued performance monitoring of the system will proceed after go-live in order to maintain the full validation requirements for this system.

APPROVAL DATE		
	05 May 2011	

By signing below, the head of the validation team approves the validation status of the Prepare*Plus*[®] PN software:

Name	Signature / Date
Dr. Guenther Boos, Vice President Global Clinical Quality Assurance, Global Medical & Clinical Affairs, Fresenius Kabi Deutschland GmbH	G. Boos 05 May 2011