JohnsonDiversey
Clean is just the beginning

Diversey

Contact

JohnsonDiversey Europe BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands
Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 29/11/11

Product Name	CLEARKLENS TEGO 2001SS VH24S
Product Code	7513403
Batch Number	WC 30704
Production Date	11/2011
Expiry Date	09/2012

This is to certify that the above batch of product has been tested internally and conforms to the manufacturing Quality Control specification for the product.

Test	Test Method	Limits	Results
Appearance	Visual	Clear Liquid	Clear Liquid
pH (100% 20°C)	JDM001	8.5 - 9.2	8.3
Specific Gravity (20°C)	JDM004	0.998 - 1.001	1.001

"SIGNATURE" C Mascoe

Name Caroline Mascoe
Function Name Pharmaroom Supervisor

Please note Johnsondiversey did change the company name to Diversey and is in the phase of implementation

CERTIFICATE OF IRRADIATION Number: B 0511293 00

FLE001

Flexible Medical Packaging Ltd
Unit 6
White Cross Industrial Estate
Hightown
Lancaster

LA1 4XS

Cust. Ref: PO17791
Date Rec'd 17/11/11
Date: 22/11/11

Isotron Limited
Roydsdale Way · Euroway Trading Estate
Bradford · West Yorkshire
BD4 6SE · United Kingdom
Telephone: +44 (0)1274 686011
Facsimile: +44 (0)1274 686061
Email: assistance@isotron.com
Website: www.isotron.com

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010093 B211110683	TEGO 2001 SS 25-45kGy	132	B/No.W030704 - CUSTOMER B/No.381072 ACTUAL DOSE....36.7 - 37.6....kGy
B2FLE0010999 B211110683	SAMPLES	1	CUSTOMER BATCH/CODE No.s AS ORDER No.PO17791 DATED 16/11/11
	Despatch Text: 3PLTS		
	Total	133	Last Page 1 of 1

All in accordance with current Technical Agreement

This is to certify that the above items have been irradiated as specified above

Authorising Signature: J. Coffee

For and on behalf of ISOTRON LIMITED

Cotes Park Industrial Estate
Sommercotes, Alfreton, Derbyshire DE55 4PA

Tel 01773 522200
Fax 01773 522247
www.diversey.com

9th March 2012

Ref: **LOW pH VALUE FOR CLEARKELNS TEGO 2001SS VH24S WO30704**

Background

A batch of ClearKlens Tego 2001SS was manufactured and after irradiation the pH result was found to be outside of specification limits:

TEST	TEST METHOD	LIMITS			RESULT
		Lower	-	Upper	
pH (100%) pre-irradiatin	JDM001	8.5	-	9.2	8.5
pH (neat) post-irradiation	JDM001	8.5	-	9.2	8.3

The stock was released without notification to receiving customers.

Investigation

The standard operating procedures at site of manufacture (QAA031 – Diversey Pharma Products, SOP 5.13 – Cleanroom Certificate of Analysis, SOP 5.14 – Using the Laboratory Work Book) includes the following steps:

pH test conducted in lab and result entered into Lab Book.
Test result entered is checked and counter signed by Supervisor/QA representative.
Results are copied from the Lab Book to the RD310 sheet (held with batch record) and then approved by Supervisor/QA representative.
From the RD310 form the results are transcribed onto the CoA by the Supervisor/QA representative.
The completed document is then checked by QA Admin.

All of the above steps were followed but an out of specification result was entered onto the certificate without the staff involved realizing the error.

Formulation Manager was contacted to confirm that the below specification pH result would not impact product performance. It was confirmed that efficacy would not be impacted.

Actions

1. Procedures used to control test results, review of results and generation of Certificates of Analysis in review.
2. Extra signature of Supervisor & QA representative to be used on internal control documentation (Laboratory Work Book and RD310 form).
3. Once procedure(s) reviewed and amended if appropriate retraining of staff to be conducted and formally recorded.
4. Test results of manufactured batches to be reviewed to confirm suitability of current specification limits.

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