REGIONE CAMPANIA
AZIENDA OSPEDALIERA DI RILIEVO NAZIONALE E DI ALTA SPECIALIZZAZIONE
"SANT'ANNA E SAN SEBASTIANO"
CASERTA

Determina Dirigenziale N. 253 del 30/03/2021

Proponente: Il Direttore UOC PROVVEDITORATO ED ECONOMATO

Oggetto: DETERMINA N.498 DEL 30.07.2020 – INTEGRAZIONE DITTA BECTON DICKINSON ITALIA SPA LOTTO N.8.

PUBBLICAZIONE
In pubblicazione dal 30/03/2021 e per il periodo prescritto dalla vigente normativa in materia (art.8 D.Lgs 14/2013, n.33 e smi)

ESECUTIVITA'
Atto immediatamente esecutivo

TRASMISSIONE
La trasmissione di copia della presente Deliberazione è effettuata al Collegio Sindacale e ai destinatari indicati nell'atto nelle modalità previste dalla normativa vigente. L'inoltro alle UU. OO. aziendali avverrà in forma digitale ai sensi degli artt. 22 e 45 D.gs. n° 82/2005 e s.m.i. e secondo il regolamento aziendale in materia.

UOC AFFARI GENERALI
Direttore Eduardo Chianese

ELENCO FIRMATARI

Antonietta Costantini - UOC PROVVEDITORATO ED ECONOMATO

Eduardo Scarfiglieri - UOC GESTIONE ECONOMICO FINANZIARIA

Eduardo Chianese - UOC AFFARI GENERALI

Oggetto: DETERMINA N.498 DEL 30.07.2020 – INTEGRAZIONE DITTA BECTON DICKINSON ITALIA SPA LOTTO N.8.

Direttore UOC PROVVEDITORATO ED ECONOMATO

Premesso che

- con determina n.498 del 30.07.2020 è stata aggiudicata la fornitura di dispositivi per preparazione terapie antiblastiche;
- l'UOC Farmacia con nota del 23.03.2021 ha trasmesso comunicazione della ditta Becton Dickinson Italia Spa relativa al confezionamento del prodotto aggiudicato al lotto 8 nell'ambito della suddetta fornitura, e precisamente ha comunicato che l'unità minima di vendita del predetto prodotto è pari a n.200pz (allegato 1);
- come riportato dalla scheda tecnica del suddetto prodotto la confezione di vendita è pari a n.200pz;
- l'UOC Farmacia nella suddetta nota chiede di integrare il quantitativo previsto nel contratto n.4600046651;

Considerato

- che nel suddetto contratto sono state inserite n.500 pz del prodotto aggiudicato al lotto n.8 della fornitura di dispositivi per preparazione terapie antiblastiche;

Ritenuto

- di dover integrare il quantitativo nel suddetto contratto di n.100 pz per un importo pari ad € 140,00 così da poter consentire l'UOC Farmacia di emettere il relativo ordine;
- che la presente proposta di determinazione è formulata previa istruttoria ed estensione conformi alla normativa legislativa vigente in materia;

DETERMINA

1. di prendere atto della comunicazione della ditta Becton Dickinson Italia Spa in merito al confezionamento del prodotto aggiudicato al lotto n.8 della fornitura di dispositivi per preparazione terapie antiblastiche come riportato nell'allegato 1;
2. di integrare il contratto n.4600046651 di n.100pz per un importo complessivo pari ad € 140,00 Iva al 22% esclusa;
3. di imputare la somma pari ad € 170,80 Iva inclusa al 22% sul conto economico 5010107010;
4. di trasmettere copia del presente atto al Collegio Sindacale, come per legge e all' UOC Farmacia.

Il Direttore UOC Provveditorato ed Economato

Dr.ssa Antonietta Costantini

ATTESTAZIONE DI VERIFICA E REGISTRAZIONE CONTABILE
(per le proposte che determinano un costo per l'AORN – VEDI ALLEGATO)

Oggetto	**Fwd: Vs ordine rif. n. 32190129**
Mittente	<umaca@ospedale.caserta.it>
Destinatario	<provveditorato@ospedale.caserta.it>
Data	23.03.2021 14:42
Priorità	Molto alta

roundcube

ALLEGATO N. 1

Dopo aver sollecitato l'ordine in oggetto relativo all'acquisto di adattatori per terapie endovescicali, si trasmette il messaggio inviato dalla ditta BD, secondo la quale l'ordine non può essere evaso per unità minima di vendita.
Si chiede la possibilità di consentire l'acquisto essendo il prodotto indispensabile per la somministrazione di farmaci endovescicali.
Si resta in attesa
Dr.ssa Teresa Marzano

Messaggio originale --------
Oggetto: Vs ordine rif. n. 32190129
Data: 2021-03-23 14:08
Mittente: Antonio CAGGIA <Antonio.CAGGIA@bd.com>
Destinatario: "umaca@ospedale.caserta.it" <umaca@ospedale.caserta.it>
Cc: Marco Rubino <Marco.Rubino@bd.com>

Buongiorno,

in merito al Vs gradito ordine in oggetto riportato, siamo con la presente ad informare il Vs spettabile Ente di quanto segue:

il codice CNH04-TPS da Voi ordinato ha unità minima di vendita pari a n. 200 pezzi.

Cordiali saluti

Antonio CAGGIA
Customer Service Specialist
Corporate/Shared Services
Via Cialdini 16 - 20161 Milano - Italy
t: +39.0248240500

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bd.com

Learn more about BD's commitment to Patient Safety;
http://eu.bd.com/patient-safety [1]

Links:
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[1] http://eu.bd.com/patient-safety/en/home

CareFusion

Scheda Tecnica

CODICE PRODOTTO: **CNH-04-TPS**

DESCRIZIONE DEL PRODOTTO **Connettore urologico con valvola needlefree**	
DESTINAZIONE D'USO	Instillazioni e lavaggi vescicali
TIPI DI SOSTANZE INFONDIBILI	Citotossici compatibili con PVC DEHP free
CARATTERISTICHE TECNICHE	
MATERIALE COMPONENTE LA PROLUNGA	• Tubo (diametro in terno 4,5 mm) in PVC DEHP free • Connettore Catetere vescicale in ABS • Valvola senza ago autosigillante in policarbonato e silicone
LATEX free	Si
DEHP free	Si
MISURE	
LUNGHEZZA TOTALE DEL SET	≈9,25 cm
VOLUME DI RIEMPIMENTO	≈1 ml
STERILIZZAZIONE	
METODO DI STERILIZZAZIONE	Ossido di Etilene
DURATA STERILIZZAZIONE	4 anni
CONFEZIONAMENTO	
CONFEZIONE DI VENDITA	200 pezzi
CONFEZIONE SINGOLA	Busta sterile
MODALITA' DI CONSERVAZIONE	
TEMPERATURA	Tra -40°C e + 52°C
UMIDITA' RELATIVA	Non eccedente il 70%
Conservare in condizioni igieniche adeguate evitando l'esposizione diretta alla luce	
RIFERIMENTI NORMATIVI	
MARCATURA CE	• Direttiva di riferimento 93/42/CE • Numero dell'Organismo notificato 0123 • Classe: I s

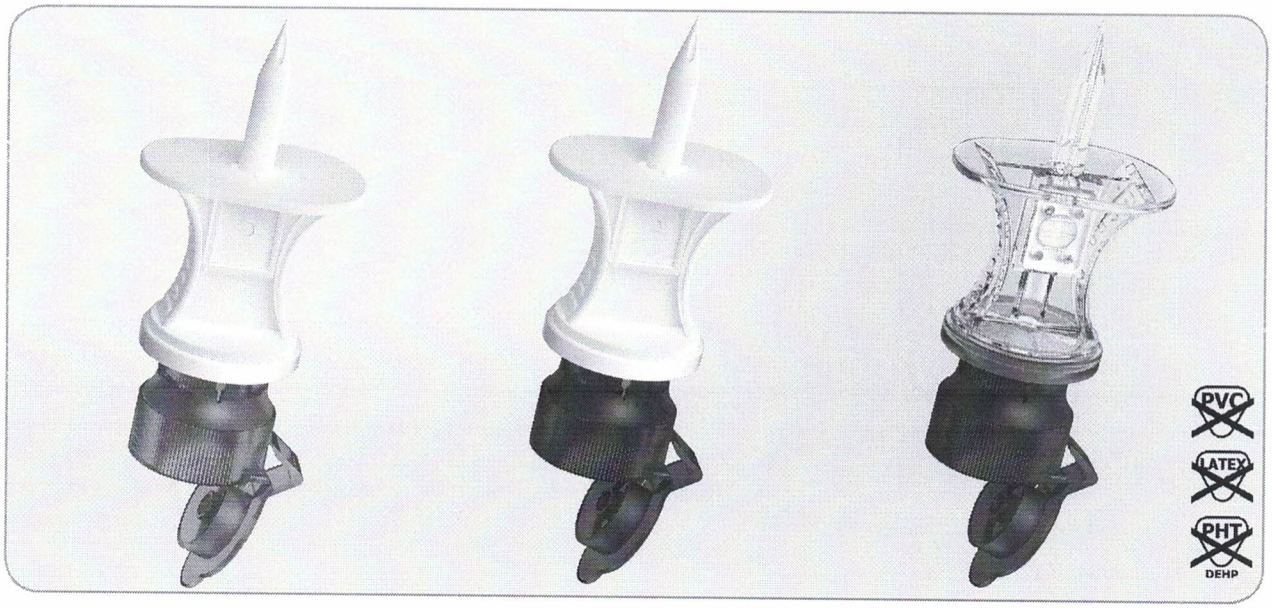
CareFusion

REGISTRAZIONE IN BANCA DATI/REPERTORIO	• Classificazione CND: U9099 • Progressivo di sistema: NON RICHIESTO
ALTRI DATI	
FABBRICANTE	SENDAL Ctra. Nacional Madrid-Càceres, s/n E-10350 Almaraz (Càceres) Espana
DISTRIBUTORE PER L'ITALIA	BECTON DICKINSON ITALIA S.p.A. Via Enrico Cialdini 16 – 20161 Milano (MI) - Italy

Le informazioni contenute in questa scheda tecnica sono fornite a titolo indicativo, e non sostituiscono documenti di riferimento, in particolar modo le **istruzioni per l'uso**.

RoweMed
Medical 4 Life

RoweSpike II



- For repeated withdrawal and aspiration of solutions, drugs and toxic substances
- Safety snap cap for Simple one-hand handling and protection against contamination
- Easy handling due to ergonomic design
- Low priming volume
- Low piercing forces
- Easy admission
- Ventilation filter 0.1 µm PTFE membrane (hydrophobic bacteria filter)

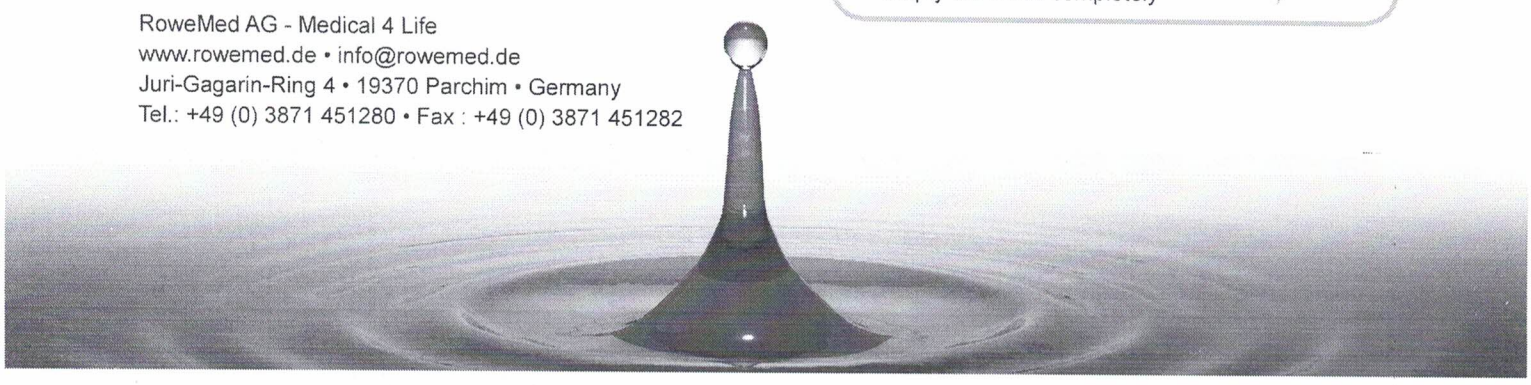
Art.-No.	Material (body)	Filling volume (ml)	Connection	Hydrophobic filter	Cap	Specifics	PU ((pcs./box) / pal.)
A-6425	ABS - w	0.25	fLL	-	green	*	300 / 16,800
A-6426	ABS - w	0.25	fLL	5 µm	blue	*	300 / 16,800
A-6427	MABS - t	0.25	fLL	5 µm, chemo	red	*	150 / 16,800
A-6453	ABS - w	0.25	fLL	-	green	eco * / **	300 / 16,800
A-6454	ABS - w	0.25	fLL	5 µm	blue	eco * / **	300 / 16,800
A-6455	MABS - t	0.25	fLL	5 µm, chemo	red	eco * / **	150 / 16,800

w = white
t = transparent

* Safety Valve variants are available

** Deep-drawn fluid opening to empty the bottle completely

RoweMed AG - Medical 4 Life
www.rowemed.de • info@rowemed.de
Juri-Gagarin-Ring 4 • 19370 Parchim • Germany
Tel.: +49 (0) 3871 451280 • Fax : +49 (0) 3871 451282



Analysing the interaction between cytotoxic chemotherapy drugs and medical devices used for preparation and administration

Sterility and operator safety are key features of the CareFusion closed system device

Elena Dreassi, Gianfranco Corbini and Assunta Zanfini
Dipartimento Farmaco Chimico Tecnologico , Università degli Studi di Siena
Siena, Italy
Silvano Giorgi, Maria Grazia Rossetti and Eleonora Cesqui
Farmacia Ospedaliera Azienda ospedaliera Universitaria Senese, Siena, Italy

Oncological galenic preparations are derived from dilutions of antiblastic drugs, and are therefore defined as magistral preparations in accordance with the Good Manufacturing Practices outlined in the Official Italian Pharmacopoeia XII Glossary - defined as 'medicinal products prepared in a pharmacy based upon an individual patient's medical prescription. All mixtures, dilutions and drug concentrations prepared for individual patients based upon medical Indications ... are also technically similar to magistral preparations'.

To date, oncological galenic preparations belong to the group that are prepared in hospital pharmacies due to the complex preparation procedures and also to the requirement to adhere to specific work safety provisions.

The majority of antiblastics, also known as antiblastic chemotherapeutics (ACs), are used in therapies that require dosage personalisation, based upon the differences between the various diseases (for example, stage of the cancer, site and presence of metastasis), the individual variations between patients and the large number of medicines used in this field of medicine, each of which possess different pharmacokinetic and pharmacodynamic properties.

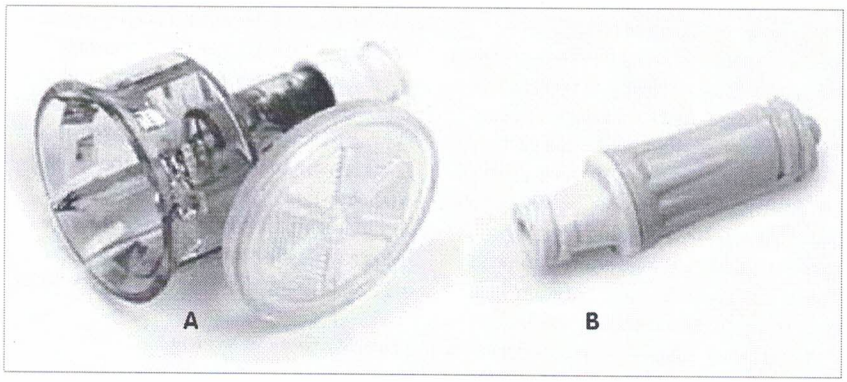


Figure 1: SmartSite® (A) and Texium® (B) devices

In almost all cases, these medicines are administered intravenously, thus the injectable antiblastic chemotherapic drugs used for cancer therapy must possess the characteristics of the injectable forms stated in the Official Italian Pharmacopeia XII, that is to say, they must be sterile, non-pyrogenic, particle-free, controlled, stable and traceable.

These preparations must be prepared in accordance with a validated protocol that regulates the environment, operator, methods and devices used. This protocol must be validated at regular intervals or each time any of the above points is changed; the pharmacist in charge of the hospital pharmacy's galenic laboratory will be responsible for performing the validation.

The healthcare professionals assigned to the preparation and administration of anti-tumour drugs are at risk every day of coming into contact with carcinogenic compounds, with the dangers of accumulation and possible onset of damage to their health. To ensure increased protection for employees, the Azienda Ospedaliera Senese (Siena's Public Hospital) has chosen sampling devices available on the market that can prevent possible leaking problems connected with

antiblastic chemotherapic drug preparation work (the opening of vials, reconstitution and transfers from vial to bag for infusion purposes), as well as guaranteeing the sterile state of the sampling and the possibility of reusing any preparation residues on subsequent days in order to reduce costs.

The SmartSite® and Texium® products fulfil these requirements (ensuring the sterile state and operator safety). As well as minimising the risk of accidental contact by the operator with the drug, these CareFusion devices also make it possible to achieve quickly and simply a closed system, which is indispensible for guaranteeing the administration of a microbiologically inert preparation to the patient.

SmartSite® is a vented vial access device, equipped with a 0.22µ filter; Texium® is a closed male valve for connection between the SmartSite® and a luer-lock syringe. Two significant risk factors in the preparation of these solutions are aerosol contamination due to needle sampling and needle stick injury to the operator. These two devices allow needle-free sampling and eliminate contamination. Both devices are equipped with nondrip technology and with an automatic locking system upon disconnection, and easy and safe connections between the parts.

The above-mentioned devices are shown in Figure 1. They are equipped with an internal plunger lubricated with medical-grade silicone oils that permit the parts inside the device to slide. They are made of polyurethane, lipid-resistant polycarbonate and silicone polymers (internal plunger). Their combined use constitutes a closed system that prevents contamination and leakage of any solution being handled.

The compatibility of these products with various solvents and drugs has already been tested during the approval phase; in our study, the investigation of the compatibility of these devices was also extended to cover the evaluation of the possible interaction that might occur with any antiblastic drugs and the verification of the actual in-use stability of the main products on the market in order to facilitate reuse and the management of production residues, thus generating considerable cost savings.

The work was carried out within the context of a collaboration between the University of Siena and the Siena University Hospital Pharmacy and stems from the latter's need to provide themselves with their own validated methods for managing AC drugs, with particular regard to the possibility of reusing the daily residues resulting from the preparation of the ACs themselves.

Where necessary, the pharmaceutical forms were reconstituted at the Siena University Hospital galenic laboratories.

Trastuzumab (Herceptin® Roche) and bortezomib (Velcade® Janssen-Cilag) were selected as being representative of the monoclonal antibodies; the logic behind this choice was that both occur as lyophiles to be reconstituted and thus present greater stability problems compared to the ready-to-use solutions for which only samplings need to be performed. Docetaxel and paclitaxel, of which the following speciality medicinal products were tested, were selected from among the drugs formulated in more aggressive solvents (ethyl alcohol): Docetaxel 20mg/ml (Actavis), Taxotere® 10mg/ml (Sanofi Aventis) and Anzatax® 6mg/ml (Pharmaplan).

All of the specialty medicinal products were sampled on the scheduled days and then diluted with super-pure water prior to the LC-UV chromatographic analysis.

The stability studies were carried out following the development and validation of appropriate chromatographic methods.

Stability tests in vial

The solutions of the various preparations were kept in the refrigerator in the dark and at ambient temperature (light and dark) with the SmartSite® valve inserted. The content of the solutions of the various drugs remains constant during the seven days of testing. The LC-UV chromatographic profiles do not indicate the presence of chromatographic peaks ascribable to possible degradation products.

Stability tests in syringe

For this purpose, the solutions of the various preparations were kept in the refrigerator in the dark and at ambient temperature (light and dark) in a polypropylene syringe with the Texium® valve inserted. The tests performed and the substantial similarity of the previously obtained results can lead us to conclude that the drugs are stable over the seven test days and that neither the materials used nor the sampling devices nor the environmental conditions cause significant variations in the content of the latter.

Migration tests

The sampling devices were manufactured in such a way as to maintain the conditions of sterility of the solutions contained in them and the manufacturer provides data regarding functionality tests on the silicone plunger located inside the device itself. These tests, performed with various solutions containing different kinds of drugs (for example fluorouracil, glycerine and insulin), have verified that the device does not suffer damage and maintains its functionality.

The specific migration tests carried out showed that there are no significant migration phenomena under the conditions used with the LC-MS detection (water, acidic or ethanolic solutions). Differences were not observed in any case between the chromatographic profiles of the solvent used before and after prolonged contact with the devices.

With regard to the medical-grade silicone oils, used as lubricants in the part of the plunger using alcoholic solutions, their extractable quantity with ethyl alcohol was determined by comparison with special calibration curves set up by analysing solutions at scalar concentration. The quantity of silicone oils extracted from the devices during the usual practice of the preparation of the drugs in alcoholic solution were below the detection limits of the GC-MS method (12µg/device).

Conclusions

The results showed that the analysed solutions are stable during the seven days of testing, since their content never goes below 96%.

The tests carried out and the substantial similarity with the contact with the glass lead us to conclude that the material the sampling devices are made of in no way affects the stability of the selected drugs during the sampling phases and/or direct contact with the same.

We also checked the possible migration by the sampling devices using various solutions and various analytical techniques (LC-MS and GC-MS). Peaks were not recorded in any case using the LC-MS technique in the tested solutions. From the results obtained with GC-MS, it was possible to establish a quantity of silicone oils extractable from the devices during the usual practice of the preparation of the drugs in alcoholic solution.

The reported data represent a real help to hospital pharmacists deciding to work according to the principles of in-use stability. These results make it possible to reuse the production residues, which would otherwise need to be discarded. This can lead to significant savings, which, during times of economic downturn, can make the system more sustainable. ●

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CASERTA

ATTESTAZIONE DI VERIFICA E REGISTRAZIONE CONTABILE
relativa alla DETERMINA DIRIGENZIALE con oggetto:
DETERMINA N.498 DEL 30.07.2020 – INTEGRAZIONE DITTA BECTON DICKINSON ITALIA SPA LOTTO N.8.

ATTESTAZIONE DI VERIFICA E REGISTRAZIONE CONTABILE 1 (per le proposte che determinano un costo per l'AORN)
Il costo derivante dal presente atto : €170,80

- è di competenza dell'esercizio 2021 , imputabile al conto economico 5010107010 - Dispositivi medici
  da scomputare dal preventivo di spesa che presenta la necessaria disponibilità
- è relativo ad acquisizione cespiti di cui alla Fonte di Finanziamento

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Caserta li, 30/03/2021

il Direttore
UOC GESTIONE ECONOMICO FINANZIARIA
Eduardo Scarfiglieri