

Collaborative Working to Develop a Standard Worksheet for Preparation of a Gene Therapy Product

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Background

As part of the onboarding process for etranacogene dezaparvovec (Hemgenix®) a collaborative approach was agreed with NHSE, SPS Quality Assurance, Pan-UK ATMP Regulatory and Technical Subgroup and the 8 NHSE commissioned Gene Therapy haemophilia centres for a number of activities including the creation of a preparation worksheet.

- NHSE
- PAN-UK ATMP Regulatory and Technical subgroup
- SPS QA Lead
- Aseptic leads for the haemophilia centres involved
- Manufacturer via SPS QA lead

Communication Working with and involving & Process

- Single pharmacist nominated led to draft the
- Single pharmacist for each hub contributed /reviewed
- Teams meeting
- SPS approved

different stakeholders

Pros

- Standardised approach to the dispensing of Hemgenix®
- Reduced workload for participating hospital sites
- Improved communication with the manufacturer by having a single point of contact asking the questions
- Improved communication with other stakeholders regarding the bigger picture timelines
- Input from centres who had experience with dispensing Hemgenix® as part of a clinical trial
- Input from centres who had experience with dispensing ATMPs
- Agree national deviation from SmPC – not to attach the giving set!
- Links with contract requirements
- Once agreed for local aseptic units to set-up on their worksheet / labelling system

Collaborative Cons Working

- With standardisation loss of ability to fully customise or have bespoke worksheets
- Relying on a number of people to input into this piece of work, when it is outside the scope of their normal practice/job role leading to some slips in timelines
- Need a lead to start the process

First national collaborative worksheet - Hemgenix®

			SES TEMPLISH PORPLE UNE MONUMENT					 swap the top of the Etrahacogene decapanioned visit with 70% IPA prepipass and allow to dry. 							ation Criecus			Prital Product Credis
Reference Code			Prepared By		Date			7. Insert a 216 vent needle through the bungs of the Etranacogene dezapaniovec vials, taking care to ensure that						aster label on the worksheet		Volume 500 mi,		
Version Number			based by		Farriers Date			the point of the resulte is above the fluid when the vial is inverted.					Labels display the correct of			Visible particles are	shower.	
Product Information								S. Using 23G needles draw up the required volume of Etranacogene desaparvovec into 50mi, syringels).					Exhelt have a batch number on the worksheet.	that matches the band written on	ш	The solution is clear	and colourless.	
Etranacogene dezaparvovec (Hemgenix) x 10 ¹⁴ genome copies in 500mL Sodium Chloride 0.9% w/s															n bag and do not obscure the infus	-	Franchisco della de	fects, additive and infusion ports
								Add the Etranacogene dezaparvovec to the Sodium Chloride 0.9% influsion bag, taking care to ensure that						name.		41	undamaged and sec	
Intravenous Infusion (Patient weight <120Kg)							solution is added into the Sodium Chloride solution and not the air space in the infusion bag.						para a					
Strength Final Container 500mi, Sodium (Noride 0.9%w/v batch Size 1							10. Gently inven	10. Gently invert the infusion bag through 190° at least 3 times to mix the solution and ensure even distribution								Over-over it light p	retective plantic and undamaged	
orenges infusion bag becomes					1966	1	of the clubed product.						Product Approval By	Tax or	h Pass / Fa	-	Date	
					11. Green down the isolator as per local SCP, ensuring a virucidal disinfectant is used.							for DC tec		No. Faled				
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Additional Information									strict accordance with the defined production method above.									Destroyed By
							strict accordance	MATE SOCIONALE WAY ON GENERAL PROJECTION HIGHER SOCION.							Come	neres		
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Batch Number Date Worksheet Prepared Worksheet Prepared By							1						Do not use filter needles during preparation of etranacogene despoembles.					
Espiry H49.M on CC/MAV/VVV Date of Dispersing Worksheet Charled 8s					Product Inspection and Starting Material Reconciliation							pe: Follow local SOP and use the						
					Starting Material Reconciliation Check by Froduct Inspection by									II KIR.				
These = 2×10 ¹⁸ genome engine, tip body weight corresponding to 2xts (kip body weight)					_mL	IX x empty Etranacesene decapanyoyee vials present Check for leakages						Must be administered via a 0.2µm polyethersulfone filter.						
Calculated By Checked By								odium Chloride 0.9% removed			Check for visible particles using black/white	LOWER	Provide appropriate Biohazard spill kits for delivery.					
							No evidence of damage or defects for components used Confirm product appearance (clear solution)											
Label Printing																		
	Merter Produc	t Label			Sample Labor			10181 10F LBD	eling	Cheo	ied by	No. Failed		Template written by:	Kevin P. Griffiths		pproved by:	A Bleck
								Reason for Fe	of the						.0			1.54
	tranacogene dezaparus		•)					PRESIDENT OF THE	and to					Signed:	K-1	- 12	gned:	And Shill
	x10 th genome co										etfnean			Oate:	29/0	5/2024 0	****	06/062024
Sodium Chloride 0.9% w/v introvenous Inflation													Paris.	kiji	A RARADE	144.		
For introvenous inflution over 60 minutes Attach sample label here										e. Label each	infusion	bag and overwrap in light protective wrap. I	ocument label &					
Store or Room Temperature between 15-25°C								product reconci	liation in table below.									
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Dete: DO/MM/NYY DRE						No. Expected				No. Issued								
No of Label		Printed By		Attached to Worksheet		o Issued for I		No. Dispensed		_		No. Attached to products						
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Labels Checked By Supervisor authorisation to proceed to assembly								No. Passed		_								
Starting Materials												No. Excess						
Assemble all starting materials listed below and enter the batch numbers and expiry dates for each item. Sign for assembling each								Product Reconciliation Completed By				No. Destroyed						
Item. Each item must then be subject to an independent documented second check.								Destroyed by										
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												All Worksheet Checks are present						
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Appropriate personal protective equipment for handling of genetically modified organisms must be worn.								Deviations are authorised (a small residual volume may be present)										
Appropriate posonal protective equipment for nationing of generally modified organisms must be worn. Clean down lookstor as per local SCP.								-										
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Inensier materneh into noletor as per local SCP. Impect consumation for defects.							stores											
									Label / groduct reconcilations tally and are recorded on the All components have a batch number, expiry a									
5. Remove volume equivalent to the dose of Etranacogene decapativover from the 500mL Sodium Chloride 0.9%								worksheet. manufacturer correctly recorded on the worksheet.										
w/v infusion bag. Label and cap the syringes as per local SOP.								facility Status has	facility Status has been confirmed as satisfactory									
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The future

Pharmacy ATMP group have a process for developing other standardised worksheets for future treatments requiring onboarding at a national level. We can take this process and apply it at a more regional/local level for promoting standardisation or best practice for other ATMPs. This would reduce the set-up times for complex medicines, assist with capacity in S10 units and longer term reduce the training burden.