CONTROL AUTHORITY BATCH RELEASE OF BLOOD PRODUCTS

2001

Solvent Detergent (SD) Plasma

Guideline title	**Official Control Authority Batch Release of Solvent Detergent (SD) Plasma**
Legislative basis	**Council Directive 89/381/EEC**
Date of first adoption	**April 2001**
Date of entry into force	**September 2001**
Status	**This guideline has undergone external consultation. It was finalised and approved by the network for OCABR on the occasion of the annual meeting 2001**
Previous titles/other references	**New Guideline**
Custodian Organisation	**The present document was elaborated by the EDQM in the OMCL network and finalised under PA/PH/OMCL (2000) 28, DEF on the occasion of the annual meeting 2001**

OFFICIAL CONTROL AUTHORITY BATCH RELEASE OF SOLVENT DETERGENT (SD) PLASMA

1 Introduction

Control Authority Batch Release of medicinal products derived from human blood and plasma is performed within the framework of article 4.3 of directive 89/381/EEC and following the current guideline on EC administrative procedure for Official Control Authority Batch Release.

All general and specific Ph.Eur. monographs relevant to this product apply.

2 Sampling and tests to be performed by the Control Laboratory

The following samples should be supplied to the Official Medicines Control Laboratory performing batch release.

At least 3 samples of 1.5 ml of each plasma pool involved in the production of this batch.

If the plasma pools have already been tested by a Control Authority, the submission of a copy of the certificate of approval is sufficient.

Plasma pool samples should be stored at –20 ^{o}C and shipped on dry ice.

and

At least 3 samples of the final product.

The Control Laboratory should perform the following tests:

On the plasma pool samples:

- Tests for viral markers
  - anti HIV 1/2
  - HBsAg
  - anti HCV and NAT for HCV RNA

On the finished product:

- Appearance
- Factor VIII
- Factor V
- APTT
- Blood Group

3 Protocol submission

A model protocol is given below. A protocol for specific product may differ in detail but it is essential that all relevant details demonstrating compliance with the Marketing Authorisation and the Ph Eur monograph should be given. WHO requirements may also serve as the model for the content and presentation of the protocol data. Results of the tests

are required (pass or fail is not sufficient, results of retest if applicable should be given). Sufficient detail should be supplied to allow recalculation of test values. Specifications for each test and dates when they were performed should also be included. Results of qualification tests on reference materials should be given for each new in-house reference material.

3.1 Summary information on the final lot of finished product

Trade name: …….

International non proprietary name (INN) /
Ph Eur name /
Common name of product (whichever is appropriate): …….

Batch number (s): …….

Finished product (final lot): …….
Final bulk: …….

Type of container: …….

Total number of containers in this batch: …….

Volume per container: …….

Blood Group: …….

Date of expiry: …….

Storage temperature: …….

Marketing authorisation number issued by (Member state/EU): …….

Name and address of manufacturer: …….

Name and address of Marketing
Authorisation Holder if different: …….

3.2 Production information

Site of manufacture: …….

Date of manufacture: …….

Summary information scheme on batch specific production data including dates of different production stages and identification numbers.

Viral Inactivation

Batch No…… has been subjected to viral inactivation treatment by the following process: (give details such as solvent, detergent, concentrations, temperature, time, etc. as appropriate), according to the method described in the Marketing Authorisation (M.A.).

3.2.1 Starting materials

Individual donations:

Source country/countries of donations:
Remuneration: yes/no
Period of collection:

Individual donations were tested negative for:

viral marker	method	test kit generation	licensing number	brand name
anti-HIV				
HBsAg				
anti- HCV				

- If applicable: Alanine Aminotransferase
  Anti-Treponema

The test methods should be those approved in the license application.

3.2.2 Plasma pool

Code number(s) of plasma pool(s):……
Date of manufacture:…….
Volume of pool / number of donations:……
Source country and supplier of plasma pool:……

This plasma pool has been obtained from the combination of individual donations originating from the following donation/plasmapheresis centres (give the list of the addresses of these centres and the period of collection for each pool):…….

Tests for viral markers: this batch was manufactured from plasma pools which each tested negative for:
(A short summary of essential data of the test results should be given.)

viral marker	method	test kit generation	licensing number	brand name	date of testing
anti-HIV					
HBsAg					
anti-HCV					
HCV NAT					

Other tests laid down in the Marketing Authorisation, e.g. protein, bacterial count ……..

OMCL testing on manufacturing plasma pool was performed by (member state) ……..
A copy of the certificate of approval should be submitted.

3.3 Finished product

3.3.1 Identification of the Batch:

Date and reference of manufacturer: ……. …...
Batch number of bulk material: …….
Blood group: …….
Date of sterile filtration: …….
Date of filling: …….
Filling volume: …….
Type, number of filled containers and number of containers released by the manufacturer: …….
Start of shelf life: …….
Expiry date: …….

3.3.2 Control tests on finished product

Depending on the Marketing Authorisation and the Ph. Eur. monographs a certificate of analysis should include the following:

- Characterisation of the product: appearance, fill volume, identity, species specific antisera tests, amount of haemogglutinin (anti-A, anti-B), pH, total protein, protein composition, activated coagulation factors, blood group…

- Safety tests on the product: sterility, endotoxin content, pyrogens, irregular erythrocyte antibodies, citrate, Hepatitis A antibodies, residual solvent/detergent…

- Other tests as specified: osmolality, electrolytes; calcium, potassium, sodium, viral markers…

Testing address and brief description of test method and principle should be indicated. Reference to test instruction and validation study in the dossier should be given.

4 Certification

Certification by qualified person taking the overall responsibility for production and control of the product:

I herewith certify that _____(name of the product) batch N°_____ was manufactured and tested according to the procedures approved by the competent authorities and complies with the quality requirements. This includes that, for any materials derived from ruminants (bovine, ovine, caprine) used in the manufacture and/or formulation of the batch of product specified above, all measures have been taken to demonstrate compliance with Directive 1999/82/EEC.

Name: _____

Function: _____

Date: _____

Signature:_____