



**Manufacturer's Batch Certificate  
For  
Medicinal Products Exported.**

**1. Name of product.**

Alzane

**2. Importing Country**

Hungary

**3. Marketing Authorization Number.**

2723/1/10 MgSzH ÁTI (10 ml).

**4. Strength/Potency**

Atipamezole HCl 5mg/ml

**5. Dosage form (pharmaceutical form)**

Injectable solution

**6. Package size (contents of container) and type (e.g.vials, bottles, blister)**

112 vials

**7. Lot/batch number.**

4048-13

**8. Date of fabrication/manufacture**

05/2014

**9. Expiry date.**

05/2016

**10. Name and address of fabricator (s)/manufacturer(s)-manufacturing ste(s).**

Laboratorios syva s.a. Avda Párroco Pablo Díez, 49-57 24010 León-Spain.

**11. Number of Manufacturing Authorisation/Licence or Certificate of GMP Compliance of a manufacturer/fabricator.**

4264-E

**12. Result of analysis.**

Attached

**13. Comments/remarks.**

-



**14. Certification statement.**

I Herby certify that the above information is authentic and accurate. This batch of product has been fabricated/manufactured, including packaging and quality control at the above mentioned site in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country / product specification file for Investigational Medicinal Products. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

**15. Name and position/title of substitute qualified person**

Jaime Fernández Souto  
Technical Director

**16. Signature of person authorizing the batch release**

**17. Date of signature**

14-11-2014

---

Written by:

Name: María García  
Signature:

Date: 14-11-2014

Reviewed by:

Name: Jaime Fernández  
Signature:

Date: 14-11-2014



## QUALITY CONTROL DEPARTMENT

## CERTIFICATE OF ANALYSIS

<b>Product</b>	ALZANE 10 ml		
<b>Batch:</b>	4048-13	<b>Expiry date:</b>	05/2016
<b>Manufacture date:</b>	05/2014	<b>Release date:</b>	14/11/2014

ASSAY	SPECIFICATIONS	RESULTS
-------	----------------	---------

Appearance	Clear, colourless solution, free from particles in suspension	Conforms
Volume	10 – 10.5 ml	10.2 ml
Sterility	Sterile	Sterile
Bacterial endotoxins	< 50 IU/ml	Conforms
Methyl-parahydroxybenzoate		
Identification		
Retention time:	Positive	Positive
Peak Purity:	Positive	Positive
UV spectrum:	Positive	Positive
Assay	90 -110 % (0.9 – 1.1 ) mg/ml	1.04 mg/ml
Atipamezole HCl		
Retention time:	Positive	Positive
Peak Purity:	Positive	Positive
UV spectrum:	Positive	Positive
Assay:	95 – 105 % (4.75 – 5.25 mg/ml)	4.98 mg/ml
Related substances		
Any unspecified degradation product:	≤ 0.2 %	N.D.
Total degradation products:	≤ 0.5 %	N.D.
Packaging:	Complies with specification	Conforms

Dictum: APT

laboratorios syva, s.a.u.  
Departamento Control Calidad  
Quality Control Department  
Avda. Pío Baroja, Pablo Diaz, 49-57  
Tel: 34 967 809 300 - Fax: 34 967 852 452  
24010 Leon-España C.I.F.: A-78603866

Quality Control

DATE:14/11/2014